8 CONSEQUENCES OF HYPOTHERMIA REVIEW

Clinical Question:

What are the consequences of inadvertent perioperative hypothermia?

Aim

To estimate the rate of adverse health outcomes in patients who are hypothermic compared to patients who are normothermic.

Search strategy

Studies were identified for this review from three sources. Firstly the RCTs included in the clinical effectiveness reviews were cross-checked to determine whether they also included data on the consequences of hypothermia. Secondly all papers sifted for the economic literature review (1,095 papers) were examined to see if they included data relevant to this review. Thirdly citation searching was carried out using review articles. Each new paper or review identified during this process was checked for any further relevant citations.

Outcomes included

All consequences of hypothermia identified were considered by the health economist for their likely impact on costs, mortality and quality of life. The following outcomes were considered to have significant cost or health consequences and were included in the review after consultation with the GDG:

- Mortality
- Length of stay (PACU, ICU or total hospital stay)
- Requirement for mechanical ventilation
- Requirement for blood transfusion and volume transfused
- Myocardial infarction
- Surgical wound infection
- Pressure ulcers.

Several additional outcomes were identified by the GDG as having the potential for significant cost or health consequences but there was no data identified on their relationship with hypothermia. These were: unplanned ICU admission; delayed extubation; return to surgery due to wound breakdown, and; intercranial pressure.

Definition of hypothermia

The purpose of this review is to allow a link to be made between the prevention of hypothermia and the prevention of adverse consequences associated with hypothermia. We are interested in studies where patients have been divided into those exposed to hypothermia intraoperatively and those not exposed. This is achieved either by randomisation to different thermal care in RCTs or by analysis according to a definition of hypothermia in cohort studies. In both cases patients should be normothermic at baseline. The most accurate determination of exposure to hypothermia would come from the lowest intraoperative temperature, but where this is not available we determined exposure to hypothermia using the mean temperature reported at any time after anaesthesia or at the end of surgery (admission to recovery). Where temperature is reported at more than one time point we have used this to consider whether one group has been maintained above the hypothermia threshold and the other group has not.

The strength of this link between exposure to hypothermia and the consequences of hypothermia will be dependent on the definition of hypothermia that is applied. Where possible we have been consistent with the definition used elsewhere in this guideline of a core temperature under 36˚C.

We will consider whether our definition of hypothermia at 36˚C has a significant impact on the estimation of the consequences of hypothermia by carrying out a sensitivity analysis in which we vary the definition of hypothermia to 36.5˚C.

Study designs included

Randomised controlled trials where patients were randomised to different interventions (usually different thermal care) which resulted in one group having a mean temperature above the hypothermia threshold (36˚C) and one group having a mean temperature below the threshold. Patients should be normothermic before randomisation, i.e. we do not include studies which looked at different methods of re-warming hypothermic patients. The alternative definition of hypothermia as a core temperature below 36.5˚C will be applied in a sensitivity analysis. If the mean temperature of a group is above or below the defined threshold for hypothermia then it is assumed that the whole group was normothermic or hypothermic respectively. Due to this assumption the evidence from the RCTs is less robust than the evidence from the cohort studies. Where the mean temperature was exactly 36˚C in one arm we treated this as the hypothermic group if it had a lower temperature than the other group and we treated it as the normothermic group if it had a greater temperature.

Cohort studies in which the exposure to hypothermia and the adverse consequences of hypothermia have been recorded, and a multivariate analysis carried out to adjust for confounding variables. Where the hypothermia threshold used by the authors has differed from our preferred definition of 36˚C, we will use sensitivity analysis to determine whether this is a cause of heterogeneity between studies.

Populations included

We are assuming that the relationship between hypothermia and its consequences is constant regardless of the population considered provided they meet the population inclusion criteria from the methods section. Hence the populations are not described in detail in this review unless the population was particularly unrepresentative.

Using the evidence in the economic model

The evidence can be split in two broad types. The first are binary outcomes such as surgical site infections, requirement for transfusion, myocardial infarction, mortality. For these we have estimated the relative risk for hypothermic patients compared to normothermic patients from the available studies. Where an adjusted odds ratio was reported, we converted this to an adjusted relative risk using the algorithm described by Zhang (1998). In the economic model we assume the relative risk can be applied across all patients covered by the guideline. For example, we assume that if the evidence shows that your risk of surgical site infection is four times higher if you become hypothermic then we assume this applies equally to all patients regardless of their preoperative probability of infection.

The second are continuous outcomes which measure the difference in the amount of outcome between two groups. For example, the mean number of units of blood used or the mean length of stay. Here we are interested in the proportional increase and we assume this does not vary across groups. So if hypothermia increases length of stay by 50% then this would mean an extra 1 days stay for patients whose average length of stay is 2 days, and an extra 1 week for patients whose average length of stay is 2 weeks.

However, the baseline risk of any consequence used in the economic model must be taken from a population that is representative of the broad majority of adult patients undergoing surgery. It was therefore necessary to use an alternative data source for the baseline risk for many of the outcomes, as the study populations included were often at higher risk of the consequence than the general surgical population.

Methodological quality of included studies (randomised controlled trials)

Seventeen randomised controlled trials were included in the review (Bennet 1994; Frank 1995; Kurz 1996; Frank 1997; Lenhardt 1997; Fleisher 1998; Mason 1998; Smith 1998; Casati 1999; Johansson 1999; Wills 1999; Winkler 2000; Scott 2001; Widman 2002; Savel 2005; Zhao 2005; Smith 2007).

Method of sequence generation was adequate in seven studies (computer generated random number table: Frank 1997; computer generated: Kurz 1996; Lenhardt 1997; Mason 1998; Winkler 2000; random numbers table: Wills 2001; block randomisation: Fleisher 1998) and unclear in the remaining studies.

The method of allocation concealment was adequate in two studies (sequentially numbered opaque sealed envelope: Johansson 1999; Wills 2001). A partially adequate method of allocation concealment was reported in eight studies (numbered opaque sealed envelope: Kurz 1996; Lenhardt 1997; Mason 1998; sealed opaque envelope: Frank 1997; Winkler 2000; sealed envelope: Casati 1999; Widman 2002; opaque envelopes: Scott 2001) and was unclear in the remaining studies.

Blinding was reported in the assessment of wound infections (Kurz 1996); and pressure ulcers (Scott 2001). Outcome assessor was blinded in one study (Smith 2007) for the following postoperative data: sublingual temperature; time to discharge, and; use of heating devices. Neither the surgeon nor the patient was aware of the infusion the patient received in the study by Widman (2002). Anaesthesia providers and PACU staff were blinded to the use of forced air warming and to body temperature data in Fleisher (1998).

Baseline comparability was demonstrated for age, gender, core temperature preinduction and duration of surgery. Exceptions are noted below.

Baseline temperature

Baseline temperature was significantly different in the following studies:

- 0.10°C higher for the group assigned to forced air warming (lower body) compared with forced air warming (upper body) (Winkler 2000);
- 0.10°C sublingual temperature higher for the usual care group compared with active warming (Smith 2007);
- 0.30°C higher for the group assigned to amino acid compared with those assigned to acetated Ringer's infusion (Widman 2002).

In one study (Casati 1999) baseline core temperatures were extracted from the graph. However, error bars were not reported so we cannot determine if the difference in baseline core temperature was statistically significant.

The differences in core temperature were as follows:

- 0.14°C higher in the group assigned to forced air warming compared to the thermal insulation group (Casati 1999).

One study (Smith 2007) reported sublingual baseline temperature [warmed: 36.7°C (SD0.4); usual care: 36.6°C (SD 0.4)]. The difference was not statistically significant.

Baseline core temperature was not reported in one study (Mason 1998).

Duration of surgery

Duration of surgery was significantly different in two studies (Bennett 1994 [3 arms]; Savel 2005):

- 0.5 hours longer in the usual care group compared with thermal insulation group (Bennett 1994);
- 0.25 hours longer in the usual care group compared with warmed insufflation group (Savel 2005).

Smith (2007) reported a significant difference in the type of surgery, with more patients having general surgery in the active warming group.

Seven studies carried out a power calculation (Kurz 1996; Lenhardt 1997; Casati 1999; Johansson 1999; Scott 2001; Widman 2002; Winkler 2000). In Casati (1999), to detect 0.5°C difference in core temperature at end of surgery at 5% alpha level, it was calculated that 20 to 25 patients were required per group. Scott (2001) calculated a sample size of 306, to detect a 10% reduction in the incidence of pressure ulcer, at 5% alpha level (90% power). Winkler (2000) estimated a sample size of 150, to provide a 90% chance of identifying a significant hypothermia-induced increase in blood loss, one-tailed at 5% level.

One study (Lenhardt 1997) calculated that 150 patients would give an 80% chance of identifying a 10 minute difference in fitness to discharge; at 5% level (two-tailed).

One study (Kurz 1996) calculated sample size based on incidence of wound infection in a pilot study. It was calculated that 400 patients would provide a 90% chance of identifying a difference at 1% level. In one study (Johansson 2005), power calculation was done to detect a decrease in total blood loss of 340ml by the Hb-method (B=0.8, two-sided p=0.05) based on data from the control group. Widman (2002) estimated that at least 30 patients are needed to detect a 300ml hypothermia-induced increase in blood loss with a power of 80% and alpha level of 5%.

The Smith (2007) study was considered to be partially confounded because 29% of patients assigned to the routine care arm received forced air warming and 9% received warmed fluids at the discretion of the anaesthetist. Although the study also reported results for subgroups of the routine care group that did and did not receive additional warming, the GDG considered the latter to be unrepresentative, as they were likely to be lower risk patients. Consequently the GDG decided to use the full results, which were likely to underestimate the size of the effect.

Methodological quality of included studies (cohort studies)

The study patients in Flores-Maldonado (2001) were sampled from one hospital only and there was no data on baseline core temperature. However, the use of multivariate analysis to correlate surgical wound infections and mild perioperative hypothermia was assumed to have reduced confounding effects to a minimum. The correlation between seven risk factors and SWI was investigated on 261 patients. There was a total of 20 SWI and the risk factors were age, diabetes mellitus precedents, prophylactic antibiotic, non-prophylactic antibiotic, wound drains, surgical time and mild perioperative hypothermia. There were less than 10 events per variable which reduces the validity of the analysis. Walz (2006) was a retrospective cohort study. There was no data on baseline core temperature. However, the study patients were recruited from multiple centres and a multivariate analysis was used to investigate correlation. The regression was on six parameters and there were 126 SSI events (8.7% of 1446) so there was an adequate number of events per parameter.

Frank (1993) did not give information on the sampling method of 100 patients used in the study. There was a multivariate analysis of 14 parameters on a sample size of 100. There were 38 ischemic episodes and 2 patients had repeated episodes. The result of this study should be treated with caution due to the low number of events per variable included in the analysis. The postoperative temperature was measured sublingually but the authors state that this was done by experienced ICU nurses who ensured sublingual placement and mouth closure during measurement.

Vorrakipokatorn (2006) was a prospective cohort study. Four variables were included in the multiple logistic regression for intraoperative transfusion and 6 variables were included in the regression for postoperative transfusion. Eighteen patients received an intraoperative transfusion and thirty-three received postoperative transfusions. The number of events per variable was low for both outcomes reducing the validity of the multivariate analysis. Stapelfeldt (1996) was a retrospective cohort study in which the predictive values of laboratory results (four variables at two time points) and the cumulative time spent in various temperature ranges intraoperatively were examined by multivariate linear regression with cumulative transfusion requirements as the dependent variable. The number of patients (100) per variable (10) was adequate if one assumes that the three temperature categories were described using two variables. However, the study is reported only as an abstract and there is minimal information on which to base quality assessment.

The studies by Janczyk (2004) and Bush (1995) were retrospective cohort studies whilst the Abelha (2005) study was prospective. None of the cohort studies had the minimum of 10 events per variable considered in the multivariate analysis which limits the validity of the results.

Other study features

The characteristics of the clinical studies used for this review (participants, exposure to hypothermia), the study results and sensitivity analysis are presented separately for each health outcome.

IPH AND SURGICAL WOUND INFECTION

Characteristics of clinical studies used for this review

We identified nine studies that reported perioperative temperature and surgical wound infection (SWI) (Barone 1999; Edwards 2003; Flores-Maldonado 2001; Kurz 1996; Melling 2001; Melling 2006; Paterson 1999; Walz 2006; Wong 2007). Three of the studies (Flores-Maldonado 2001; Kurz 1996; Walz 2006) were included in this review and the reasons for rejecting the remaining six are given in Appendix E. The three studies accepted for the review of this outcome are described in Appendix C. Two were cohort studies and the other was a randomised controlled trial (RCT). There were a total of 1907 patients in the studies, and each study had at least 200 patients. In the sensitivity analysis, we re-assessed the nine studies identified (see above) and found that only one study (Kurz 1996) met the new threshold criterion.

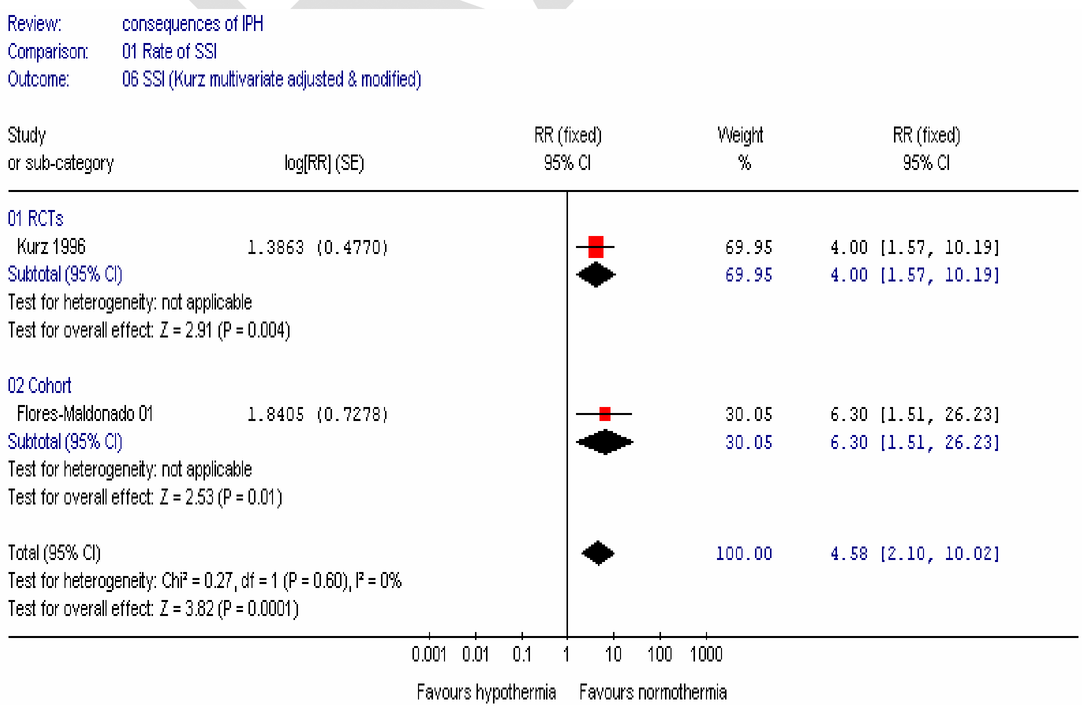
Participants: Kurz (1996) was an RCT with 104 normothermic patients with a mean age of 61 years and 96 hypothermic patients with a mean age of 59 years. Flores-Maldonado (2001) was a prospective cohort study of 261 patients with a mean age of 40 years. Walz (2006) was a retrospective cohort study of 1446 patients with a median age of 57 years. Kurz (1996) was on patients scheduled for elective colorectal surgery and the average surgery duration was 3.1 hours. The second study, Flores-Maldonado (2001), was on patients scheduled for elective cholecystectomy and the surgery duration was less than 60 minutes. Walz (2006) was on patients scheduled for bowel surgery and the surgery classification was mixed (elective, urgent and emergency).

Exposure to hypothermia: The study patients in Kurz (1996) were randomly assigned to either of the two thermal management groups. In one group, the normothermic group, patients' temperature values were maintained near 36.5˚C by using forced air warming and intravenous fluid warming. In the hypothermic group, no form of extra warming was carried out and the core temperature decreased to approximately 34.5˚C. Tympanic core temperature was measured in the intraoperative phase. In Flores-Maldonado (2001) mild perioperative hypothermia was defined as a tympanic temperature <36 ˚C on admission to recovery and 59.8% of the cohort met this criterion. The association between hypothermia and infection was examined with multivariate logistic regression. Walz (2006) investigated the correlation between intraoperative temperature nadir and surgical wound infection in a multivariate analysis. Intraoperative temperature nadir was set as a continuous variable.

Study results

It was reported in the Kurz study (1996) that there were six SWI in the 104 normothermic patients (mean temperature 36.6˚C, SD, 0.5˚C). There were 18 SWI in the 96 hypothermic patients (mean temperature 34.7˚C, SD, 0.6˚C). They did a multivariate analysis and an odds ratio of 4.9 (95% CI: 1.7 – 14.5) was estimated for hypothermic compared to normothermic patients. We converted the adjusted odds ratio to a relative risk used this in the meta-analysis (Figure 1). The study by Flores-Maldonado (2001) reported that hypothermia was an independent predictor of SWI with an adjusted relative risk of 6.3 (p=0.01) after a multivariate logistic regression analysis and this was included in the meta-analysis. The study by Walz (2006) reported an odds ratio of 1.33 for a unit increase in intraoperative temperature nadir after multivariate logistic regression. This is the opposite relationship to that reported by Kurz (1996) and Flores-Maldonado (2001) as a higher temperature is associated with an increase in infection risk rather than a lower temperature. The results of the study by Walz (2006) cannot be combined with the other two studies as temperature is treated as a continuous variable in Walz (2006) and as a dichotomous variable in the other two studies (hypothermia or normothermia). The two remaining studies were combined in a meta-analysis despite having different study designs. The combined relative risk of SWI for hypothermic patients is 4.58 (95% CI, 2.10 – 10.02). There was no heterogeneity between studies (I^2=0%, p=0.60).

Figure 1: Relative risk of SWI in patients with IPH



Sensitivity analysis on definition of IPH: Kurz (1996) was the only study to meet the inclusion criteria when using the alternative definition of hypothermia (<36.5˚C) so the estimate from this study alone (RR 4.00, 95%CI 1.57 – 10.19) is used in this sensitivity analysis.

IPH AND MORBID CARDIAC EVENTS

Characteristics of clinical studies used for this review

The GDG defined morbid cardiac events to include only unstable angina/ischemia, cardiac arrest and myocardial infarction. We identified three studies that reported perioperative temperature and morbid cardiac events (Bush 1995; Frank 1993; Frank 1997). We included two of them (Frank 1993; Frank 1997) and the reasons for rejecting the third one is given in Appendix E. A description of the two studies used for this review is given in Appendix C. One of the studies is an RCT and the other, a cohort study.

Participants: Frank (1993) was a cohort study of 100 patients with a mean age of 65 years. Frank (1997) was an RCT of 300 patients with a mean age of 71 years. Patients in Frank (1993) were scheduled for lower extremity vascular reconstruction. The authors noted that patients having this procedure have a high incidence of coronary artery disease and perioperative morbidity. The mean duration of surgery was 5.7 hours in the normothermic group and 5.0 in the hypothermic group. Study patients in Frank (1997) were scheduled for abdominal, thoracic or peripheral vascular surgery. Patients also had to have either coronary artery disease or be at high risk of coronary artery disease. The surgery duration for patients assigned to the normothermic and hypothermic groups were 3.6 and 3.4 hours respectively.

Exposure to hypothermia: In Frank (1993) patients with a postoperative temperature less than 35˚C were defined as hypothermic while those with temperature greater than or equal to 35˚C were defined as normothermic. Patients in Frank (1997) were randomised across two thermal management groups. In the hypothermic group patients received routine thermal care and their mean postoperative temperature was 35.4˚C (SD, 0.1˚C). The normothermic group received additional forced air warming intraoperatively, and their mean postoperative temperature was 36.7˚C (SD, 0.1˚C). Forced air warming was also continued postoperatively in the normothermic group.

Study results

The study by Frank (1993) reported an odds ratio of 1.82 (1.09 – 3.02) for myocardial ischemia for a one degree centigrade decrease in postoperative sublingual temperature. This result is not in a format suitable for our analysis in this review and we will not use it further. It was reported in Frank (1997) that there were 10 morbid cardiac events in 158 hypothermic patients and two events in 142 normothermic patients. The two events in the latter case were exclusively unstable angina/ischemia and the 10 events in the former case were unstable angina/ischemia (7), cardiac arrest (2) and myocardial infarction (1). Using a multivariate analysis, a relative risk of 2.2 (95% CI, 1.1 – 4.7) for morbid cardiac event was reported for patients assigned to the hypothermic group after adjusting for preoperative beta-adrenergic blocker use and history of hypertension.

Sensitivity analysis on definition of IPH: Frank (1997) is the only study that could be used in a sensitivity analysis and it has been described above. The results are the same with those presented above. They are not different because the use of the new threshold to categorise the results of studies was based on the mean core temperature reported in the studies.

IPH AND MECHANICAL VENTILATION

Characteristics of clinical studies used for this review

There are four studies that reported IPH and mechanical ventilation (Bock 1998; Frank 1995; Frank 1997; Gentilello 1997). We included two of them (Frank 1995; Frank 1997) and the reasons for rejecting the other two are given in Appendix E. The two accepted studies are RCTs and are described in Appendix C. There were a total of 374 patients and the minimum number of patients in each study arm was 37.

Participants: Frank (1995) studied patients, aged 65 years on average, who were scheduled for thoracic, abdominal, or lower extremity vascular surgery. The study participants in Frank (1997) have been described previously.

Exposure to hypothermia: Patients in Frank (1995) were randomly assigned to two thermal management groups. One group received routine care warming and were classified as hypothermic (mean postoperative temperature in PACU was 35.3˚C, SD, 0.1˚C). Patients in the second group received forced air warming and had their core temperature maintained at or near 37˚C (mean postoperative temperature in PACU was 36.7˚C, SD, 0.1˚C). They were classified as normothermic. Patients' exposure to hypothermia in Frank (1997) has been described previously.

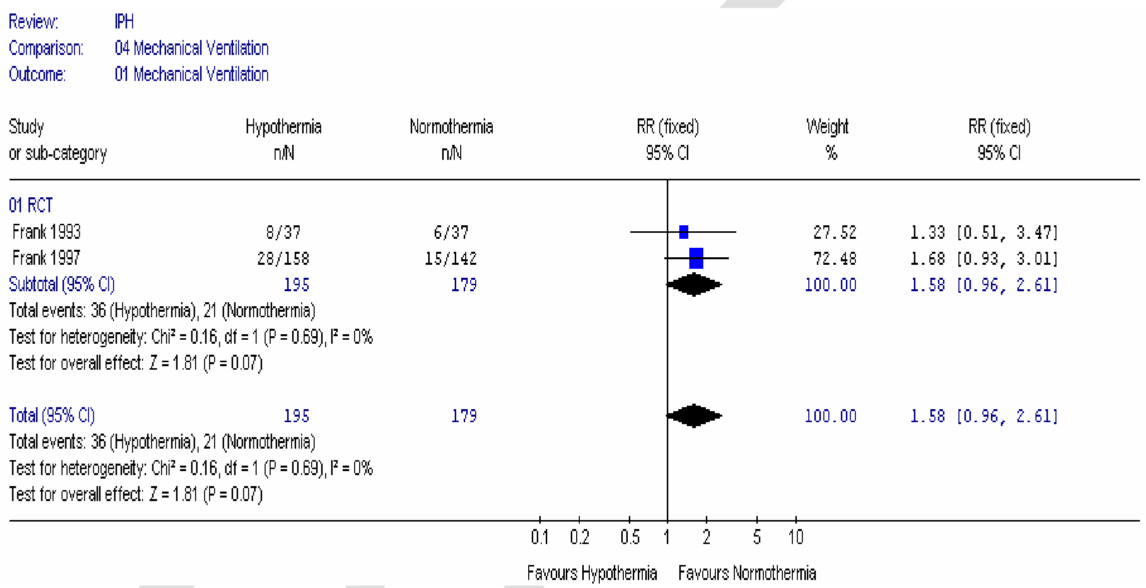
Study results

It was reported in the Frank (1995) study that six of the 37 normothermic patients required mechanical ventilation. Eight of the 37 hypothermic patients required mechanical ventilation.

The study by Frank (1997) found that 15 of the 142 normothermic patients (mean postoperative core temperature of 36.7˚C) required mechanical ventilation, and 28 of the 158 hypothermic patients (mean postoperative core temperature of 35.4˚C) required mechanical ventilation. We used the estimates of the two studies in our meta-analysis (Figure 2). Meta-analysis of the two RCTs gave a relative risk of mechanical ventilation in patients with IPH of 1.58 (95%CI 0.96, 2.61). This was not statistically significant, but favoured normothermia. There was no heterogeneity between studies (I^2=0%, p=0.69).

Sensitivity analysis on definition of IPH: Frank (1995) and Frank (1997) met the inclusion criteria when applying the alternative definition of hypothermia (<36.5˚C) and no additional studies met the inclusion criteria. Therefore, the results do not differ when applying the alternative definition for hypothermia.

Figure 2: Relative risk of requiring mechanical ventilation in patients with IPH



IPH AND BLOOD TRANSFUSION

Characteristics of clinical studies used for this review

We identified 18 studies that reported IPH and blood transfusion (Bennett 1994; Bock 1998; Bush 1995; Frank 1997; Hetz 1997; Janczyk 2004; Johansson 1999; Kurz 1996; Lenhardt 1997; Schmied 1996; Schmied 1998; Staplefeldt 1996; Vorrakitpokatorn 2006; Widman 2002; Winkler 2000; Wong 2007; Zhao 2005; Leung 2007). We included eleven of them (Bennett 1994; Frank 1997; Johansson 1999; Kurz 1996; Lenhardt 1997; Schmied 1996; Vorrakitpokatorn 2006; Zhao 2005; Widman 2002; Staplefeldt 1996; Leung 2007) and the reasons for rejecting the other seven are given in Appendix E. Nine of the included studies were RCTs and two were cohort studies (Staplefeldt 1996; Vorrakitpokatorn 2006), all of which are described in Appendix C. There was a total of 1179 study patients. Two studies (Bennett 1994; Zhao 2005) had 20 or less patients in each study arm. Four studies had between 21 and 30 (Johansson 1999; Schmied 1996; Widman 2002; Leung 2007) and the remaining three RCTs had at least 74 patients in each arm. Vorrakitpokatorn (2006) had a cohort of 128 patients and Stapelfeldt (1996) had a cohort of 100 patients.

Participants: The mean patient age was 50 to 60 years in two RCTs (Lendhart 1997; Zhao 2005), 60 to 70 years in five RCTs (Johanson 1999; Kurz 1996; Schmied 1996; Widman 2002; Leung 2007) and greater than 70 years in two RCTs (Bennett 1994; Frank 1997). The mean age was 49 years in the Vorrakitpokatorn cohort study (2006) and was not stated in the Stapelfeldt cohort study (1996). Patients in Widman (2002) were scheduled for hip arthroplasty and surgery lasted for 78 and 80 minutes in the two study arms. Schmied (1996) studied patients who had hip arthroplasty and whose surgery lasted for 85 and 87 minutes in the two study arms. Lenhardt (1997) studied patients scheduled for abdominal surgery. Surgery duration was 3.4 and 3.2 hours in the two study arms. Patients in Bennett (1994) were scheduled for hip arthroplasty and surgery duration was 2.0, 2.3 and 2.5 in the three groups studied. Johansson (1999) studied patients scheduled for hip arthroplasty and the average surgery duration was 102 and 100 minutes in the two study arms. Zhao (2005) was an RCT of patients in two study arms and they were on average 44 and 52 years respectively. Patients were scheduled for abdominal surgery which lasted for 204 and 230 minutes in the two study arms. In Leung (2007) patients had mixed abdominal surgery. Stapelfeldt (1996) and Vorrakitpokatorn (2006) were cohort studies of liver transplantation and percutaneous nephrolithotomy patients respectively. The mean duration of surgery in the later study was 120 minutes but this was not reported in Stapelfeldt (1996).

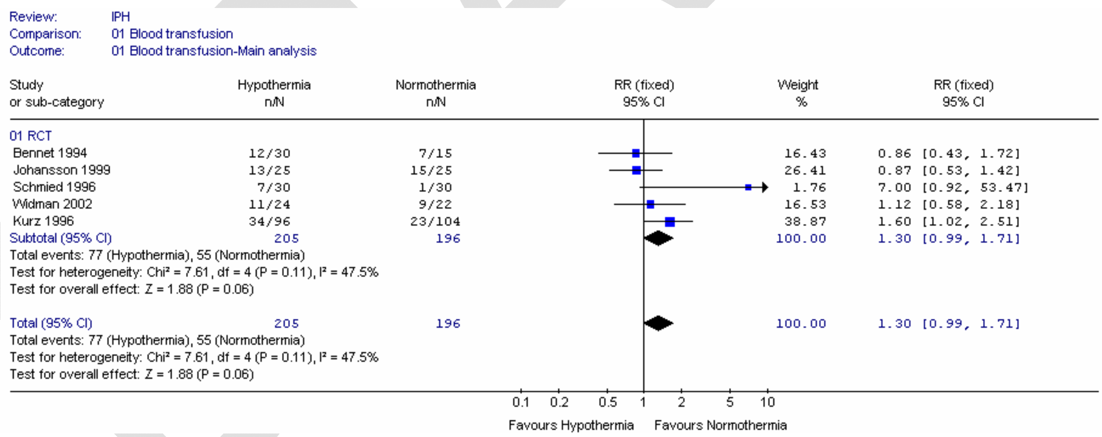
There was some overlap of the cohorts enrolled in the Lenhardt (1997) and Kurz (1996) studies with 100 patients enrolled in both studies.

Exposure to hypothermia: The patients in Widman (2002) were randomised across two groups. One group received amino acid infusion and mean postoperative core temperature was 36.2˚C (normothermic); the other group received acetated Ringer's solution and mean postoperative core temperature was 36.0˚C (hypothermic). Schmied (1996) studied patients who were randomly assigned to two thermal management groups. One group received forced air warming and their mean final intraoperative core temperature was 36.6˚C (normothermic). The other group (hypothermic) did not receive extra warming and their mean final intraoperative core temperature was 35.0˚C. Lenhardt (1997) was an RCT of patients assigned to two groups of extra warming (mean core temperature 36.7˚C, normothermic) and routine thermal care (mean core temperature 34.8˚C, hypothermic). Patients in Bennett (1994) were randomised into three groups namely, forced-air warming, thermal insulation and usual care. The postoperative core temperature in the three groups was 36.5˚C, 35.8˚C and 35.1˚C respectively. We have taken the actively warmed group as normothermic and we have combined the results from the other two groups as they are both hypothermic. Johansson (1999) was an RCT and patients were assigned to two groups. One group was assigned to receive forced air warming and their mean minimum temperature was 36.3˚C (normothermic). The other group received usual care and their mean minimum temperature was 35.4˚C (hypothermic). Patients in Zhao (2005) were assigned to either the group that received forced air warming and fluid warming or those that were covered with cotton blanket. Those in the first group achieved an intraperative temperature of 36.4˚C (normothermic) while those in the second group achieved a temperature of 35.3˚C (hypothermic). Leung (2007) randomised patients across two thermal management groups. One group received forced air warming and achieved a final temperature of 36.2˚C (normothermia) while the other group received electric heating pad and achieved a temperature of 35.2˚C (hypothermic). The patients in Vorrakitpokatorn (2006) were classified as intraoperative hypothermia if their body temperature was equal to or below 35.0˚C. Strapelfeldt (1996) classified patients into three temperature ranges (<33, <35 and >=35) and examined the number of units transfused per hour spent within each temperature range. Patients' exposure to hypothermia in Frank (1997) and Kurz (1996) have been described previously.

Study results

The number of patients transfused was reported in six of the RCTs (not reported in Zhao 2005 or Frank 1997). We excluded Lendhart (1997) from the meta-analysis as the patient cohort overlapped with the Kurz (1966) study and the latter study was the larger cohort. Meta-analysis of the six studies gave a relative risk estimate of 1.30 (95%CI, 0.99, 1.71). The result was not quite statistically significant (p=0.06), and favoured normothermia, and whilst there was some heterogeneity across the studies (I^2= 47.5%) but it was non-significant (p=0.11).

Figure 3: Relative risk of blood transfusion in patients with IPH



The mean number of units transfused across each arm (including non-transfused patients) is given in Table 1. Where the study gave the number of units but not the volume of one unit we have assumed that one unit is equivalent to 450ml. Otherwise we have converted the volumes given to units of 450ml. We converted all volumes to units by assuming that 450ml is equivalent to one unit. Data from Frank (1997) has not been included in the meta-analysis as the mean and standard deviation are only given as whole numbers of units resulting in a standard deviation of zero which is uninformative for meta-analysis. Lenhardt (1997) was excluded from the meta-analysis as the cohort of patients studies partially overlapped with the Kurz (1996) study. There was a significant increase in the mean number of units transfused

(0.10 U, 95%CI 0.01 – 0.20). There was significant heterogeneity (I^2=51.8%, p=0.05) as three studies showed a lower volume for hypothermic patients and four showed a higher volume. If the studies for which the volume of a unit was not available are excluded, then the volume transfused in no longer significantly increased.

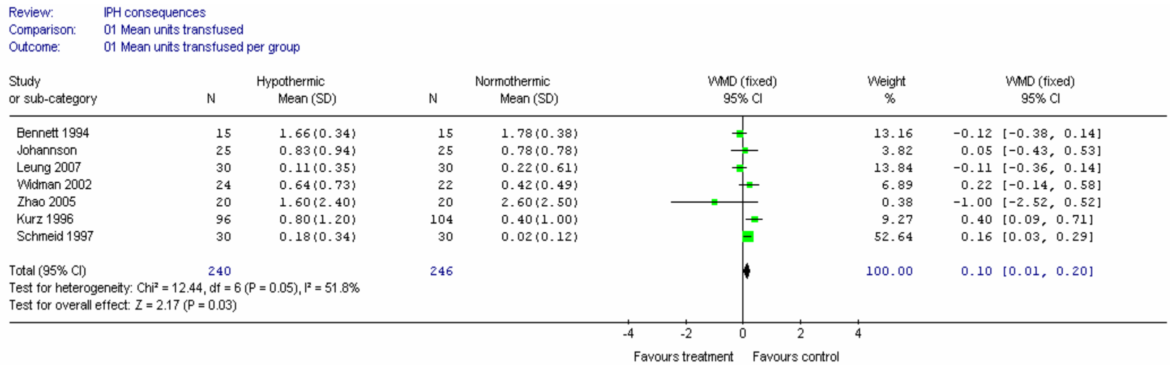
Stapelfeldt (1996) reported that 1.7 units of blood was transfused per hour in hypothermic patients (<35˚C) and 0.7 units per hour in normothermic patients (>35˚C). The authors stated that the increase was significant but it was not possible to verify this independently from the data presented. Vorrakitpokatorn (2006) reported that hypothermia was not statistically significantly related to intraoperative or postoperative transfusion but no odds ratio or relative risk was provided. We could not combine the results of the studies by Stapelfeldt (1996) and Vorrakitpokatorn (2006) in the meta-analysis as the data was not presented in sufficient detail.

Table 1. Mean quantity of blood transfused across normothermic and hypothermic patients (One unit defined as 450ml)

	Mean (sd) quantity of blood, units (=450ml)		
Study	**Normothermic**	**Hypothermic**	**Difference**
Kurz (1996)	0.4* (1.0)	0.8* (1.2)	0.4
Widman (2002)	0.42 (0.49)	0.64 (0.73)	0.22
Lenhardt (1997)	0.40* (1.1)	0.80* (1.2)	0.40
Bennett (1994)	1.78 (0.38) active 1.92 (0.16) thermal	1.66 (0.34)	-0.12 vs active -0.26 vs thermal
Zhao (2005)	2.60* (2.5)	1.60* (2.4)	-1.0
Schmied (1996)	0.02	0.18	0.16
Johansson (1999)	0.78 (0.78)	0.83 (0.94)	0.06
Frank (1997)	1* (0)	1* (0)	0
Leung (2007)	0.22 (0.61)	0.11 (0.35)	

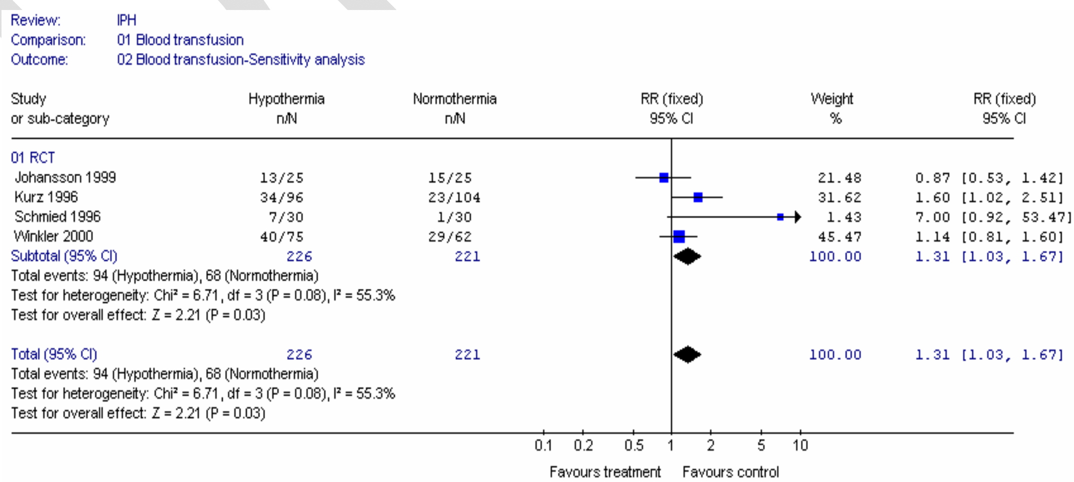
*Volume of one units not given by author, assumed equal to 450ml

Figure 4: Volume transfused for hypothermic compared to normothermic patients (mean across all patients including those who were not transfused)



Sensitivity analysis on definition of IPH: We identified four studies that could be used for the sensitivity analysis. Three of them (Johansson 1999; Kurz 1996; Schmied 1996) have been used in the main analysis and have been described above. Winkler (2000) is an RCT of patients aged over 60 years and who were scheduled for hip arthroplasty. Patients were assigned to two thermal management groups. One group was aggressively warmed to maintain a core temperature of 36.5˚C whereas the other group was conventionally warmed to maintain a temperature of 36.0˚C. Patients in the first group achieved an intraoperative temperature of 36.5˚C and we classify them as normothermic. Patients in the second group achieved an intraoperative temperature of 36.1˚C and we classify them as hypothermic. Surgery duration was 102 and 97 minutes in two study arms. The rate of transfusion was 29/62 in the normothermic arm and 40/75 in the hypothermic arm. The mean volume transfused across all patients was 0.64 units (SD, 0.91) for normothermic patients and 0.89 units (SD, 1.04) in the hypothermic patients. The results of the four studies are combined in a meta-analysis (Figure 5) and the relative risk of having a blood transfusion in hypothermic patients is 1.31 (95% CI: 1.03, 1.67).

Figure 5: Sensitivity analysis of the relative risk of blood transfusion in patients with IPH



IPH AND PRESSURE ULCER

Characteristics of clinical studies used for this review

One study reported perioperative hypothermia and pressure ulcers (Scott 2001) and our review of this outcome is based on the results of this study. The study is described in Appendix C.

Participants: Scott (2001) was an RCT of 324 patients aged with a mean age of 68 years. Patients were scheduled for orthopaedic, colorectal, gastrointestinal, urology and vascular surgery and the duration of surgery was 111 and 116 minutes in the two study arms.

Exposure to hypothermia: Scott (2001) randomised patients across two groups. One group received forced-air warming, IV fluid warming, and standard care. Patients in this group achieved an intraoperative core temperature of 36.09˚C, and we classify them as normothermic. The second group received standard care, but fluid warming was determined by clinical need. Patients in this group achieved an intraoperature core temperature of 35.7˚C and we classify them as hypothermic.

Study result

Scott (2001) reported that there was pressure ulcer in nine of the 161 normothermic patients and in 17 of 163 hypothermic patients. This is equivalent to a relative risk of 1.87 (95%CI, 0.86, 4.06).

IPH AND MORTALITY

Characteristics of clinical studies used for this review

There were nine studies that reported IPH and mortality (Abelha 2005; Bernabei 1992; Bush 1995; Frank 1997; Gentilello 1997; Janczyk 2004; Kurz 1996; Slotman 1985; Wong 2007). We included five (Frank 1997; Kurz 1996; Abelha 2005; Bush 1995; Janczyk 2004) in this review and the reasons for excluding the remaining studies are given in the Appendix E. Two included studies were RCTs with a total of 500 patients, three were cohort studies with a total of 547 patients and they are described in Appendix C.

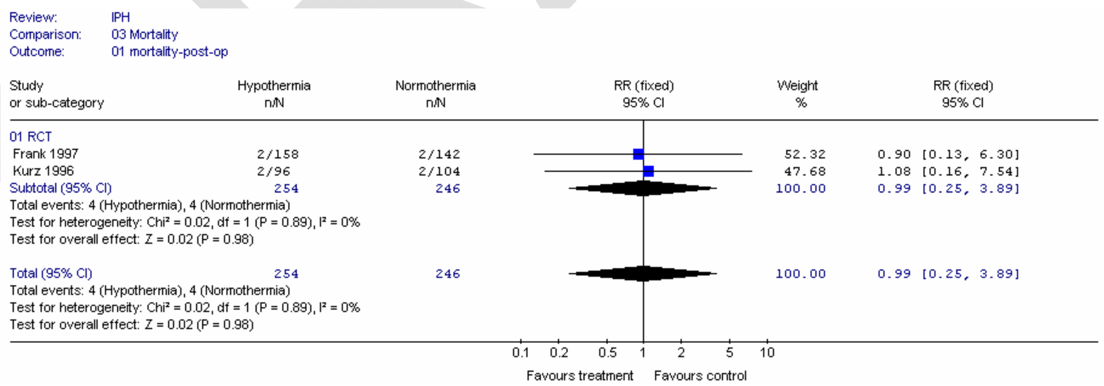
Participants: Janczyk (2004) was a cohort study of 100 patients with a mean age of 74 years. Patients were included if they presented with a ruptured abdominal aortic aneurysms and survived at least to the operating room for surgical repair. The mean duration of surgery was 213 minutes. Abelha (2005) was a cohort study of 185 patients with a mean age of 66 years who were scheduled for noncardiac surgery. Bush (1995) was a cohort study of 272 patients undergoing elective abdominal aortic aneurysm repair and with a mean age of greater than 70 years. Participants in Frank (1997) and Kurz (1996) have been described previously.

Participants exposure to hypothermia: Patients in Abelha (2005) were classified as hypothermic if they arrived at ICU with core temperature values of less than 35˚C. Bush (1995) classified patients into hypothermic and normothermic groups according to their admission temperature to the surgical intensive care unit or post anesthesia care unit. Hypothermia was defined as a core temperature <34.5˚C. Janczyk (2004) did not classify patients as hypothermic or normothermic. Lowest intraoperative patient temperature was treated as a continuous variable in the analysis. Patients' exposure to hypothermia in Frank (1997) and Kurz (1996) have been described previously.

Study results

Kurz (1996) reported two deaths in each of the two thermal management groups. The study by Frank (1997) also reported two deaths in both thermal management groups. Janczyk (2004) reported that hypothermia was significantly associated with mortality (p=0.006) but there was no estimate of risk measure. Abelha (2005) reported that core temperature was not a significant predictor of mortality. Bush (1995) reported that lowest body temperature was a significant predictor of multiple organ dysfunction syndrome and this was a significant predictor of mortality but hypothermia itself was not an independent predictor of mortality. The studies by Frank (1997) and Kurz (1996) have been combined in a meta-analysis. The relative risk of mortality for patients with IPH is 0.99 (95% confidence interval, 0.25 – 3.89) (Figure 6). There is no hetereogeneity between the studies (I^2=0%, p=0.89) but the confidence interval of the estimate shows that there is much uncertainty in the relationship between hypothermia and mortality.

Figure 6: Relative risk of mortality in patients with IPH



Sensitivity analysis on definition of IPH: The Frank (1997) and Kurz (1996) studies were suitable for the analysis using the alternative definition of hypothermia (36.5˚C) and no further suitable studies were identified. The relative risk is therefore unchanged when applying the alternative definition.

IPH AND LENGTH OF STAY

Characteristics of clinical studies used for this review

We identified 26 studies that report IPH and length of stay. We included thirteen of them (Casati 1999; Fleisher 1998; Frank 1997; Kurz 1996; Lenhardt 1997; Mason 1998; Savel 2005; Smith 1998; Smith 2007; Wills 2001; Abelha 2005; Bush 1995; Vorrakitpokatorn 2006) in this review and the reasons for excluding the rest (Bock 1998; Champion 2006; Conahan 1987; Cory 1998; Farley 2004; Gentilello 1997; Hamza 2005; Nguyen 2002; Panagiotis 2005; Slim 1999; Wong 2007; Smith 1994, Selldén 1999) are included in Appendix E. Ten of the included studies are RCTs, and three are cohort studies (Abelha 2005; Bush 1995; Vorrakitpokatorn 2006) and they are described in Appendix C. Three studies had 21 or fewer patients in each study arm (Savel 2005; Smith 1998; Wills 2001). The rest of the studies had 25 patients or more in each of the study arms. Six studies reported on hypothermia and PACU length of stay (Casati 1999; Fleisher 1998; Lenhardt 1997; Mason 1998; Smith 1998; Smith 2007), one on ICU (Frank 1997) and four on hospital length of stay (Frank 1997; Kurz 1996; Savel 2005; Wills 2001).

Participants: The mean age of participants in either or both of the study arms was less than 40 years of age in three studies (Mason 1998; Savel 2005; Smith 1998), between 40 and 59 in five studies (Fleisher 1998; Kurz 1996; Lenhardt 1997; Smith 2007; Wills 2001), and more than 60 in three studies (Casati 1999; Frank 1997; Bush 1995). The types of surgery carried out in the studies include hip arthroplasty; gastric bypass; gynaecologic, plastic, orthopaedic, urologic surgery or general surgery; abdominal, thoracic or peripheral vascular surgery; colorectal surgery; laparoscopic fundoplication; and laparoscopic-Roux-en-Y gastric bypass. The surgery duration ranged from one hour (Smith 2007; Wills 2001) to more than three hours (Fleisher 1998; Frank 1997; Kurz 1996; Lenhardt 1997).

Participants' exposure to hypothermia: The ten RCTs achieved temperatures above and below 36˚C in the hypothermic and normothermic groups by applying different thermal management care in each arm. This varied from using active versus passive warming or usual care, to warmed versus unwarmed fluids or heated versus unheated insufflation gas. The details of the different thermal management used in each arm and the temperatures achieved for each RCT are given in Appendix C.

Patients' exposure to hypothermia in the cohort studies by Vorrakitpokatorn (2006), Abelha (2005) and Bush (1995) has been described previously.

Study results

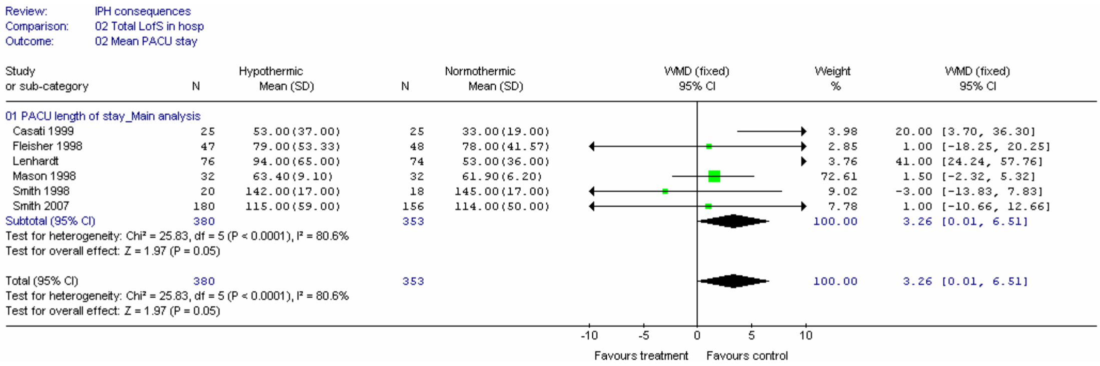
PACU length of stay: Four of the six studies showed that hypothermic patients did not spend a significantly longer time in PACU (Table 2). Meta-analysis of the study results gave a weighted mean difference of 3.26 (95%CI, 0.01, 6.51) (Figure 7) but this analysis is associated with a high level of hetereogeneity (I^2=80.6%, p<0.001). We could not explain the high level of heterogeneity through the ASA level of study patients, baseline core temperature or type of anaesthesia used on study patients.

Table 2: Length of stay in the PACU, ICU and hospital across normothermic and hypothermic patients

Study	Normothermia	Hypothermia	Surgery type	Surgery duration
	PACU length of stay (minutes)			
Casati 1999	33.0	53.0	Hip arthroplasty	TgA: 100minutes TgB: 105minutes
Lenhardt 1997	53.0	94.0	Abdominal surgery	TgA: 3.4hours TgB: 3.2hours
Mason 1999	61.9	63.4	Gastric bypass	TgA: 156.1minutes TgB: 156.9minutes
Fleischer 1998	78.0	79.0	Gynecologic, plastic, orthopaedic, or general surgery	TgA: 250.6minutes TgB: 222.0minutes
Smith 1998	145.0	142.0	Gynaecological surgery	TgA: 67minutes TgB: 75minutes
Smith 2007	114.0	115.0	Ambulatory gynecologic, orthopaedic, urologic and general surgery.	TgA:56 TgB:56 Minutes
	ICU length of stay (hours)			
Frank 1997	21.0	22.0	Abdominal, thoracic or peripheral vascular surgery	TgA: 3.6hours TgB: 3.4hours
	Hospital length of stay (days)			
Kurz 1996	12.1	14.7	Colorectal surgery	TgA: 3.1hours TgB: 3.1hours
Savel 2005	3.2	4.0		

‡TgA and TgB represent the normothermic and hypothermic groups respectively

Figure 7: IPH and PACU length of stay

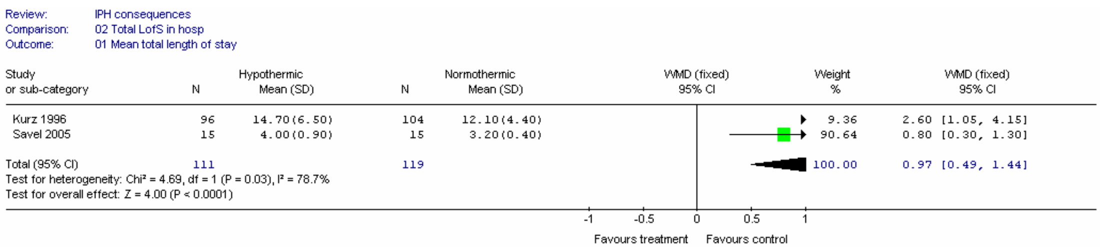


ICU length of stay: Frank (1997) reported that normothermic patients spent 21 hours in the ICU while hypothermic patients spent 22 hours and this difference was not statistically significant (p=0.1). Abelha (2005) reported that hypothermia at ICU admission did not significantly predict ICU length of stay.

Total hospital length of stay: Seven studies reported the relationship between intraoperative hypothermia and total length of hospital stay. Two RCTs (Kurz 1996; Savel 2005) showed that hypothermic patients spent longer time in the hospital than normothermic patients. It was reported in Frank (1997) that normothermic patients spent 8 (range, 5-11) days in the hospital and the hypothermic ones 8 (range, 5-13) days. Wills (2001) reported a median time to discharge of three (range, 2 – 4) days in each group. The results of Wills (2001) and Frank (1997) are not presented in a manner that allows them to be combined with other results in a meta-analysis. Vorrakitpokatorn (2006) reported that intraoperative hypothermia seemed to increase length of stay but not statistically significantly (p>0.05). Insufficient data was presented to calculate additional stay. Abelha (2005) reported that hypothermia at ICU admission did not significantly predict hospital length of stay. Bush (1995) reported that low body temperature was predictive of prolonged hospital stay but the data presented was not sufficient to calculate additional stay.

Meta-analysis of the studies that could be combined (Kurz 1996; Savel 2005) gave a weighted mean difference of 0.97 (95%CI, 0.49, 1.44). As there were significant differences in the duration of stay for normothermic patients across the two studies, we converted the data to a standardised scale. This reduced the heterogeneity (I^2 = 0, p=0.73) and resulted in a estimated increased of 22.9% (95% CI, 13.0% - 32.8%) in total hospital length of stay.

Figure 8: IPH and hospital length of stay



Sensitivity analysis on definition of IPH The sensitivity analysis for PACU length of stay was done with five studies that were used in the main analysis (Casati 1999; Fleisher 1998; Lenhardt 1997; Mason 1998; Smith 1998). A meta-analysis of these five studies gave a weighted mean difference of 3.35 (95% CI, 1.01, 5.70) and a high heterogeneity level (I^2=84.4%, p<0.0001). Sensitivity analysis for hospital length of stay could only be done with one study (Kurz 1996) and the result is the same as that already reported (2.60 (95% CI, 1.05, 4.15). When this was estimated as a proportionate increase on the length of stay for normothermic patients, this resulted in an estimate of 21.5% (95% CI, 8.7% - 34.3%).

9 DETECTION AND MONITORING

Techniques and equipment used vary widely in current NHS practice. Diverse technologies have been developed to replace traditional mercury thermometers (MHRA 04144, 2005). Many devices currently available to healthcare professionals promote quick and simple measurement techniques, with patient comfort an important feature of modern equipment. The Medicines and Healthcare products Regulations Agency (MHRA) produced a comprehensive overview of relevant procurement of temperature recording devices and looked at alternative technologies for intermittent temperature measurement in the human body. The MHRA overview is acknowledged in this guideline as a definitive source for users of this guidance.

Methods of recording temperature

Examples of diverse methods of intermittent temperature measurement within clinical effectiveness reviews were:

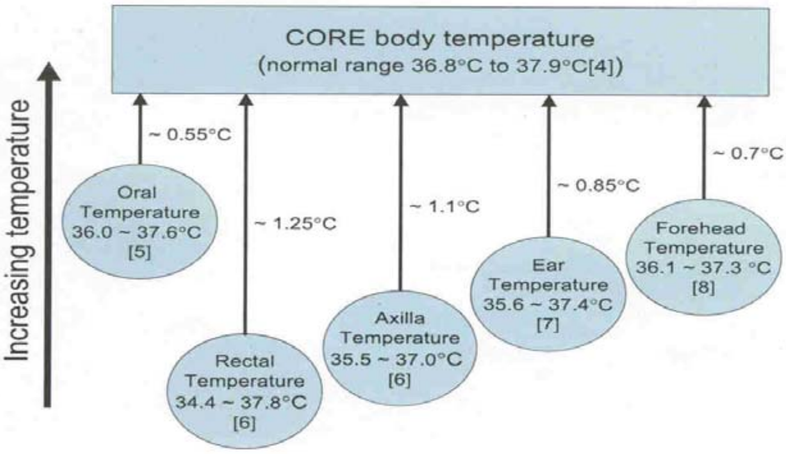
- Sublingual devices (Conahan 1987; Goldberg 1992);
- Tympanic membrane devices (Hynson 1992; Nelskylä 1999; Johansson 2003);
- Nasopharyngeal devices (Stone 1981; Wills 2001; Champion 2006);
- Oesophageal devices (Tølløfsrud 1984a; Tølløfsrud 1984b; Youngberg 1985; Joachimsson 1987; Ouellette 1993; Mouton 1999; Saad 2000; Nguyen 2002; Farley 2004; Hamza 2005);
- Rectal devices (Eckerbom 1990);
- Pulmonary artery devices (Bäcklund 1998).

In establishing this diversity of available equipment, and acknowledging variations in practice across England and Wales, the GDG determined that the guideline would make consensus recommendations on the appropriate timing of intermittent temperature measurement throughout the perioperative patient pathway. This consensus approach, whilst pragmatic, recognises that there are a number of devices available for use through the Purchasing and Supplies Agency (PaSA), an arms length body of the Department of Health and central supplier to the NHS.

Temperature measurement

Normal body temperature has diurnal variations (see physiology review). Figure 1 overleaf summarises differences in temperature reading across a number of commonly used intermittent temperature measurement sites. It is derived from core temperature clinical studies, using mouth, rectum, axilla, ear and forehead sites in healthy adults and teenagers. Common to this area of study, the temperature range differences can only ever be expressed as approximations. ‘Some temperature recording devices automatically encode the physiological offset figure into the thermometer’s displayed value, so the temperature at ‘familiar’ body sites (e.g. oral) is predicted from measurements at other sites (e.g. ear and forehead). Other thermometers do not automatically add the physiological offset and provide the actual temperature measured at that site' (MHRA 2005, p.3-4).

Figure 1: From MRHA 04144, Thermometer Review: Evaluation 2005



Best Practice

Given this uncertainty, the GDG recognised the importance of healthcare professionals being trained in the use of intermittent temperature measurement equipment within their NHS Trust.

Monitoring the patient's temperature throughout the perioperative journey is an important aspect of medical and nursing assessment, and in particular, in establishing a baseline temperature prior to induction of anaesthesia and looking at temperature variations through the intraoperative and post operative periods. Emerging technology has recently (Smith, 2000) seen a shift towards the use of tympanic membrane thermometers, promoted by a Health and Safety Executive directive. The GDG notes that technology will continue to emerge, with temporal artery thermometers becoming more widely used.

Given this context, understanding of temperature recording equipment used in patient care is the responsibility of all healthcare professionals. This includes appreciation of normal body variations in temperature and knowledge of the devices manufacturer's guidance and suppliers instructions.

10 PREVENTION OF INADVERTENT PERIOPERATIVE HYPOTHERMIA

Clinical Questions:

Are warming devices/mechanisms effective in preventing IPH in adults in the different phases of perioperative care?

Which pharmacological interventions are clinically and cost effective in the prevention of IPH?

SELECTION CRITERIA

Selection criteria are as outlined in the general methods section, with the exception of those specific to the warming mechanisms and pharmacological agents reviews, which are described below.

Warming Mechanisms

Types of intervention

The following interventions were considered:

1. Active warming mechanisms

Active warming was defined as a process that transfers heat to the patient.
The following types of warming mechanism were to be considered under active warming:

a. Forced air warming
b. Electric blanket
c. Radiant heater
d. Water mattress
e. Warmed cotton blankets
f. Heating gel pads
g. Fluid warmers
h. Heated-humidifiers
i. Heat and moisture exchange

2. Thermal insulation mechanisms

Thermal insulation was defined as a process that deliberately prevents heat loss.
The following mechanisms were considered under thermal insulation:

a. Reflective blankets
b. Reflective clothing (e.g. hats, jackets).

3. Other warming mechanisms

I) Fluid warming cabinets

The GDG decided that active and other methods of irrigation fluid warming could be combined due to the rapid method of delivery of irrigation fluids.

Other types of heat loss prevention, such as cotton sheets, cotton blankets, or wool blankets were to be considered as 'usual care'.

The reviews considered the following questions:

i) Does warming work?
ii) If so, in which phase is it most effective?
iii) Which warming device is the most effective within each phase?

i. Does warming work?

The forest plot (Figure I) combines the results for all types of warming devices, in the pre, intra, and pre and intraoperative phases for the core temperature at 60 minutes after induction of anaesthesia.

Meta-analysis of 21 studies [23 comparisons] with 899 patients showed significant heterogeneity overall (I^2= 48.3%, p=0.001). The mean core temperature was significantly higher in the warmed group; WMD 0.32°C (95%CI 0.26, 0.37). The overall picture suggests that warming does work to increase the core temperature (Figure I).

Examining the heterogeneity, we noted that thermal insulation, water mattress and warmed insufflation gases did not show a significant difference in mean core temperatures at 60 minutes, but the other interventions showed a significant effect. A sensitivity analysis (Figure II) without these subgroups showed a significantly higher mean core temperature for warming mechanisms, with no significant heterogeneity: WMD 0.47°C (95%CI 0.39, 0.54); I^2=9%, p=0.35.

Figure I: Warming mechanisms all types and phases

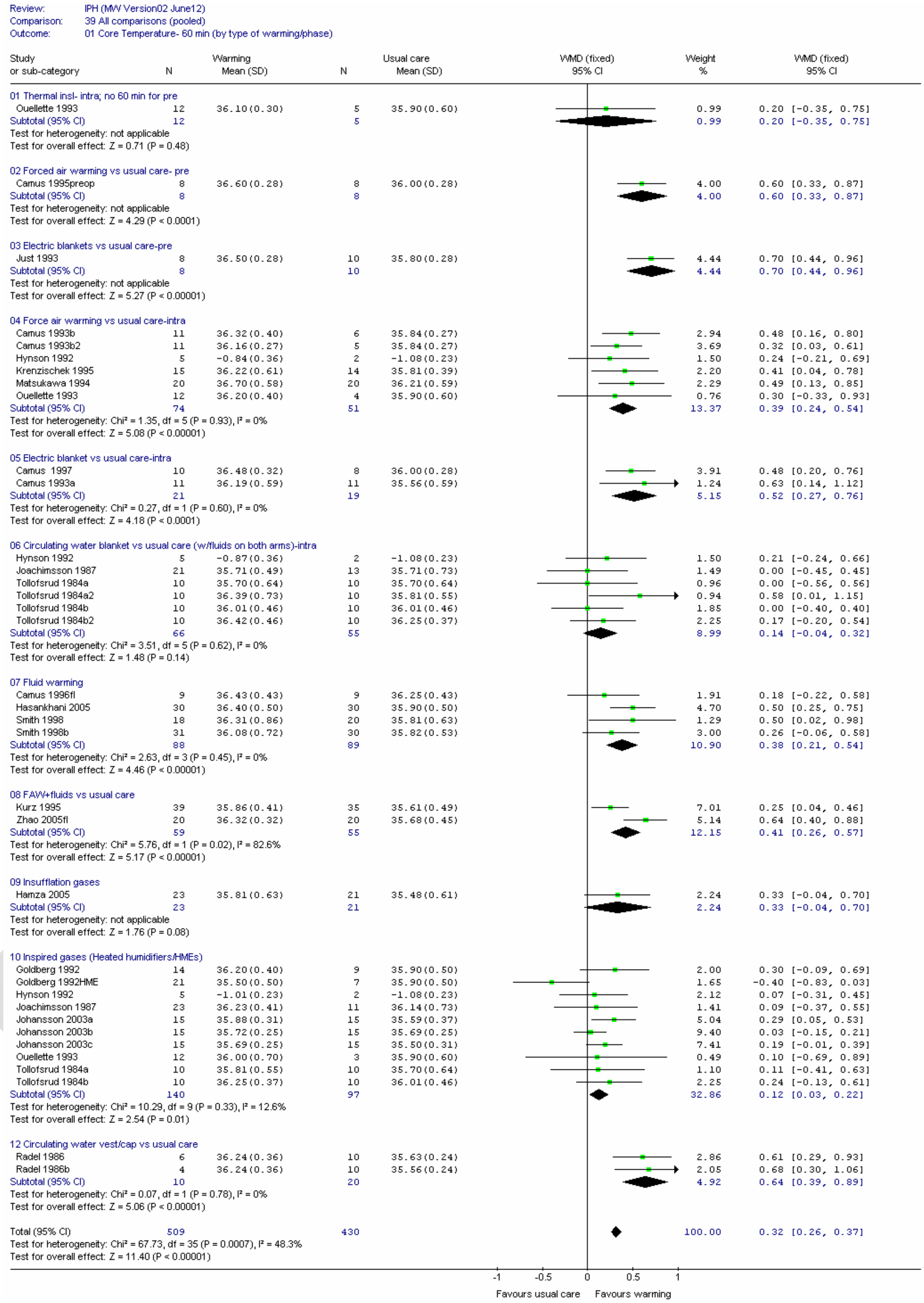
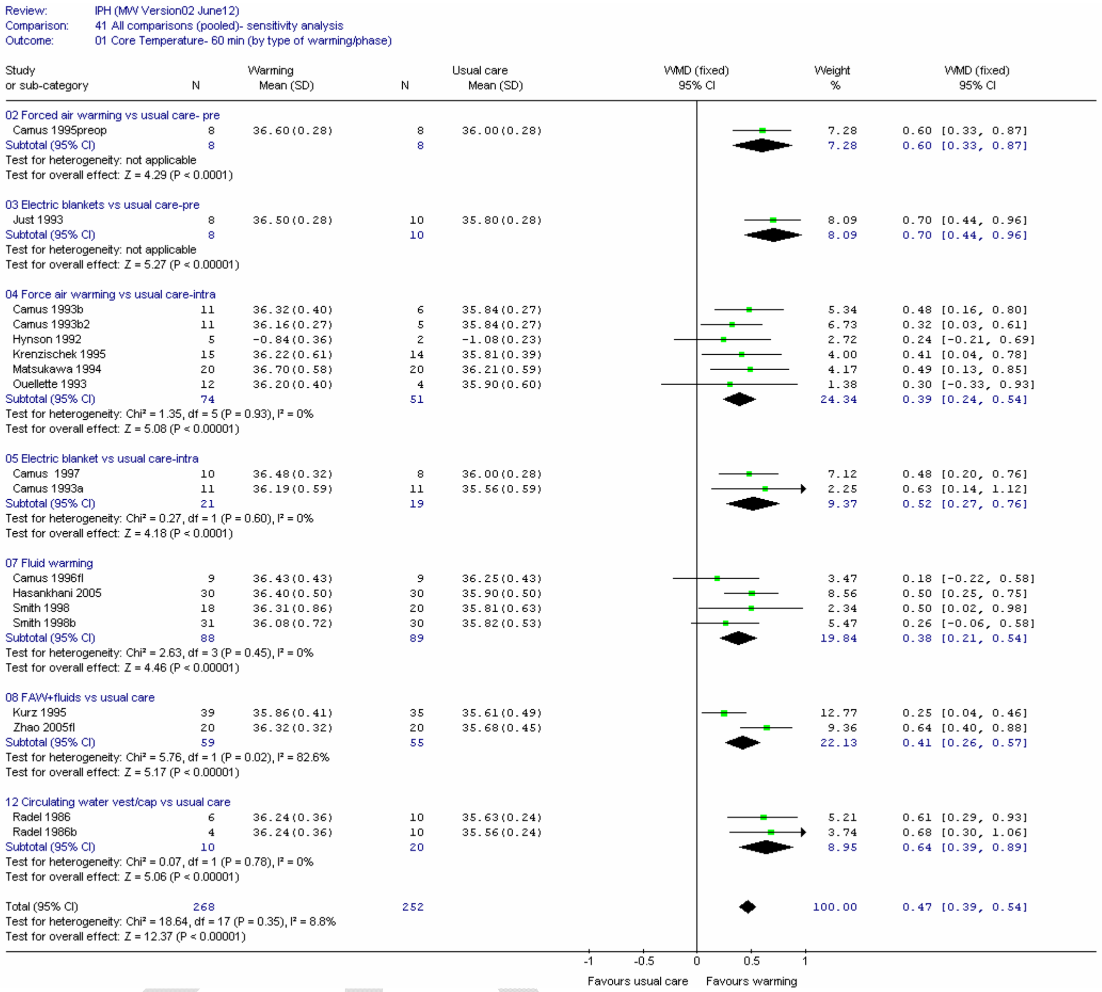


Figure II: Warming mechanisms all types and phases, sensitivity analysis



ii. In which phase is warming most effective?

The GDG decided that the perioperative phases should be considered separately as the purpose was to determine whether warming works effectively and whether they are cost effective in each phase of the perioperative journey. Sections 10.1 to 10.3 will consider the preoperative, intraoperative and the pre and intraoperative phases, respectively.

The phases were defined as follows:

- **Preoperative phase**
  - From the time of preparation for surgery/administration of premedication
  - To the time of first anaesthetic intervention.

- **Intraoperative phase**
  - From time of anaesthetic intervention
  - To entry into the operating room.

In addition to examining the effectiveness of the warming mechanisms, we also considered the adverse effects associated with them (section 10.4).

iii. Which device works best in each phase?

It was decided that patient warming devices (thermal insulation, forced air warming, electric blankets and water mattress) would be presented separately to warmed fluids and warmed gases. Uncertainty relating to heterogeneity reported in the evidence, coupled with the need to determine the cost effectiveness for each device, determined the technical team's advice to the GDG that the studies should also be split by the type of warming device.

For the active patient warming devices such as forced air warming and electric blankets, we have chosen to combine studies using devices from different manufacturers. Two studies (Macouillard 1986; Camus 1998) have compared different methods of forced air warming blankets and have shown the systems performance was comparable.

Within each review, the GDG originally decided to stratify only by presence/absence of comorbidities, trauma, and hyperthermia. It was also decided to combine all comparisons of active warming versus usual care, regardless of the presence of other active patient interventions, fluid or warmed gas interventions.

However, a post-hoc decision was made to stratify by type of anaesthesia [general; regional; combined], as these were expected to have different mechanisms of action.

Types of comparison

The following comparisons were included:

A. Intraoperative phase

1 Warming versus usual care
2 Warming versus usual care
3 Active Type 1 versus active type 2
4 Thermal insulation type 1 versus type 2
5 Type 1 + Type 2 versus type 1
6 Active warming versus thermal insulation
7 Duration 1 versus duration 2
8 Temperature setting 1 versus setting 2
9 Warming site 1 versus site 2

B. Preoperative phase

1. Warming versus usual care
2. Active warming Type 1 versus active type 2
3. Thermal insulation type 1 versus type 2
4. Type 1 + Type 2 versus type 1

5. Duration 1 versus duration 2
6. Temperature setting 1 versus setting 2
7. Active warming versus thermal insulation

D. Pre and intraoperative phases

Same intervention in both phases

1 Warming versus usual care
2 Active Type 1 versus active type 2
3 Thermal insulation type 1 versus insulation type 2
4 Type 1 + Type 2 versus type 1
5 Duration 1 versus duration 2
6 Temperature setting 1 versus setting 2
7 Active warming versus thermal insulation
8 Active warming + thermal insulation versus thermal insulation

E. Different warming devices in the two phases, for example:

1 Active 1 (pre) + active 2 (intra) versus usual care
- This is a subgroup of D1 above

2 Active 1 (pre) + active 2 (intra) versus thermal insulation 1 (pre) + insulation 2 (intra)
- This is a subgroup of D7 above

3 Active 1 (pre) + thermal insulation 1 (intra) versus active 2 (pre) + insulation 2 (intra)
4 Warming 1(pre) + Warming 2 (intra) versus Warming 2 (intra).

Pharmacological agents

Types of intervention

Any pharmacological agent for the prevention of inadvertent perioperative hypothermia was to be considered, including those expected to reduce heat redistribution (e.g.vasoconstrictors) and those likely to increase metabolic heat production (thermogenesis, e.g. amino acids).

Types of comparison

The following comparisons were to be included:

- Intervention versus placebo / no intervention;
- Intervention 1 + intervention 2 versus intervention 2 alone;
- Intervention Class 1 versus class 2 (e.g. amino acids versus sugars);
- Intervention type 1 versus type 2 within class;
- Duration 1 versus duration 2;
- Perioperative phase 1 versus phase 2;
- Dose 1 versus dose 2;
- Pharmacological intervention versus other intervention.

It was decided to combine the two types of comparison: (i) Intervention versus placebo / no intervention and (ii) Intervention 1 + intervention 2 versus intervention 2 alone, and to examine this decision, where appropriate, using sensitivity analyses.

Outcomes

This review considers pharmacological agents specifically for the prevention of IPH. Clearly pharmacological agents are used for other purposes, including the prevention of shivering. The latter may be associated with hypothermia or may occur by a different mechanism. We planned to include studies of pharmacological agents only if they reported core temperatures intra or postoperatively or the incidence of inadvertent perioperative hypothermia. Shivering was not to be recorded as an outcome for this review.

Stratification and subgroup analyses

We planned to stratify the studies by the following:

- Classes of drugs;
- Trauma patients – elective and emergency surgery considered together initially;
- General, regional and combined regional/general anaesthesia;
- Co-morbidities that affect metabolism such as hypothyroidism;
- Patients with hyperthermia.

We planned to carry out subgroup analyses by the following:

- Type of pharmacological agent within a class;
- Dose;
- Duration: when the drug was given in relation to induction of anaesthesia;
- ASA grade (I-II and III+);
- Magnitude of surgery (major / medium / minor);
- Duration of anaesthesia (less than 30 minutes, 30 to 60 minutes, 1 to 2 hours, more than 2 hours);
- Intubated / ventilated patients or not.

10.1 ACTIVE WARMING AND THERMAL INSULATION IN THE PREOPERATIVE PHASE FOR THE PREVENTION OF IPH

CHARACTERISTICS OF CLINICAL STUDIES INCLUDED IN THE REVIEW (APPENDIX C)

Nine studies were included in this preoperative warming mechanisms review (Bock 1998; Buggy 1994; Camus 1995; Fossum 2001; Just 1993; Melling 2001; Sheng 2003 [1]; Sheng 2003 [2]; Wong 2007). An additional study (Horn 2002) was included as indirect evidence, and is presented separately: participants were pregnant women undergoing elective Caesarean section with epidural anaesthesia. The excluded studies are listed in Appendix E.

Four of the studies (Bock 1998; Buggy 1994; Wong 2007; Horn 2002, indirect) are described in the pre and intraoperative review (i.e. the patients received warming mechanisms for both the pre and intraoperative periods, compared with usual care). These studies contribute to this preoperative review only for the outcomes in the preoperative phase; the characteristics of these studies are given in the pre and intraoperative review (Section 10.3). A total of 647 patients were included in the six remaining studies (Camus 1995; Fossum 2001; Just 1993; Melling 2001; Sheng 2003 [1]; Sheng 2003 [2]). The total number of patients in each study ranged from 16 (Just 1993; Camus 1995) to 421 (Melling 2001). Two studies had fewer than 20 patients in the intervention arm (Just 1993; Camus 1995).

Participants

The age of the patients ranged from 22 to 68 years with a mean age (where given) ranging from 37.5 to 64 years. Two studies included patients with ASA I to II status (Just 1993; Camus 1995) and three studies had patients with ASA I to III status (Fossum 2001; Sheng 2003 [1]; Sheng 2003 [2]).

One study was conducted in the UK (Melling 2001); three studies were conducted in the US (Fossum 2001; Sheng 2003 [1]; Sheng 2003 [2]) and two were conducted in France (Camus 1995; Just 1993).

Anaesthesia and surgery

A range of procedures were undertaken including: total hip arthroplasty (Just 1993); laparoscopic cholecystectomy (Camus 1995); a mixture of gynaecological, orthopaedic or urological procedures (Fossum 2001). Sheng 2003 (1) and Sheng 2003 (2) did not indicate the type of surgery.

Grade of surgery was classified as 2 in Melling (2001), a mixture of 2 and 3 in Fossum (2001), 4 in Just (1993) and was unclear in both Camus (1995) (laparoscopic cholecystectomy) and Melling (2001) (hernia repair: unclear; varicose vein: grade 2; breast surgery: unclear). Type of surgery was not stated for Sheng (2003).

Classification by magnitude of surgery was possible for the following studies:

- Just (1993): major surgery
- Melling (2001): minor surgery.

However, insufficient information on the surgery was given for classification of the remaining studies:

- Camus (1995): elective abdominal surgery; could be major or intermediate
- Fossum (2001): gynaecological, orthopaedic, or urological surgical procedures requiring general anaesthesia (1 to 3 hours anaesthesia time); could be major or intermediate
- Sheng (2003) (1) and (2): no details of surgery given.

Patients were induced with general anaesthesia in three studies (Just 1993; Camus 1995; Fossum 2001) and assumed to be general anaesthesia in the remaining three studies (Melling 2001; Sheng 2003 [1]; Sheng 2003 [2]). Duration of anaesthesia was more than 60 minutes in all studies but two (Sheng 2003 [1]; Sheng 2003 [2]). These studies lasted more than 30 minutes, but no further information was given.

Two of the six studies gave premedication:

- Just (1993) gave flunitrazepam, 1mg orally, one hour before admission on the operating ward; patients were warmed at least 90 minutes before induction
- Camus (1995) gave oral hydroxyzine 100mg, one hour before surgery, and patients were pre-warmed at least one hour before induction.
- The other studies did not mention premedication, but it is not clear if the studies failed to report this or it was not given:
  - Fossum (2001) gave few details about anaesthesia
  - Sheng (2003) and Melling (2001) did not give any details about anaesthesia.

All studies indicated that patients underwent elective procedures. Information on the duration of surgery was reported in two studies (Just 1993; Melling 2001). Duration of surgery (where given) ranged from 48 minutes (Melling 2001) to 180 minutes (Just 1993).

Interventions

There were a range of interventions used, the most common of which was forced air warming, as used in three studies (Camus 1995; Fossum 2001; Melling 2001). The temperature settings and durations of warming were:

- Bair Hugger® 41°C, 60 minutes before induction (Camus 1995)
- Bair Hugger® 38°C, at least 45 minutes before induction (Fossum 2001)
- Forced air warming blanket, a minimum of 30 minutes before induction (Melling 2001).

Other interventions included electric blanket 42°C to 43°C, for at least 90 minutes before induction (Just 1993); reflective hats and jackets (Sheng 2003 [1]) and reflective hats (Sheng 2003 [2]).

Setting

Three studies reported that the procedures were undertaken in an outpatient surgery clinic (Fossum 2001; Sheng 2003 [1]; Sheng 2003 [2]). 87% of patients in Mellling (2001) were day cases. The other studies did not state whether the patients were inpatients or had day surgery.

The following comparisons were reported:

1. Thermal insulation versus usual care (Sheng 2003 [2]; Buggy 1994 -preoperative outcomes only);
2. Thermal insulation 1 (pre) + thermal insulation 2 (intra) versus thermal insulation 2 (intra) (Sheng 2003 [1]) [cross-phase];
3. Active warming versus usual care (Camus 1995; Melling 2001). Bock (1998); Wong (2007); Horn (2002, indirect) had preoperative outcomes only;
4. Active warming (pre) + Active warming (intra) versus Active warming (intra) (Just 1993) [cross-phase];
5. Active warming 1 versus Active warming 2 (Fossum 2001; Melling 2001).

There were no studies identified that compared one thermal insulation mechanism with another, or that directly compared active warming and thermal insulation.

More specifically the comparisons were:

A. Thermal insulation versus usual care

- Reflective hats versus usual care (Sheng 2003 [2])
    - From arrival in outpatients to just before transfer to operating room;
- Reflective blankets versus usual care (surgical drape), from before induction: duration not specified (Buggy 1994)
    - Preoperative outcomes only (continuation into intraoperative phase).

B. Thermal insulation 1 (pre) + thermal insulation 2 (intra) versus thermal insulation 2 (intra)

- Reflective hats and jackets versus usual care (Sheng 2003 [1])
    - From arrival in outpatients to just before transfer to theatre
    - Patients were then randomised to reflective blanket or cloth blanket during the intraoperative period. It is unclear if the distribution of these is comparable amongst the preoperative hats and jackets and control groups.

C. Active warming versus usual care

- Forced air warming (up to shoulders) and cotton sheet versus wool blanket for 60 minutes before induction (Camus 1995)
- Forced air warming (whole body) versus usual care for at least 30 minutes before induction (Melling 2001)
- Forced air warming (upper body) versus usual care from 30 minutes before induction (Bock 1998)
    - Preoperative outcomes only (continuation into intraoperative phase)
- Warming mattress versus placebo warming mattress (switched off) from 30 minutes before induction (Wong 2007)
    - Preoperative outcomes only (continuation into intraoperative phase)
- Radiant heat dressing (non-contact local warming to the wound) versus usual care for at least 30 minutes before induction (Melling 2001)
- Forced air warming (upper body) versus cotton blanket, regional anaesthesia, from 15 minutes before insertion of the epidural catheter (indirect evidence: Horn 2002)
    - Preoperative outcomes only (continuation into intraoperative phase).

D. Active warming (pre) + Active warming (intra) versus Active warming (intra)

- Preoperatively: electric blanket versus usual care for 90 minutes before induction
    - Intraoperatively: electric blanket for both groups (Just 1993).

E. Active warming 1 versus active warming 2

- Forced air warming versus warmed cotton blanket (66°C) from 45 minutes before induction (Fossum 2001)
- Forced air warming versus local non-contact radiant heat dressing from 30 minutes before induction (Melling 2001).

The GDG decided that it was acceptable to combine sections A and B, and C and D.

Outcomes

The studies measured the following outcomes:

Primary outcomes

One study (Fossum 2001) measured the number of patients with IPH, but most recorded the core temperature at different times. For this outcome, an increase of 0.5°C over the control group temperature was considered to be clinically significant for a control group temperature above 36.0°C, and a difference of 0.2°C was considered to be clinically significant for control group temperatures below 36.0°C.

Four studies (Fossum 2001; Melling 2001; Sheng 2003 [2]; Camus 1995) warmed the patients only in the preoperative phase, but recorded temperatures intraoperatively. Four studies warmed the patients in the preoperative phase and recorded temperatures preoperatively only (Buggy 1994; Bock 1998; Wong 2007; Horn 2002, indirect).

Core temperature was measured at the following stages:

- In the holding area (Buggy 1994; Sheng 2003 [1]; Sheng 2003[2])
- At the end of pre-warming (Bock 1998; Just 1993; Camus 1995; Fossum 2001; Melling 2001*; Sheng 2003 [1]; Sheng 2003 [2]; Wong 2007; Horn 2002, indirect)
- In the intraoperative period (Camus 1995; Sheng 2003 [1]; Just 1993)
- In PACU (Fossum 2001; Camus 1995; Sheng 2003 [1])

Core temperature was measured at the tympanic membrane for all of the studies except Buggy (1994) and Wong (2007), in which the nasopharyngeal temperature was measured.

Other outcomes were:

- Shivering (Just 1993; Camus 1995; Fossum 2001)
- Thermal discomfort (end of preoperative phase: Fossum 2001; Horn 2002, indirect).

Postoperative complications

- Surgical site infection rates (Melling 2001)
- Pain (Fossum 2001).

Subgroup analyses were planned by type of warming device, power, and duration of warming.

METHODOLOGICAL QUALITY OF INCLUDED STUDIES (Appendix D)

An adequate method of sequence generation was recorded in two studies (Camus 1995, random numbers table; Fossum 2001, shuffled packets) and unclear in four studies (Just 1993; Melling 2001; Sheng 2003 [1]; Sheng 2003 [2]).

A partially adequate method of allocation concealment was reported in two studies (Fossum 2001: sealed packets; Melling 2001: opaque envelopes) and unclear in four studies (Just 1993; Camus 1995; Sheng 2003 [1]; Sheng 2003 [2]).

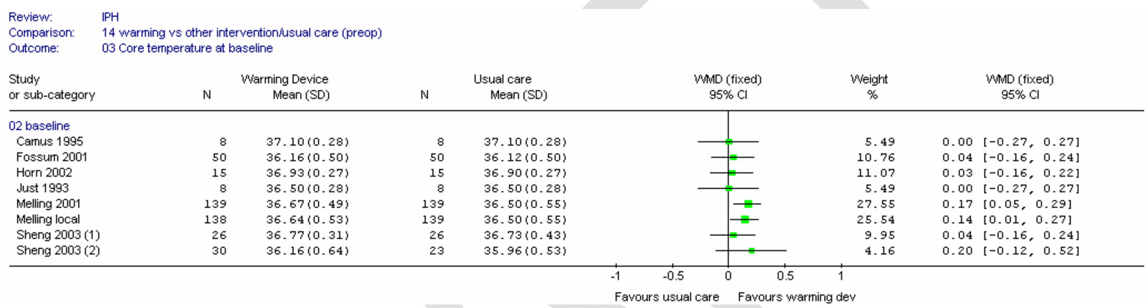
Blinding for assessment of core temperature was not stated in any of the studies. Blinding of the outcome assessors for shivering was stated in two studies (Just 1993; Camus 1995). One study reported blinding of the method of warming for the outcome assessor of wound infection (Melling 2001).

* *Data on core temperatures provided for only active 1 and active 2 for post warming. Data for all 3 groups presented at post operative phase.*

Two of the studies demonstrated baseline comparability (Just 1993; Sheng 2003 [1]). One study indicated a larger number of women to men (19:11) in the thermal insulation group (Sheng 2003 [2]) and one reported a difference in preoperative ambient temperature of 0.7°C between the groups, which was statistically significant (Camus 1995). The GDG did not consider either of the differences in baseline to be of importance for this review.

Baseline core temperatures were also recorded and are shown in Figure 1. The two Melling (2001) comparisons had statistically significant differences in baseline temperature, with higher temperatures being found for the active warming groups (0.17 and 0.14°C) compared with usual care. These comparisons were considered with caution, although the importance of this bias was related to the size of effect recorded.

Figure 1: Baseline temperatures



The Wong (2007) study only gave the median and range baseline core temperatures for each group. The median was 36.5°C for each and the authors reported a p value of 0.880 (i.e. not statistically significant).

One study described an *a-priori* power calculation (Melling 2001). This was based on wound infection, which was the primary outcome of the study. In order to detect a significant reduction of infection at the 5% level, in either of the two warmed groups compared with the non-warmed group, the 90% power calculation estimated a sample size of 402, with 134 patients in each of the three groups. In Horn (2002), in order to detect a treatment effect of 1.0°C at the 5% level, the 80% power calculation estimated a sample size of 30 for each group.

Three studies (Fossum 2001; Sheng 2003 [1]; Sheng 2003 [2]) indicated that all patients were included in the analysis. Only one study reported dropouts, which were less than 20% (Melling 2001). In the local warming group (n=139), one patient's operation was cancelled and four patients out of 279 patients (2 local warming and 2 standard) were lost to follow-up. Loss of patients to follow-up was unclear in the remaining studies.

RESULTS

A. Thermal insulation versus usual care

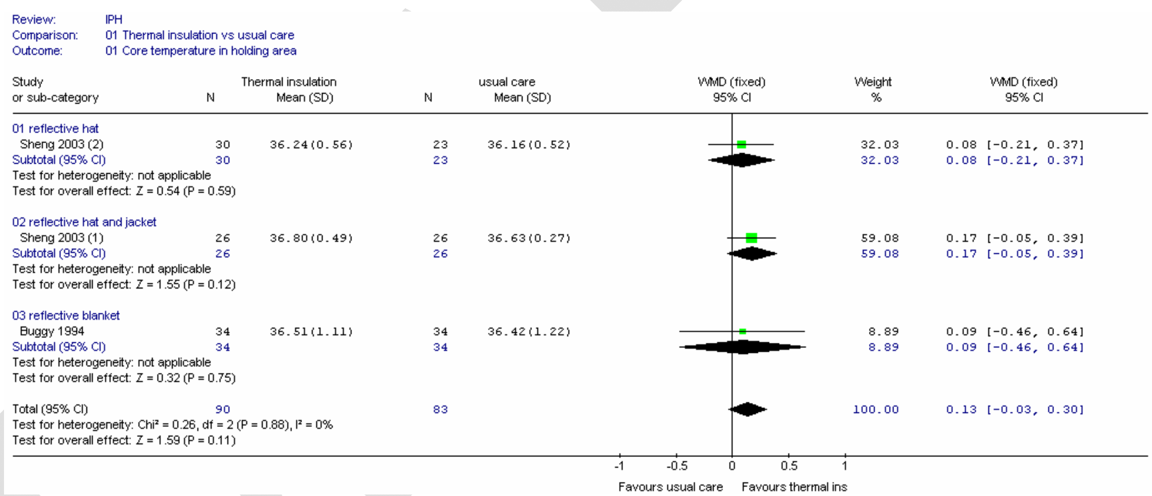
Sheng (2003 [2]) compared thermal insulation (reflective hats) with usual care in the preoperative period. Sheng (2003 [1]) compared reflective hats and jackets with usual care in the preoperative phase, but in the intraoperative phase the patients were re-randomised to reflective blanket or usual care. The Sheng study reported core temperatures on a graph, but it was unclear if the error bars were recording standard deviation, standard error or confidence limits. We deduced, from the p values given, that these were standard errors.

Buggy (1994) compared a reflective blanket with usual care in the preoperative phase, but the results for the intraoperative phase were not appropriate for this review because the randomisation was continued intraoperatively.

1. Core temperature: holding area

Meta-analysis of three studies in 173 patients showed no significant difference between groups and no heterogeneity (I^2=0%, p=0.88) (Figure 2). We note that the control group core temperatures are above 36.0°C.

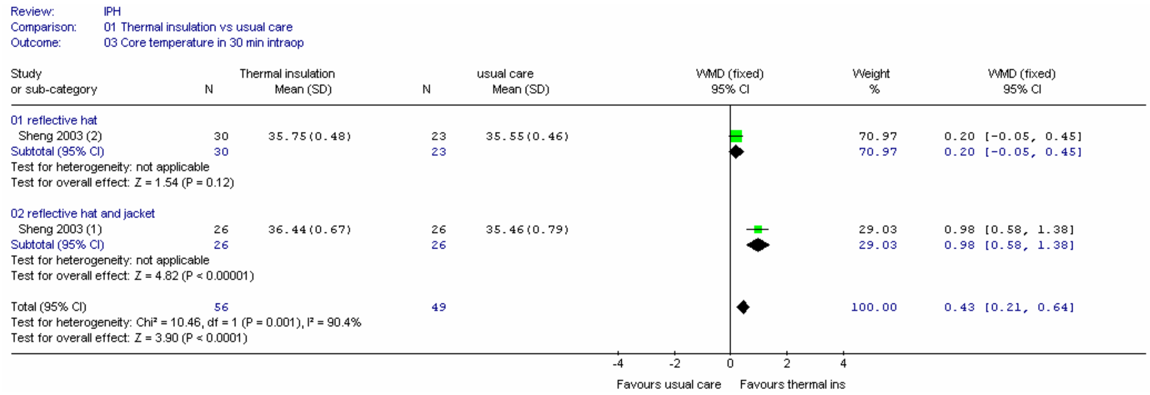
Figure 2: Core temperature: holding area; thermal insulation versus usual care



2. Core temperature: 30 minutes intraoperatively

Two studies (Sheng 2003 [1] and Sheng 2003 [2]) reported core temperatures 30 minutes after induction (Figure 3). Confidence intervals were fairly wide, but there was a large significant difference between hats and jackets and usual care (MD 0.98 (95%CI 0.58, 1.38), but not between reflective hat and usual care. Thus, there was significant heterogeneity in the meta-analysis (I^2=90%, p=0.001). We note that the patients in Sheng 2003(2) were re-randomised to reflective blankets and usual care in the intraoperative phase, but the proportion of the two intraoperative interventions in each of the preoperative groups was not reported, and differences may have led to the size of the effect.

Figure 3: Core temperature: 30 minutes into intraoperative period; thermal insulation versus usual care

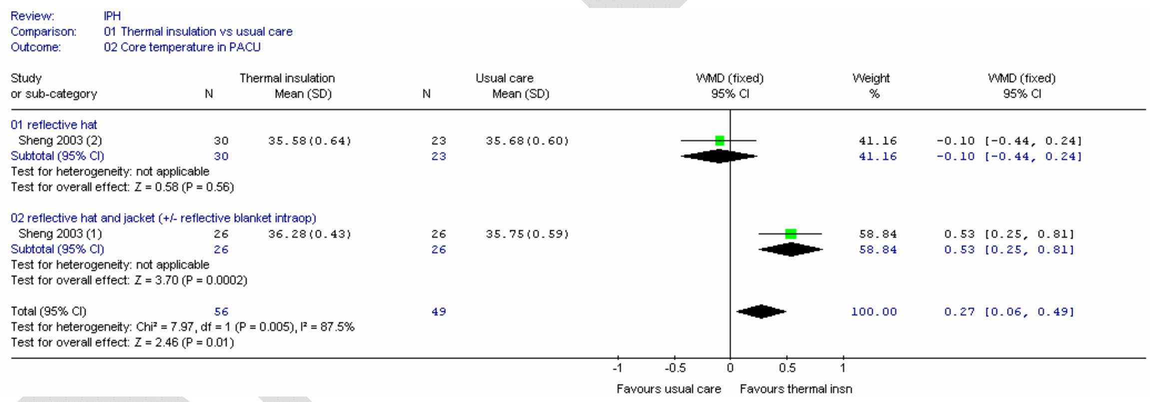


NB: scale -4 to 4

3. Core temperature - arrival in PACU

Two studies (Sheng 2003 [1] and Sheng 2003 [2]) reported core temperatures in PACU (Figure 4). Confidence intervals were fairly wide, but there was a significant difference between hats and jackets and usual care, but not between hat and usual care.

Figure 4: Core temperature: arrival in PACU; thermal insulation versus usual care



B. Active warming versus usual care

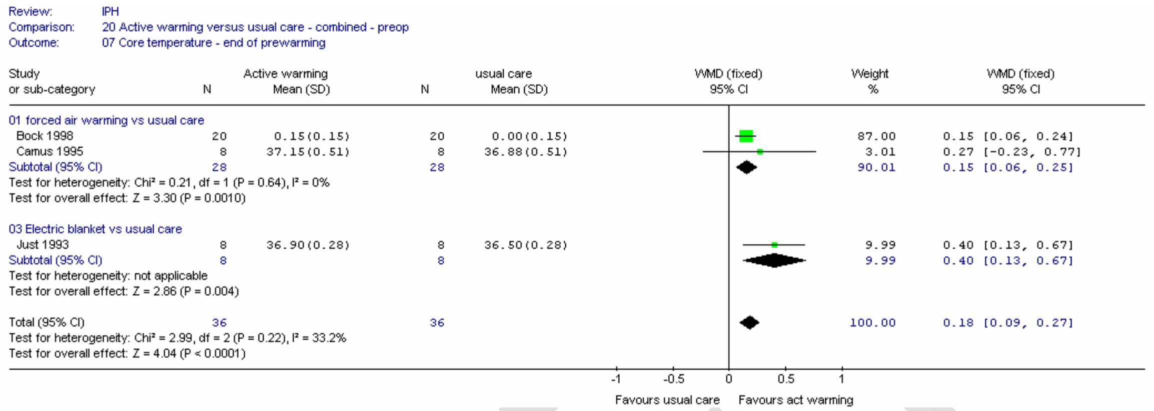
Six studies compared active warming with usual care, four of which had other interventions in both arms in the intraoperative phase (Bock 1998; Just 1993; Wong 2007; Horn 2002, indirect). Just (1993) investigated the added effect of preoperative warming for patients given electric blankets in the intraoperative phase, but the other three studies continued the randomisation from the preoperative phase (Bock 1998; Wong 2007; Horn 2002, indirect), so these are only considered for outcomes in the preoperative phase. The other two studies gave active warming solely in the preoperative phase (Camus 1995; Melling 2001). The GDG considered it acceptable to combine any studies comparing active warming versus usual care, regardless of whether or not all patients received active warming in the intraoperative phase.

1. Core temperature: end of pre-warming

Two studies (Bock 1998; Camus 1995) gave forced air warming and one (Just 1993) gave the prewarmed group electric blankets. All recorded the temperature at the end of prewarming.

The duration of warming ranged from 60 minutes (Camus 1995) to 90 minutes (Just 1993). The indirect study (Horn 2002) with 30 patients measured core temperature at the end of 15 minutes warming. It is noted that Camus (1995) had the forced air warmer donated by Augustine Medical Inc, the manufacturers.

Figure 5: End of prewarming

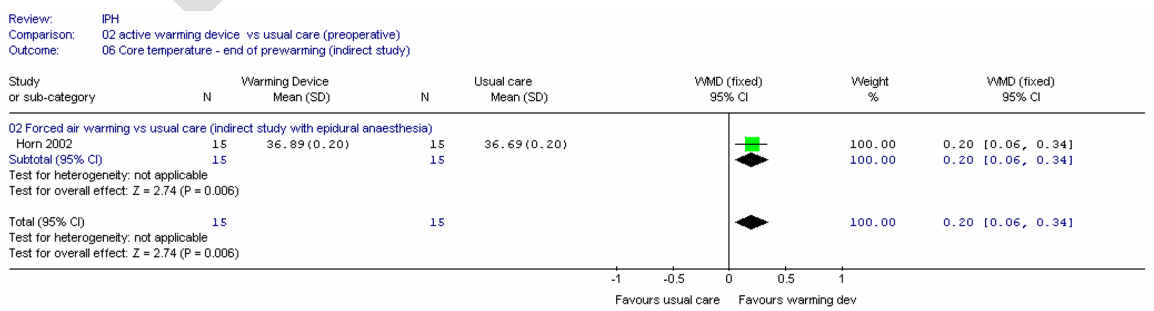


Meta-analysis of the two forced air warming studies in 56 patients gave significantly higher core temperatures for the active warming group: WMD 0.15°C (95% CI 0.06, 0.25), for a control group temperature of 36.9°C. For the Just (1993) study (n=16), the electric blanket group had significantly higher core temperatures; MD 0.40°C (95% CI 0.13, 0.67), for a control group temperature of 36.5°C. The confidence interval is fairly wide, however. Meta-analysis across the different warming devices showed a little heterogeneity, which was not significant: WMD 0.18 (95% CI 0.09, 0.27), I^2=33%, p=0.22.

In Horn (2002), the indirect study in 30 patients showed a significantly higher mean core temperature for the intervention group after 15 minutes warming (Figure 6).

The GDG recommended that the types of warming device were treated separately.

Figure 6: Core temperature: end of prewarming; active warming versus usual care [indirect study]



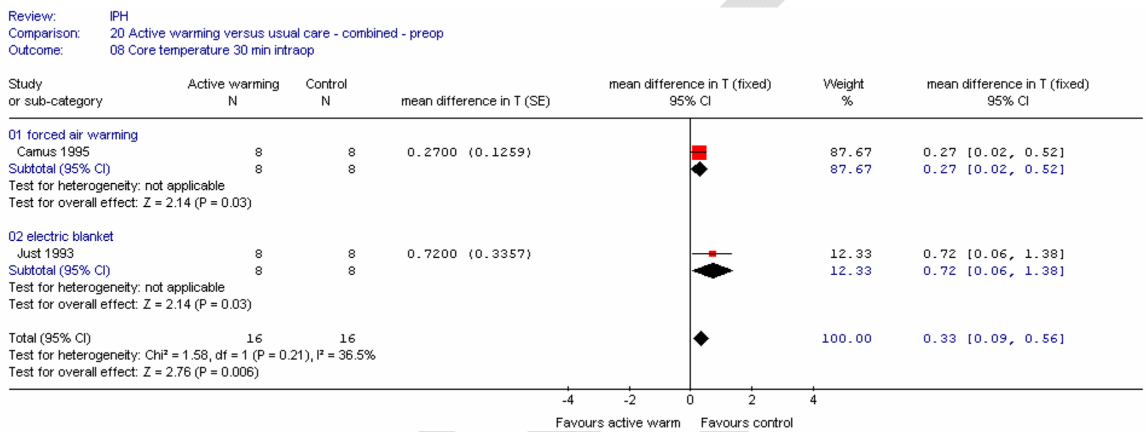
2. Core temperature intraoperatively

Two studies with 16 patients in each (Just 1993; Camus 1995) recorded the core temperature at various points in the intraoperative period.

a) Core Temperature at 30 minutes intraoperatively

Each type of warming device gave significantly higher core temperatures for the warming device. The mean differences for each of these small studies (n=16) were: forced air warming 0.27°C (95% CI 0.02, 0.52); electric blanket 0.72°C (95% CI 0.06, 1.38). This confidence interval was wide, however.

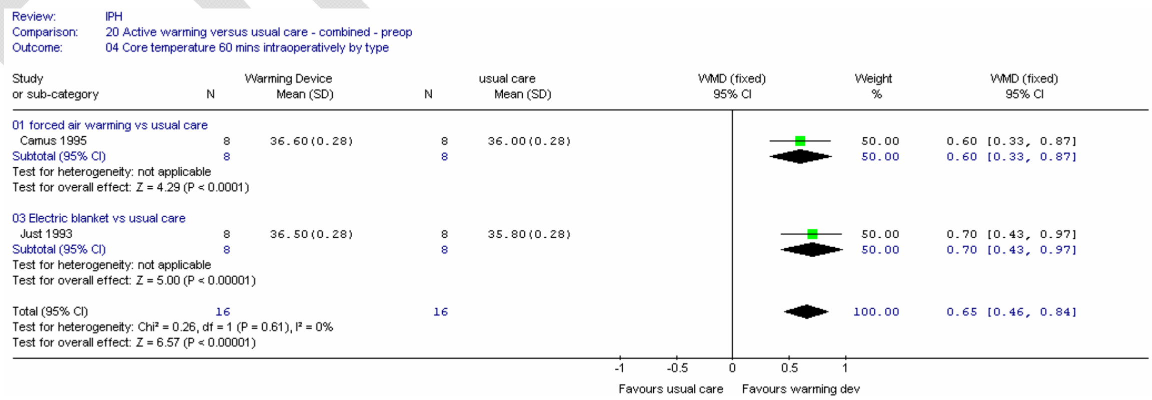
Figure 7: 30 minutes intraoperatively



b) Core Temperature at 60 minutes intraoperatively

Each type of warming device gave significantly higher core temperatures for the warming device. The mean differences were: forced air warming 0.60°C (95% CI 0.33, 0.87); electric blanket 0.70°C (95% CI 0.43, 0.97).

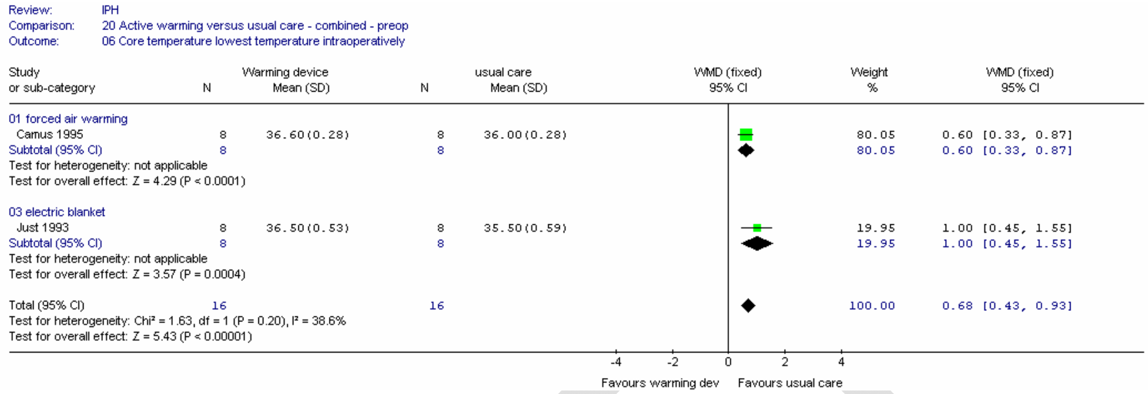
Figure 8: 60 minutes intraoperatively



3. Lowest intraoperative temperature

There was a statistically significant difference in the lowest preoperative temperature for each type of warming device. Just (1993) reported the lowest intraoperative temperature for the warming group at 60 minutes (which remained at the same temperature until 105 minutes) and at 105 minutes for the control group. The difference was statistically and clinically significant at 1.00°C (95% CI 0.55, 1.45) for a control group temperature of 35.5°C, but the confidence interval was fairly wide and the study size small.

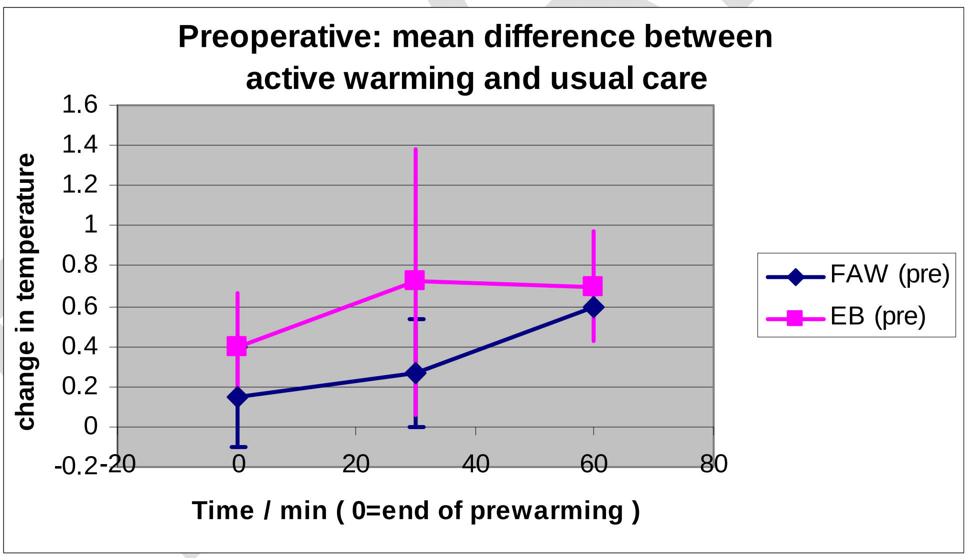
Figure 9: Lowest intraoperative temperature



4. Core Temperature Trends

We plotted the mean differences with their 95% confidence intervals for the active versus usual care comparisons; the values at time zero are those at the end of prewarming.

Figure 10: Mean difference between active warming and usual care

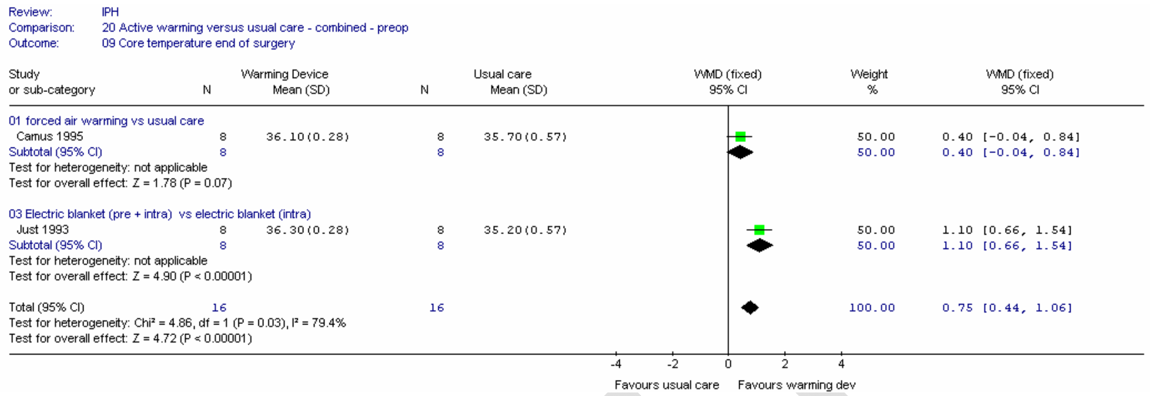


5. Core temperature: end of surgery

Two studies (Just 1993; Camus 1995) recorded the core temperature at the end of surgery (Figure 11).

The duration of surgery was not stated in Camus (1995). In Just (1993), the mean duration of surgery was 177 minutes, and the use of electric blanket warming preoperatively in addition to intraoperatively gave a statistically significant improvement in core temperature, compared with intraoperative warming alone, of 1.10°C (95%CI 0.66,1.54) for a control group temperature of 35.2(0.57)°C; the confidence interval was fairly wide.

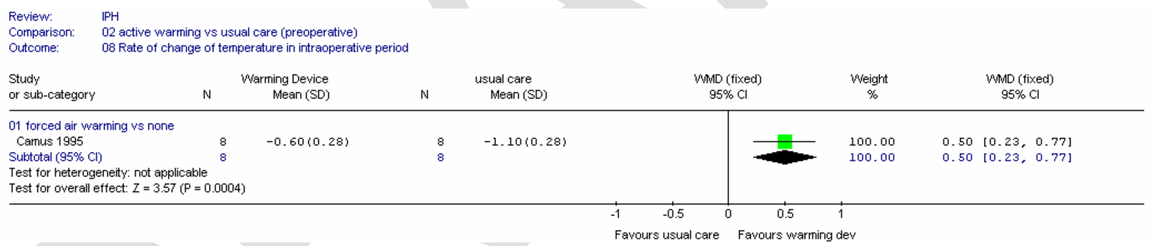
Figure 11: Core temperature: end of surgery; active warming versus usual care



6. Rate of change of temperature

One small study in 16 patients (Camus 1995) recorded the rate of change of temperature in the intraoperative period (Figure 12). The decrease in temperature was significantly less in the warming group and the difference in rate was 0.50°C/h (95% CI 0.23, 0.77).

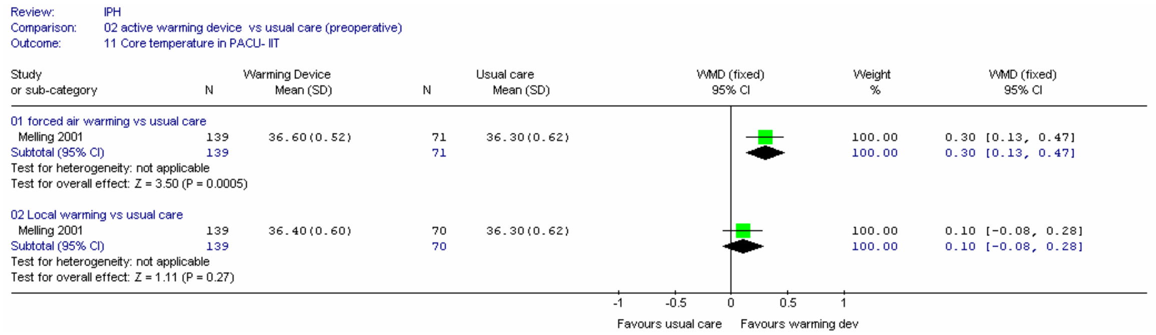
Figure 12: Rate of change of temperature; active warming versus usual care



7. Core temperature: PACU

One large study (n=419) recorded the core temperature in the postoperative period (Melling 2001). Temperature was measured immediately after surgery within 5 minutes of entering the recovery area. Mean durations of surgery were as follows: 48 (SD 17.52) minutes (usual care), 49.3 (SD 15.63) minutes (forced air warming), and 49.5 (19) minutes (local warming group). For the forced air warming group the core temperature was significantly higher for the warming group; MD 0.30°C (0.13, 0.47), for a control group rate of 36.30°C. The mean difference was not significant for the local warming group (Figure 12). We note that in both comparisons the core temperature for the control group was above 36.0°C, and the baseline temperatures were significantly higher in the control group (0.17°C and 0.14°C for forced air warming and local warming respectively). This difference in baseline is comparable with the effect size and therefore conclusions were not drawn from these results.

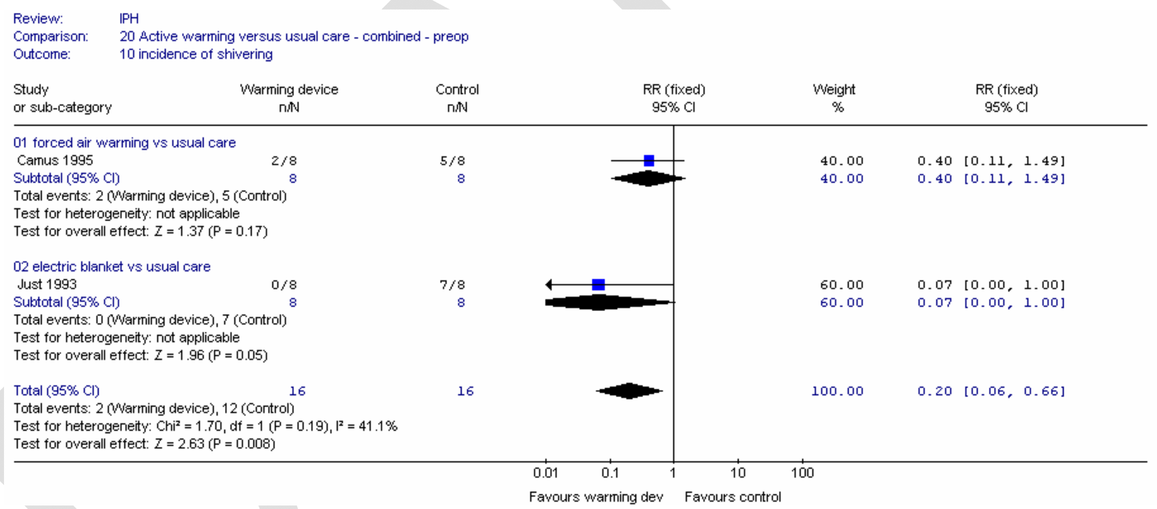
Figure 13: Core temperature: PACU; active warming versus usual care



8. Shivering

Two studies with 16 patients in each (Just 1993; Camus 1995) assessed shivering in the recovery room (Figure 14). The categories used for evaluation of shivering were unclear in Camus (1995), but the incidence of shivering for each group was reported. Meta-analysis of the two studies showed a significantly larger effect of warming on the incidence of shivering, although the confidence interval was wide. This corresponds to a NNT of 2 (95% CI 2, 17) for a control group rate of 63 to 88%.

Figure 14: Shivering; active warming versus usual care



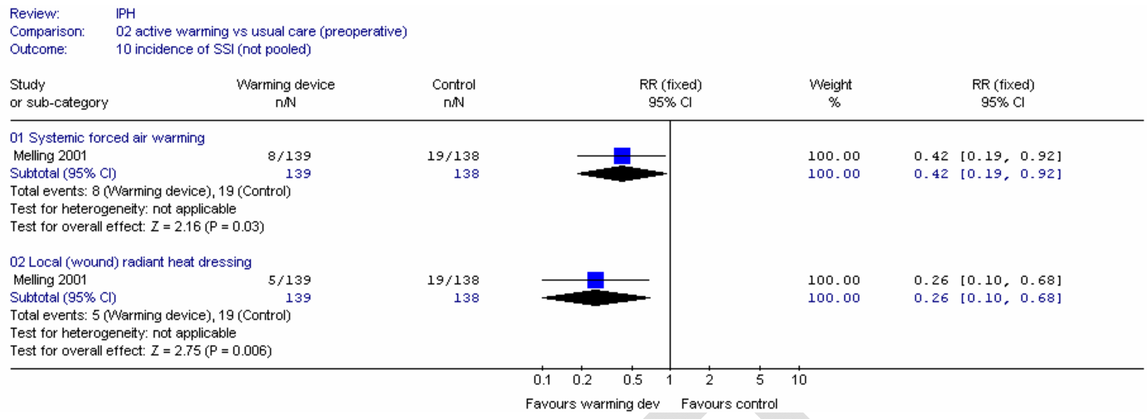
Postoperative Complications

9. Surgical site infection

One study assessed the effect on surgical site infection rates of local warming (non-contact radiant dressing) or whole body forced air warming in the preoperative phase compared with usual care (Melling 2001) (Figure 15).

The duration of warming was longer for the forced-air warming group (44.9 minutes) compared with that for the non-contact radiant dressing group (38.7 minutes). Overall, there was a statistically significant reduction in the incidence of SSI, for each of the warming devices groups, giving NNTs of 13 (95% CI 7, 100) and 10 (95% CI 6, 25) for forced air warming and radiant heat respectively (for a control group rate of 14%).

Figure 15: Surgical site infection; active warming versus usual care



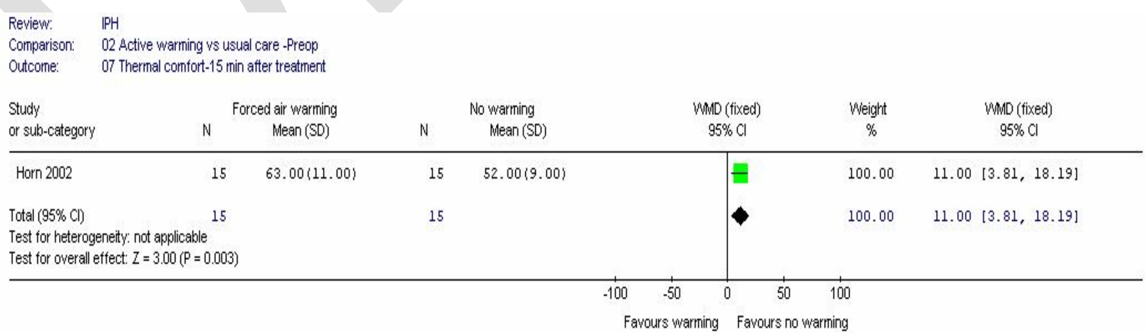
10. Adverse Effect: thermal discomfort at the end of the preoperative period

One study with 16 patients (Just 1993) and the indirect study with 30 patients (Horn 2002) reported on thermal discomfort at the end of the preoperative period (Figure 16).

The methods used to assess thermal discomfort varied between the studies. Just (1993) classified thermal comfort as *comfortable*, *indifferent,* or *unbearably hot*, and recorded this at 5 minute intervals. The study did not provide data for each group but simply reported that all patients assessed pre-warming as *comfortable* or *indifferent*.

In Horn (2002), the patients assessed thermal discomfort on a visual analogue scale, with 0 representing *cold*, 50 representing *neutral* and 100 representing *insufferably hot* and the result is presented below. Patients were significantly more uncomfortable in the intervention group; MD 11.00 (95% CI 3.81, 18.19).

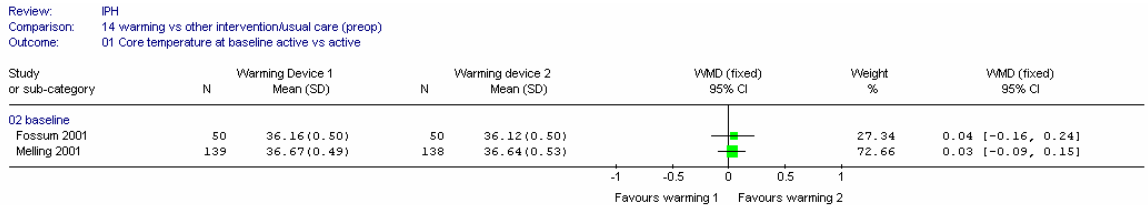
Figure 16: Thermal comfort; active warming versus usual care



C. Active warming 1 versus Active warming 2

Two studies (Fossum 2001; Melling 2001) compared two active warming mechanisms, their baseline temperatures are shown below. Neither showed a significant difference in temperature.

Figure 17: Baseline temperature



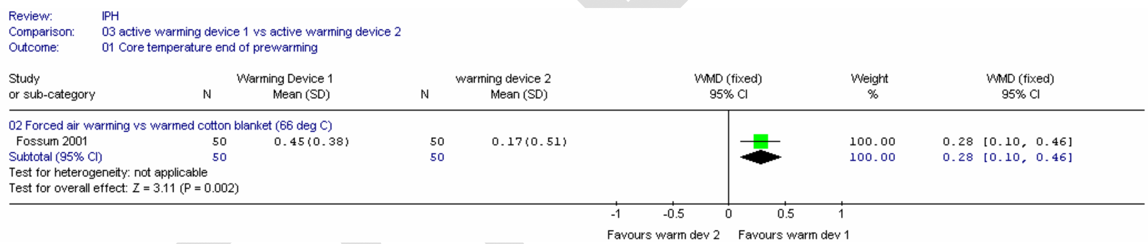
C1. Forced air warming versus warmed cotton blanket

One study in 100 patients compared forced air warming versus warmed cotton blanket (66°C) from 45 minutes before induction (Fossum 2001).

1. Core temperature: end of pre-warming

There was a statistically significant difference in the change from baseline, favouring forced air warming.

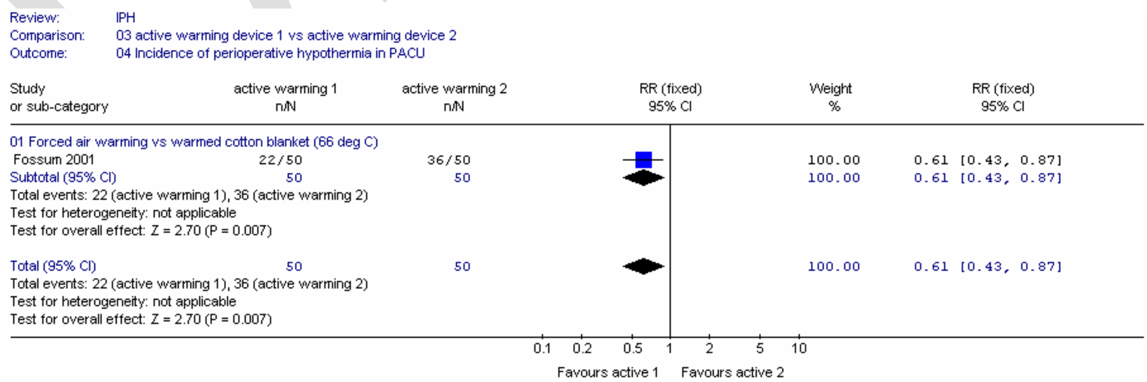
Figure 18: Core temperature end of prewarming



2. Incidence of IPH in PACU

Fossum (2001) reported the incidence of hypothermia in PACU for the comparison, forced air warming versus warmed cotton blanket.

Figure 19: Incidence of IPH in PACU

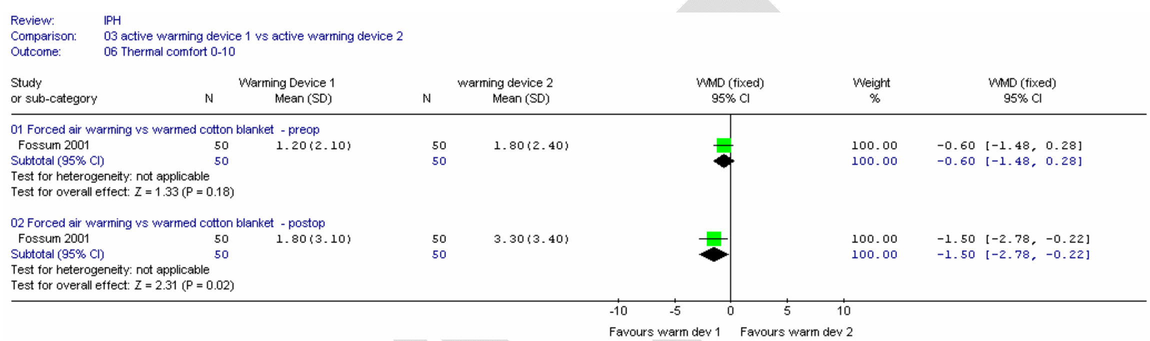


There was a statistically significant difference between the groups, favouring forced air warming: RR 0.61 (95% CI 0.43, 0.87). This corresponds to an NNT of 4 (95% CI 3, 12) for a control group rate of 72%.

3. Thermal discomfort – end of preoperative period

Fossum (2001) reported on thermal discomfort at the end of the preoperative period and in PACU, using a Likert scale, with 0 representing *most comfortable* and 10 representing *extremely uncomfortable* (*either hot or cold).* The study reported that patients randomised to the forced air warming group expressed positive comments about feeling warm and comfortable compared with the control group who verbalised negative comments about being cold. There was no significant difference between the groups preoperatively, but in PACU the patients had significantly less thermal discomfort in the forced air warming group.

Figure 20: Thermal discomfort; active 1 versus active 2 warming



C2. Whole body forced air warming versus local non contact radiant heat dressing

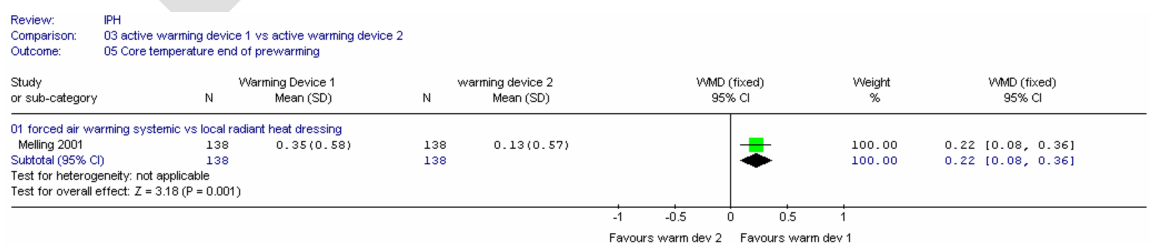
One study in 278 patients compared whole body forced air warming versus a local, non-contact radiant heat dressing from at least 30 minutes before induction (Melling 2001).

We note that there was a difference between groups in the duration of warming: 44.9 minutes and 38.7 minutes for forced air warming and radiant heat dressing respectively.

1. Core temperature: end of prewarming

There was a statistically significant difference in the change from baseline, favouring forced air warming.

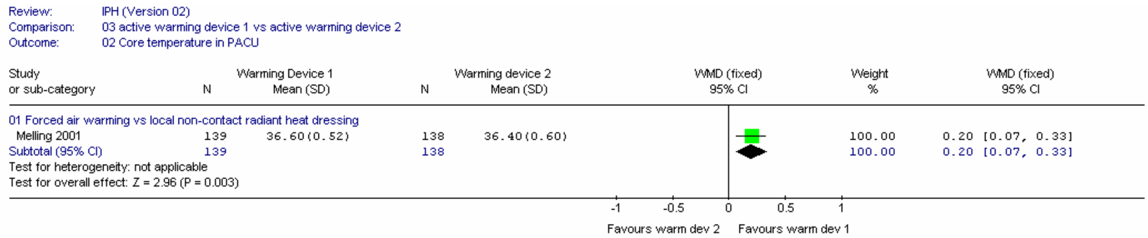
Figure 21: Core temperature – end of prewarming; active 1 versus active 2



2. Core Temperature: PACU

Melling (2001) reported the core temperature upon arrival in PACU (Figure 22). There was a significantly higher core temperature for the forced air warming group compared with the group given local radiant heat dressing.

Figure 22: Core temperature – PACU; active 1 versus active 2 warming

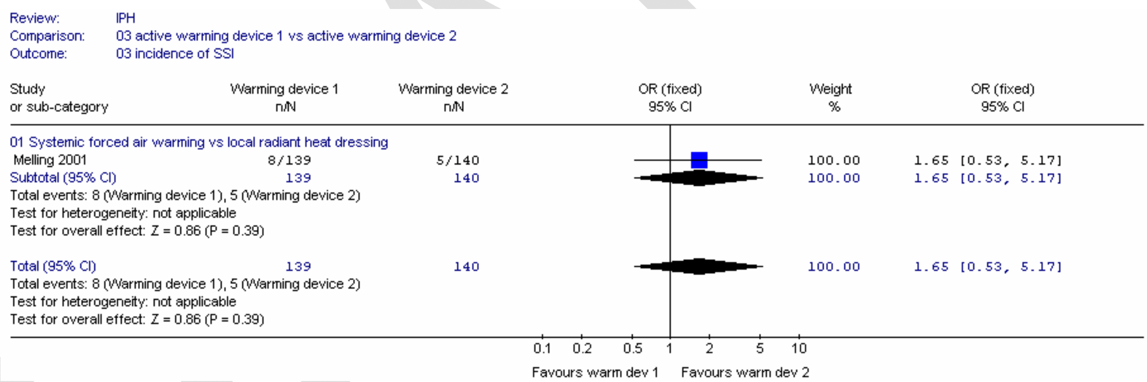


Postoperative Complications

3. Surgical Site Infection

Melling (2001) reported the incidence of surgical site infection (Figure 23). The mean durations of warming for forced air warming and radiant heat dressing were different between the two groups at 44.9 minutes and 38.7 minutes respectively, so that two variables were changed at once. For this study in 279 patients, the confidence interval is wide so we cannot draw conclusions.

Figure 23: Surgical site infection; active 1 versus active 2 warming



10.2 ACTIVE WARMING AND THERMAL INSULATION IN THE INTRAOPERATIVE PHASE FOR THE PREVENTION OF IPH

CHARACTERISTICS OF CLINICAL STUDIES INCLUDED IN THE REVIEW (APPENDIX C)

The search strategy for all interventions in all databases searched gave 11,407 abstracts, which were sifted by one reviewer. This resulted in 258 full papers being obtained, with 58 studies [70 comparisons] included in this review (Baxendale 2000; Bennett 1994 [3 comparisons]; Berti 1997; Borms 1994; Bourke 1984(1); Bourke 1984(2); Camus 1993a; Camus 1993b [2 comparisons]; Camus 1997; Casati 1999; Dyer 1986; Erickson 1991[2 comparisons]; Frank 1995; Frank 1997; Harper 2007; Hetz 1996; Hindsholm 1992; Hoyt 1993; Hynson 1992; Janicki 2001; Janicki 2002; Joachimsson 1987; Joachimsson 1987a; Johansson 1999; Kabbara 2002; Kamitini 1999; Krenzischek 1995; Kurz 1993a; Kurz 1993b; Kurz 1996; Lee 2004; Lenhardt 1997; Leung 2007; Lindwall 1998; Mason 1998; Matsukawa 1994; Matsuzaki 2003; Mogera 1997; Motamed 2000; Müller 1995; Negishi 2003; Ng 2006; Ouellette 1993 [2 comparisons]; Radel 1986 [2 comparisons]; Radford 1979; Rasmussen 1998; Russell 1995 [3 comparisons]; Scott 2001; Sheng 2003; Smith 1994; Smith 1994a; Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Torrie 2005; Whitney 1990; Winkler 2000; Wong 2004; Yamakage 1995 [3 comparisons]). Hetz (1996) and Harper (2007) were only available in an abstract form. There was insufficient information in the Hetz (1996) study but additional information was available from the author (academic in confidence) in Harper (2007). The excluded studies are listed in Appendix E.

A total of 3,319 patients were included. Thirty studies (Bourke 1984 [2]; Tølløfsrud 1984a [3 comparisons]; Tølløfsrud 1984b [3 comparisons]; Radel 1986; Whitney 1990; Erickson 1991; Hindsholm 1992; Hynson 1992; Camus 1993a; Camus 1993b; Hoyt 1993; Kurz 1993a; Ouellette 1993; Bennett 1994; Borms 1994; Matsukawa 1994; Krenzischek 1995; Müller 1995; Russell 1995; Yamakage 1995 [2 comparisons]; Radel 1986; Berti 1997; Camus 1997; Mogera 1997; Lindwall 1998; Rasmussen 1998; Motamed 2000; Janicki 2001; Negishi 2003; Harper 2007) had fewer than or equal to 20 patients in each arm.

Participants

The age range of participants across studies (where given) ranged from 18 to 92 years, with the mean age (where given) ranging from 39 to 74 years. One of the exclusion criteria for one study (Radford 1979) was patients less than 14 years old. As the study did not provide the range it is unclear how many of the included patients were under 18; however as the mean was 48 years this study was accepted.

Six studies were conducted in the UK (Radford 1979; Bennett 1994; Russell 1995; Scott 2001; Baxendale 2000; Harper 2007), 19 in the USA (Bourke 1984(1); Bourke 1984(2); Radel 1986; Whitney 1990; Erickson 1991; Hynson 1992; Hoyt 1993; Ouellette 1993; Smith 1994; Smith 1994a; Krenzischek 1995; Frank 1995; Frank 1997; Lenhardt 1997; Mason 1998; Janicki 2001; Janicki 2002; Kabbara 2002; Sheng 2003), five in Japan (Matsukawa 1994; Yamakage 1995; Kamitini 1999; Matsuzaki 2003; Negishi 2003), five in Austria (Kurz 1993a; Kurz 1993b; Kurz 1996; Müller 1995; Winkler 2000), four in France (Camus 1993a; Camus 1993b; Camus 1997; Motamed 2000), four in Sweden (Joachimsson 1987; Joachimsson 1987a; Lindwall 1998; Johansson 1999), two in Denmark (Hindsholm 1992; Rasumussen 1998), two in Italy (Berti 1997; Casati 1999), two in Norway (Tølløfsrud 1984a; Tølløfsrud 1984b), two in Australia (Dyer 1986; Lee 2004), two in New Zealand (Wong 2004; Torrie 2005), two in Hong Kong, People’s Republic of China (Ng 2006; Leung 2007), one in Belgium (Borms 1994) and one in India (Mogera 1997).

The ASA grade was stated to be I and II in 16 studies (Bourke 1984(1); Bourke 1984(2); Hindsholm 1992; Camus 1993a; Camus 1993b; Borms 1994; Matsukawa 1994; Smith 1994; Smith 1994a; Berti 1997; Rasumussen 1998; Yamakage 1995; Camus 1997; Motamed 2000; Matsuzaki 2003; Negishi 2003); I, II and III in 11 studies (Frank 1997; Lenhardt 1997; Casati 1999; Kamitini 1999; Winkler 2000; Kabbara 2002; Sheng 2003; Torrie 2005; Ng 2006; Harper 2007; Leung 2007); II, III, and IV in one study (Janicki 2001); I, II, III, and IV in two studies (Lindwall 1998; Scott 2001) and not stated in the remaining studies.

A range of procedures were undertaken:

- Abdominal surgery in fourteen studies (Joachimsson 1987; Joachimsson 1987a; Erickson 1991; Hoyt 1993; Matsukawa 1994; Camus 1993a; Camus 1993b; Camus 1997; Lenhardt 1997; Rasmussen 1998; Kamitini 1999; Motamed 2000; Janicki 2001; Negishi 2003);
- Orthopaedic surgery in twelve studies:
    - Seven hip arthroplasty (Hindsholm 1992; Kurz 1993b; Bennett 1994; Borms 1994; Casati 1999; Johansson 1999; Winkler 2000);
    - Two arthroscopic knee surgery (Smith 1994; Smith 1994a);
    - Orthopaedic surgery in lower extremities (Radel 1986);
    - Total knee or hip arthroplasty (Berti 1997);
    - Total knee replacement (Ng 2006);
- Orthotopic liver transplant in three studies (Müller 1995; Russell 1995; Janicki 2002);
- Neurosurgical procedures in three studies:

- Craniotomy for intracranial tumours or aneurysms (Radford 1979);
- Neurosurgical procedures (Bourke 1984 [2]);
- Intracranial procedures (Mogera 1997);

- Urological procedures in two studies:
  - Transurethral resection of the prostate (Dyer 1986; Torrie 2005);
- Two abdominal, thoracic, or vascular surgery (Frank 1995; Frank 1997);
- Two laparoscopic cholecystectomy (Matsuzaki 2003; Wong 2004);
- Mixed procedures:
  - Abdominal, vascular or thoracic surgery (Krenzischek 1995);
  - Lower abdomen or a lower extremity (Yamakage 1995);
  - Oesophageal, rectal or bladder carcinoma (Lindwall 1998);
  - Colorectal, gastrointestinal, orthopaedic, urology or vascular surgery (Scott 2001);
  - Major gynaecologic, orthopaedic, otolaryngologic, plastic or general surgery (Kabbara 2002);
  - Laparatomy (pancreatic, gastric, hepatobiliary, colectomy, abdominal aortic aneurysm, cystectomy) (Leung 2007);
  - Major abdominal or orthopaedic surgery (Baxendale 2000);
  - Gynaecological, vascular and breast surgery (Harper 2007);
- Other procedures:
  - Maxillofacial surgery (Kurz 1993a);
  - Carotid endarterectomy (Bourke 1984 [1]);
  - Gynaecological abdominal surgery (Whitney 1990);
  - Kidney transplant (Hynson 1992);
  - Cervical or lumbar laminectomy (Ouellette 1993);
  - Abdominal aorta (Tølløfsrud 1984a);
  - Extra-abdominal vascular surgery [femoropopliteal bypass and profunda plasta] (Tølløfsrud 1984b);
  - Colorectal resection for cancer or inflammatory bowel disease and abdominal-peritoneal pull-through procedures (Kurz 1996);
  - Gastric bypass (Mason 1998);
  - Non-cardiac surgery (Lee 2004).

One study did not state type of surgery (Sheng 2003).

Type of surgery was stated as elective in 39 studies (Radford 1979; Joachimsson 1987; Joachimsson 1997a; Bourke 1984 (1); Bourke 1984 (2); Tølløfsrud 1984a; Tølløfsrud 1984b; Whitney 1990; Erickson 1991; Hindsholm 1992; Camus 1993a; Camus 1993b; Hoyt 1993; Ouellette 1993; Bennett 1994; Borms 1994; Matsukawa 1994; Smith 1994; Smith 1994a; Frank 1995; Krenzischeck 1995; Kurz 1996; Berti

1997; Lenhardt 1997; Mogera 1997; Lindwall 1998; Mason 1998; Rasmussen 1998; Casati 1999; Johansson 1999; Kamitini 1999; Kabbara 2000; Motamed 2000; Mastsuzaki 2003; Negishi 2003; Torrie 2005; Ng 2006; Baxendale 2000; Harper 2007) elective or emergency in one study (Lee 2004) and not stated in the remaining studies.

Mean duration of surgery was between 30 to 60 minutes in three studies (Smith 1994; Smith 1994a;Torrie 2005), from 1 to 3 hours in 32 studies (Radford 1979; Bourke 1984 (1); Tølløfsrud 1984a; Tølløfsrud 1984b; Radel 1986; Whitney 1990; Erickson 1991; Hindsholm 1992; Hynson 1992; Camus 1993a; Camus 1993b; Hoyt 1993; Ouellette 1993; Bennett 1994; Borms 1994; Matsukawa 1994; Yamakage 1995; Berti 1997; Camus 1997; Joachimsson 1987; Mason 1998; Casati 1999; Johansson 1999; Kamitini 1999; Kabbarra 2000; Winkler 2000; Scott 2001; Matsuzaki 2003; Lee 2004; Wong 2004; Baxendale 2000; Harper 2007), greater than 3 hours in 20 studies (Dyer 1986; Kurz 1993a; Kurz 1993b; Bourke 1984 (2); Joachimsson 1987a; Krenzischeck 1995; Müller 1995; Russell 1995; Kurz 1996; Frank 1997; Lenhardt 1997; Mogera 1997; Lindwall 1998; Rasmussen 1998; Motamed 2000; Janicki 2001; Janicki 2002; Negishi 2003; Ng 2006; Leung 2007) and was not stated in the remaining two studies.

Type of premedication, dose and method of delivery where stated were as follows:

- Midazolam:
  - 1 to 3mg (Hynson 1992);
  - 7.5mg orally the night before and approximately 2 hours before surgery (Winkler 2000);
- Midazolam with other premedications:
  - Midazolam (2 to 3mg) and atropine (0.01mg/kg) i.m. 30 minutes before induction (Matsukawa 1994);
  - Midazolam (2 to 3mg) and atropine (0.5mg) 30 minutes before surgery (Negishi 2003);
  - Midazolam (up to 5mg) and/or morphine (0.1mg/kg) i.m. (Frank 1995);
  - Midazolam (dose not stated) and fentanyl (Janicki 2001; Janicki 2002);
- Diazepam:
  - 5 to 20mg orally according to age (Hindsholm 1992);
  - 10mg orally about 1 hour before induction of anaesthesia (Kurz 1993a; Kurz 1993b);
  - 0.3mg/kg orally 30 minutes prior to combined spinal-epidural anaesthesia (Casati 1999);
- Flunitrazepam:
  - One hour before surgery; dose not stated (Camus 1993a; Camus 1993b);

- Atropine along with other premedications:
    - Atropine (0.3 to 0.6mg) or hyoscine (0.2 to 0.4mg) given i.m.; [patients with intracranial aneurysms and normal level of consciousness were given papaveretum (10mg) i.m.] (Radford 1979);
    - Atropine (0.4mg) i.m. with diazepam (0.1 mg/kg) p.o (Radel 1986);
    - Atropine dose not stated; given along with meperidine or diazepam (Joachimsson 1987);
    - Atropine and hydroxyzine; doses not stated (Kamitini 1999);
    - Atropine (0.5mg) i.m. 30 minutes before surgery pentazocine (15mg), hydroxyzine (25mg) (Matsuzaki 2003);
- Diazepam with other premedications:
    - Diazepam (3mg/kg) given orally and atropine (.01mg/kg) given i.m. after arrival to OR (Berti 1997);
    - Diazepam (0.2mg/kg) orally at bedtime followed by promethazine (0.5mg/kg) i.m.) or triazolam (.125mg) (Mogera 1997);
    - Diazepam (5mg) by mouth for sedation; ephedrine and midazolam. For thrombosis phropenoxaparing sodium (50mg) injected s.c. on evening before the operation and given daily until discharge (Johansson 1999).

Other premedication:

- Papaveretum (15 to 20/mg i.m.) and hyoscine (0.2mg) i.m. administered 60 minutes prior to surgery (Bennett 1994);
- Lorazepam (2.5mg) administered sublingually 30 minutes prior to induction (Borms 1994);
- Temazepam, metoclopramide and ranitidine (Russell 1995);
- Calcium-channel blocker or ß–Adrenergic blockers (Frank 1997);
- Cefamandole (2g) IV every 8 hours and metronidazole (500mg) IV every eight hours before induction of anaesthesia (Kurz 1996);
- Hydroxyzine (100mg) orally 1hour before surgery (Motamed 2000);
- Diazepam (10mg) or 125mg triazolam depending on age (less than 70 years: 0.25mg) or (3 patients) (Rasmussen 1998);
- Morphine (5 to 15mg) given i.m in patients below 75 years of age, combined with scopolamine (0.2 to 0.6mg) 30 to 60 minutes before arriving in the operating theatre suite;
- Atropine (0.5mg) and pethidine (30mg) given i.m. for patients over 75 years of age (Tølløfsrud 1984a; Tølløfsrud 1984b).

Four studies stated that patients received no premedication (Yamakage 1995; Lenhardt 1997; Torrie 2005; Leung 2007). Five studies did not report on premedication (Smith 1994; Smith 1994a; Muller 1995; Scott 2001; Ng 2006).

Patients underwent surgery under:

- General anaesthesia in 33 studies (Radford 1979; Tølløfsrud 1984a; Tølløfsrud 1984b; Radel 1986; Joachimsson 1987; Erickson 1991; Hynson 1992; Camus 1993a; Camus 1993b; Kurz 1993a; Kurz 1993b; Ouellette 1993; Bennett 1994; Borms 1994; Matsukawa 1994; Smith 1994; Smith 1994a; Muller 1995; Russell 1995; Kurz 1996; Camus 1997; Lenhardt 1997; Mogera 1997; Mason 1998; Motamed 2000; Janicki 2001; Janicki 2002; Kabbara 2002; Matsuzaki 2003; Negishi 2003; Baxendale 2000; Harper 2007 [11 patients also received regional anaesthesia]; Leung 2007);
- Regional anaesthesia in five studies (Dyer 1986; Yamakage 1995; Johansson 1999; Winkler 2000; Torrie 2005);
- Combined spinal-epidural in two studies (Casati 1999; Ng 2006);
- Combined general and regional anaesthesia in five studies (Joachimsson 1987a; Berti 1997; Lindwall 1998; Rasmussen 1998; Kamitini 1999);
- Mixed anaesthesia (general and/or regional) in two studies (Krenzischek 1995 [70% received general anaesthesia]; Scott 2001 [55% received general anaesthesia]).

In two studies patients received general, regional or general/regional anaesthesia [GA+ intrathecal dose of 0.5mg morphine; the authors referred to this as a ‘combined’ anaesthesia] (Frank 1995; Frank 1997). In the four studies (Krenzischek 1995; Frank 1995; Frank 1997; Scott 2001) with mixed anaesthesia, results are considered under the general anaesthesia section as majority of the patients in each study received general anaesthesia.

Type of anaesthesia was unclear in the remaining studies.

Duration of anaesthesia was less than 60 minutes in one study (Torrie 2005), and over 1 hour in all other studies but two in which it was not stated (Sheng 2003; Wong 2004).

Interventions

Thermal insulation

The type of the thermal insulation included types of space blankets:

- Metallised plastic sheeting (Bennett 1994:Thermolite; Radford 1979: Thermos);
- Thermadrape (Whitney 1990;Erickson 1991;Berti 1997);
- Aluminised Tyvek (Bourke 1984 [1]; Bourke 1984 [2]);
- Sun-Flex aluminised plastic sheeting (Hindsholm 1992);
- Thermolite (Borms 1994; Sheng 2003).

Type of reflective sheet was not stated in four studies (Dyer 1986; Ouellette 1993; Casati 1999; Kamitini 1999). Three studies (Hoyt 1993; Erickson 1992; Kamitini 1999) used head covers. The type of head cover was Thermadrape in Erickson (1992) and Hoyt (1993) and not stated in Kamitini (1999).

We note that there are differences between studies in the type of reflective material used, which has changed over the years. The US patent (1988) for a non-conducting reflective blanket gives further information (PatentStorm 1998). Cundy (1980) observed in the earlier materials that the insulation layer in the metallised plastic sheeting is thin and there is a serious risk of burns from aberrant earthing (e.g. when using diathermy and metal operating tables). The reflective surgical drape of the 1988 patent was non-conductive and puncture resistant and therefore posed no electrical hazard in the operating room environment.

Three studies (Radford 1979; Bourke 1984 [1]; Bourke 1984 [2]) used conducting materials and the Radford (1979) study suggested that the effectiveness of their blanket was reduced or lost by condensed perspiration.

Active warming mechanisms

There was a range of active warming interventions used, most common was the forced air warming device.

Forced air warming

Forced air warming was used in 38 studies (Hynson 1992; Camus 1993b; Kurz 1993a; Kurz 1993b; Ouellette 1993; Bennett 1994; Borms 1994; Matsukawa 1994; Smith 1994; Frank 1995; Krenzischeck 1995; Russell 1995; Yamakage 1995; Kurz 1996; Berti 1997; Camus 1997; Frank 1997; Mogera 1997; Rasmussen 1997; Lindwall 1998; Mason 1998; Johansson 1999; Casati 1999; Motamed 2000; Winkler 2000; Janicki 2001; Scott 2001; Janicki 2002; Matsuzaki 2003; Müller 1995; Negishi 2003; Lee 2004; Wong 2004; Torrie 2005; Ng 2006; Baxendale 2000; Harper 2007; Leung 2007).

The temperature settings on the forced air warmer were:

- High setting:
  - Bair Hugger® set to 43°C (Bennett 1994; Hynson 1992; Camus 1993b; Matsukawa 1994; Smith 1994; Smith 1994a; Camus 1997; Lindwall 1998; Rasmussen 1997; Kabbara 2002; Torrie 2005; Wong 2004; Ng 2006; Baxendale 2000; Leung 2007);
  - Warm Touch® set to ‘high’ (43°C) (Motamed 2000);

    - Bair Hugger® set to ‘high’ (42°C) (Negishi 2003);
    - Bair Hugger® set to ‘high’ (approximately 40°C) (Kurz 1993a; Kurz 1993b; Borms 1994; Müller 1995; Kurz 1996);
    - Howarth forced air warming (under mattress) set to ‘high’ (about 40°C) (Russell 1995);
    - Forced air warmer set to ‘high’ (43°C) (Janicki 2001);
    - Forced air warm set to ’maximum’ (Harper 2007).
- Medium setting:
    - Bair Hugger® 38°C (Matsukawa 1994; Berti 1997; Kabbara 2002);
    - Bair Hugger® 37°C (Yamakage 1995);
    - Bair Hugger® set to ‘medium’ (36.5°C to 38°C) (Mogera 1997);
    - Warm Touch® set to ‘medium’ (Mason 1998; Matsuzaki 2003).
- Low setting:
    - Bair Hugger® set to ‘low’ (Ouellette 1993).
- Variable setting:
    - Warm Touch® set to high or medium to maintain core temperature near 37°C (Krenzischeck 1995);
    - Warm Touch® set to high or medium to maintain core temperature near 37°C (Frank 1995);
    - Forced air warming (set to ‘high’, 42°C to 48°C initially, which automatically reset to ‘medium’, 36°C to 41.5°C after 45 minutes) (Russell 1995);
    - Forced air warming (set to ‘high’, 43°C initially, then set to ‘medium’, 36°C if patients core temperature was greater than 37°C) (Janicki 2002).
- Setting was not stated in six studies (Frank 1997; Casati 1999; Johansson 1999; Winkler 2000; Scott 2001; Lee 2004):
    - In one study (Frank 1997) setting was adjusted to maintain core temperature at or near 37°C.
    - In one study (Winkler 2000) temperature of the warmers was adjusted to maintain target core temperature (36.5°C for the aggressively warmed group and 36.0°C for the conventionally warmed group).

Electric blanket

Five studies used an electric over blanket at the following settings:

- Electro Concept (electric blanket) 40°C (Camus 1997);
- Chromexset (electric warming blanket) at approximately 42°C to 43°C (Camus 1993a; Camus 1993b);
- SmartCare (carbon-fibre resistive heating blanket) set to ‘medium’ (Matsuzaki 2003);
- SmartCare (resistive heating blanket) set to 42°C (Negishi 2003).

Two studies used an electric under blanket at the following settings:

- JMW Medical (electric under blanket) cut-outs set to 39°C and 41°C (Russell 1995);
- Inditherm (electric warming mattress) 37°C (Harper 2007).

Two studies used an electric heating pad at the following settings:

- Operatherm set to 39°C (Ng 2006; Leung 2007).

Water mattress

Ten studies used a water mattress. The settings were as follows:

- Meditherm set to 42°C (Negishi 2003)
- Circulating water mattress set at 42°C (Müller 1995)
- Gorman Rupp set at 38°C to 40°C (Tølløfsrud 1984a; Tølløfsrud 1984b)
- Blanketrol set to 40°C (Hynson 1992)
- Full-length circulating water mattress with a measured temperature of 40°C (Kurz 1993a; Kurz 1993b)
- Heto (Birkerod) set to 39°C (Joachimsson 1987; Joachimsson 1987b;)
- Blanketrol set to 38°C (Matsuzaki 2003).

Radiant heat

Three studies used radiant heaters. The make and settings were as follows:

- Suntouch set to 41°C (Torrie 2005; Wong 2004);
    - In Wong (2004) it was stated that warming was applied over 20cm x 30cm with an energy intensity of 100mW/cm^2 and placed 40cm above the patient.
- Suntouch – temperature not stated (Lee 2004).

Area and intensity of warming were not reported in the other two studies.

Circulating water vest and cap

- Circulating fluid connected to a Gaymar Medi-Therm heat exchange console set to 38°C (Radel 1986).

Water garment

- MTRE Whole body water garment set to 36.8°C (Janicki 2001; Janicki 2002).

Warmed cotton blankets

Four studies used warmed blankets. In two studies (Smith 1994; Smith 1994a) blankets in warming cabinets were warmed at 60°C. The temperature setting was not stated in two studies (Whitney 1990; Mason 1998).

Primary outcomes (including surrogate measures)

Nine studies measured the number of patients with IPH, but most recorded the mean core temperature at different times. For this outcome, an increase of 0.5°C over the control group temperature was considered to be clinically significant for a control group temperature above 36°C and a difference of 0.20°C was considered to be clinically significant for control group temperatures below 36°C.

- Incidence of hypothermia (Joachimsson 1987; Joachimsson 1987a; Mason 1998; Casati 1999; Lee 2004; Torrie 2005; Ng 2006; Harper 2007; Leung 2007).

Core temperature was measured at the following stages:

- In the intraoperative period (Radford 1979; Bourke 1984(1); Bourke 1984(2); Tølløfsrud 1984a; Tølløfsrud 1984b; Dyer 1986; Radel 1986; Joachimsson 1987; Joachimsson 1987a; Whitney 1990; Hindsholm 1992; Hynson 1992; Camus 1993a; Camus 1993b; Kurz 1993a; Kurz 1993b; Ouellette 1993; Krenzischek 1995; Kurz 1996; Borms 1994; Matsukawa 1994; Smith 1994; Smith 1994a; Krenzischek 1995; Russell 1995; Yamakage 1995; Berti 1997; Camus 1997; Mogera 1997; Lindwall 1998; Mason 1998; Rasmussen 1998; Casati 1999; Kamitini 1999; Johansson 1999; Motamed 2000; Winkler 2000; Janicki 2001; Janicki 2002; Kabbara 2002; Matsuzaki 2003; Negishi 2003; Sheng 2003; Lee 2004; Torrie 2005; Ng 2006; Baxendale 2000; Harper 2007; Leung 2007);
- At the end of surgery (Camus 1993a; Camus 1993b; Kurz 1993a; Kurz 1993b; Bennett 1994; Frank 1995; Krenzischek 1995; Müller 1995; Camus 1997; Frank 1997; Lenhardt 1997; Casati 1999; Johansson 1999; Lee 2004; Wong 2004; Torrie 2005; Ng 2006; Leung 2007);
- In PACU (Erickson 1991; Smith 1994; Frank 1995; Kurz 1996; Mogera 1997; Lindwall 1998; Torrie 2005; Harper 2007);
- ICU (Frank 1997).

Other outcomes were:

- Shivering (Bourke 1984(1); Erickson 1991; Camus 1993a; Camus 1993b; Matsukawa 1994; Camus 1997; Frank 1997; Rasmussen 1998; Casati 1999; Lee 2004; Torrie 2005; Ng 2006)
- Blood loss (Bennett 1994; Mason 1998; Winkler 2000)
- Pain (Krenzischek 1995)
- Admission to ICU (Kurz 1996)
- Length of stay (Kurz 1996; Casati 1999)
- Duration of hospitalisation (Kurz 1996)
- Time to fulfil discharge criteria (Casati 1999)
- Postoperative nausea and vomiting (Casati 1999)

- Pressure ulcers (Scott 2001)
- Wound infection (Kurz 1996)
- Death (Kurz 1996).

Postoperative complications:

- Humanistic outcome group: thermal comfort (Krenzischek 1995; Yamakage 1995; Ng 2006)

Core temperature was measured at the following sites:

- Tympanic (Erickson 1991; Hynson 1992; Hindsholm 1992; Camus 1993b; Bennett 1994; Smith 1994; Krenzischek 1995; Yamakage 1995; Kurz 1996; Berti 1997; Camus 1997; Frank 1995; Frank 1997; Lenhardt 1997; Lindwall 1998; Rasmussen 1998; Johansson 1999; Kamitini 1999; Winkler 2000; Scott 2001; Matatsuzaki 2003; Negishi 2003; Sheng 2003; Ng 2006);
- Oesophageal (Radford 1979; Tølløfsrud 1984a; Tølløfsrud 1984b; Ouellette 1993; Bourke 1984(1); Bourke 1984(2); Radel 1986; Joachimsson 1987; Joachimsson 1987a; Whitney 1990; Hoyt 1993; Kurz 1993b; Mogera 1997; Janicki 2002; Baxendale 2000);
- Distal oesophageal (Camus 1993a[†]; Borms 1994; Motamed 2000; Kabbara 2002; Lee 2004‡; Wong 2004);
- Bladder (Mason 1998; Casati 1999)
- Rectal (Kurz 1993a; Matsukawa 1994; Janicki 2001; Torrie 2005; Ng 2006);
- Pulmonary artery (Müller 1995[#]; Russell 1995);
- Nasopharyngeal probe (Harper 2007; Leung 2007);
- Temporal artery scan (Harper 2007);
- Sublingual (Dyer 1986);
- Axilla (Smith 1994a; Müller 1995*).

‡*for baseline and recovery measured with tympanic; *before induction and immediately after induction;*
[#]*intraoperative period;*[†]*; temperature measurement prior to induction measured at rectal.*

Subgroup analyses were planned by type of warming device and setting of warming.

METHODOLOGICAL QUALITY OF INCLUDED STUDIES

The method of sequence generation was adequate in 14 studies (computer generated: Smith 1994; Smith 1994a; Kurz 1996; Frank 1997; Lenhardt 1997; Mason 1998; Motamed 2000; Winkler 2000; Janicki 2002; Kabbara 2002; Matsuzaki 2003; Negishi 2003; random number tables: Erickson 1991; Whitney 1990; Lee 2004; Wong 2004; Torrie 2005; drawing lots: Ng 2006; Leung 2007; coin toss: Hoyt 1993), partially adequate in 1 study (randomisation table: Berti 1997; blocked randomisation: Scott 2001) and unclear in the remaining studies. In Hindsholm (1992) it was unclear how many patients were randomised into each group and it was assumed there was an equal distribution. In one study (Frank 1997) randomisation was stratified on the presence or absence of documented coronary artery disease. In one study (Mogera 1997) patients were randomised once anaesthesia was established. It was considered that this was methodologically dubious and the study will not be considered.

The method of allocation concealment was adequate in one study (sequentially numbered opaque sealed envelope: Johansson 1999). A partially adequate method of allocation concealment was reported in 14 studies (sequentially numbered opaque envelopes: Matsuzaki 2003; Negishi 2003; numbered opaque sealed envelope: Kurz 1996; Lenhardt 1997; Mason 1998; opaque sealed envelope: Krenzischek 1995; Frank 1997; sealed envelope: Russell 1995; Winkler 2000; Casati 1999; Harper 2007; opaque envelopes: Scott 2001; Lee 2004; Torrie 2005) and was unclear in the remaining studies. In one study (Kabbara 2000) it was stated that sealed envelopes were not used and it is assumed no other method of allocation concealment was used so the study must be considered dubious.

Blinding was reported in eight studies for shivering (Camus 1993a; Camus 1993b; Bourke 1984(1); Smith 1994a; Kurz 1996; Camus 1997; Mason 1998; Casati 1999). In Casati (1999), an observer blinded to treatment assessed postoperative nausea, vomiting and undesired side effects. In one study (Kurz 1996) assessment of thermal comfort and wound infections were evaluated by observers blinded to patients' group assignments and core temperature. In one study (Scott 2001) assessment of pressure ulcers were conducted by outcome assessors blinded to treatment. In one study (Lenhardt 1997) all postoperative qualitative assessments were made by physicians blinded to patients' group assignment and core temperatures. In one study (Winkler 2000) observers assessing blood loss were blinded to group assignment and core temperature. One study (Berti 1997) stated the study was unblinded; and one noted that it was a single blind study (Harper 2007). One study (Lenhardt 1997) reported it was a double-blind study.

Baseline comparability in age, weight, gender, duration of surgery, duration of anaesthesia, preoperative baseline core temperatures were demonstrated in most of the studies. The exceptions are noted below.

In one study (Bennett 1994; 3 arms) duration of surgery was significantly different for the two comparisons:

- Thermal insulation versus usual care: 0.5 hours longer in the usual care group (p= 0.004);

- Active versus thermal: 0.3 hours longer in the active warming group (p= 0.006).

Two studies (Wong 2004; Harper 2007) noted that there was a significant difference in body mass index (BMI).

- Higher in the group randomised to radiant warmer (31.3 kg/m^2 [SD 5.3]) compared with the forced air warming group (28.1 kg/m^2 [SD 3.9] p=0.03) (Wong 2004).
- Higher in the group randomised to forced air (31.6 kg/m^2 [SD 7.8]) compared with the mattress group (25.7 kg/m^2 [SD 4.0]) p=0.003) (Harper 2007).

The GDG did not consider that these were clinically significant differences.

Baseline comparability in core temperature before induction was demonstrated in majority of the studies (Figures 1a to 1d).

Figure 1a. Baseline comparison: thermal insulation versus usual care

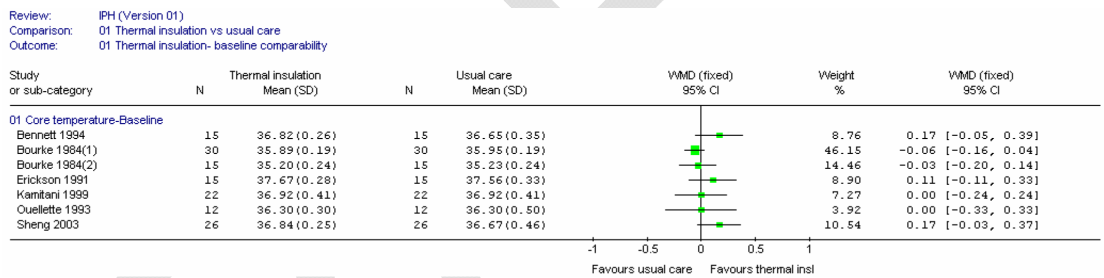
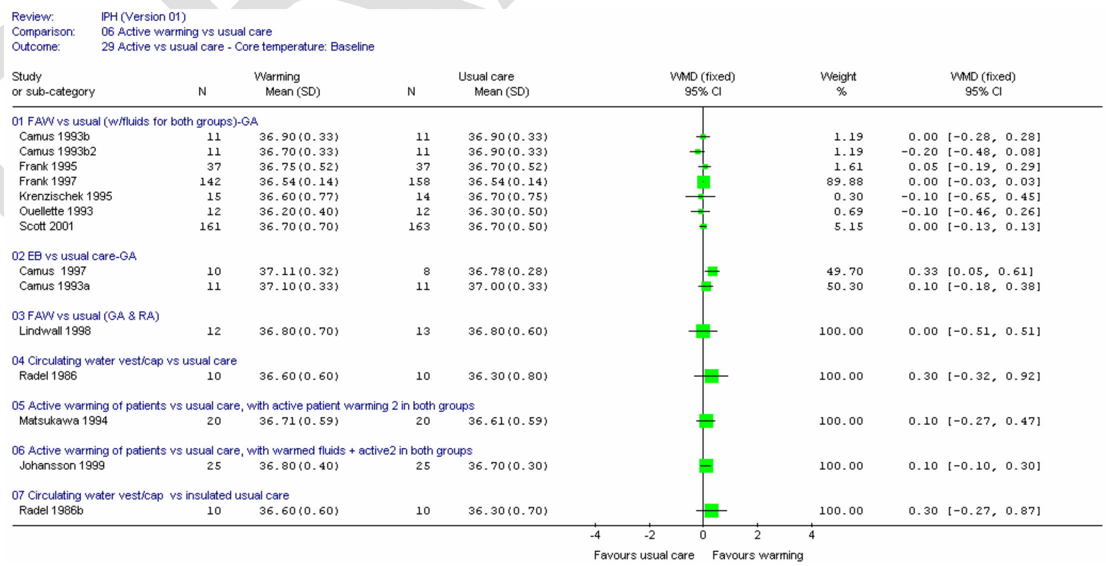


Figure 1b: Baseline comparison: active warming versus usual care



NB: Scale -4 to 4

Figure 1c: Baseline comparisons: active warming versus thermal insulation

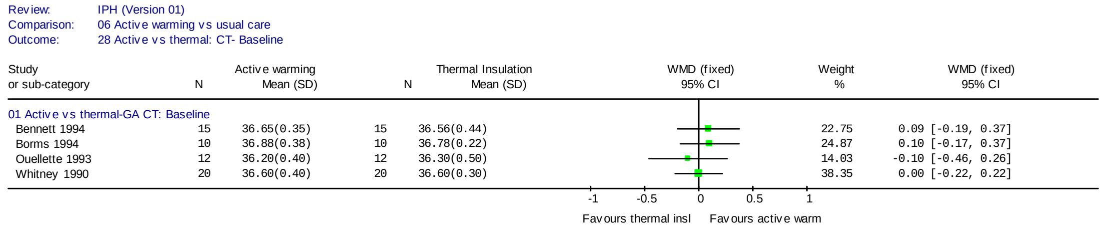
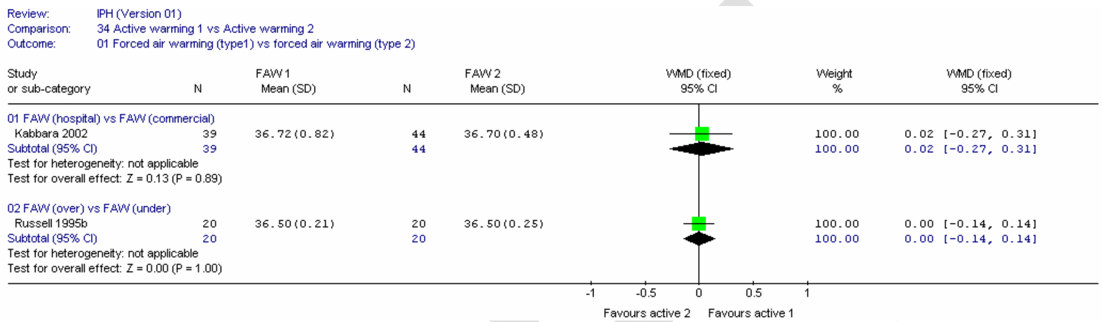
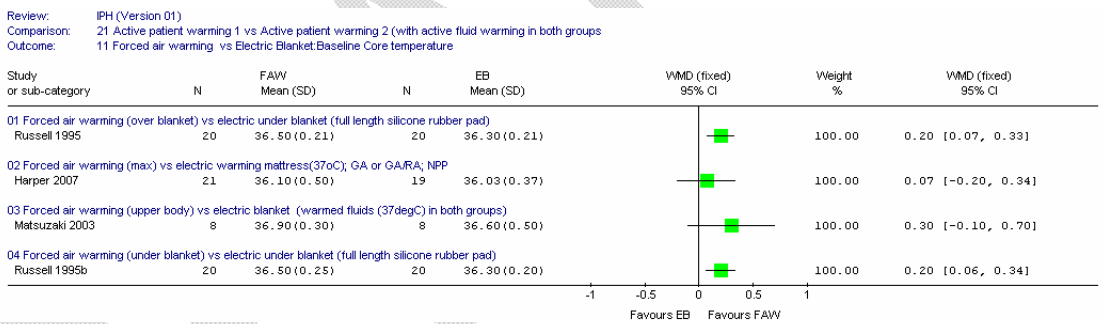


Figure 1d: Baseline comparison: Core temperature: active 1 versus active 2

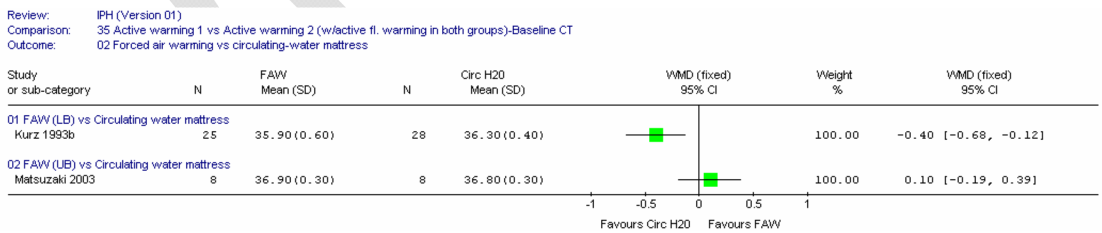
Forced air warming versus Forced air warming



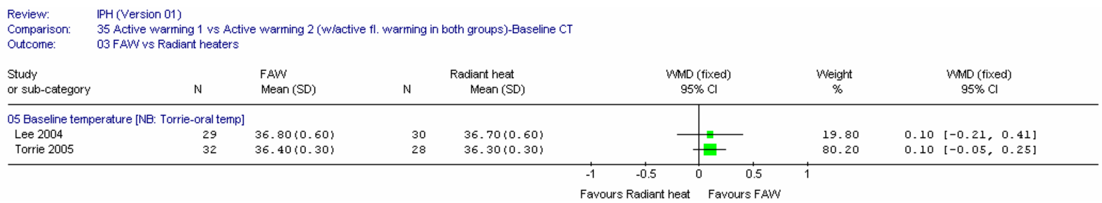
Forced air warming versus Electric blanket



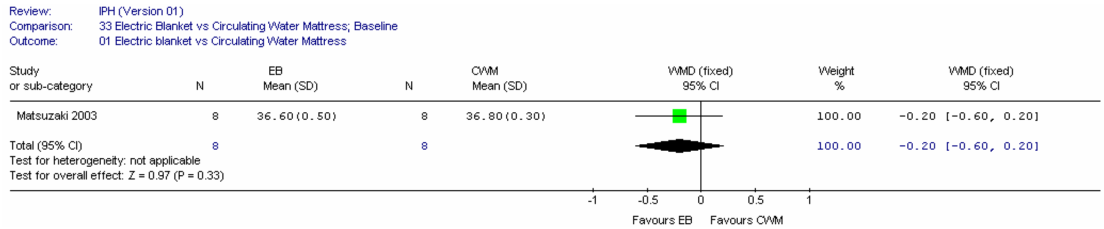
Forced air warming versus circulating water mattress



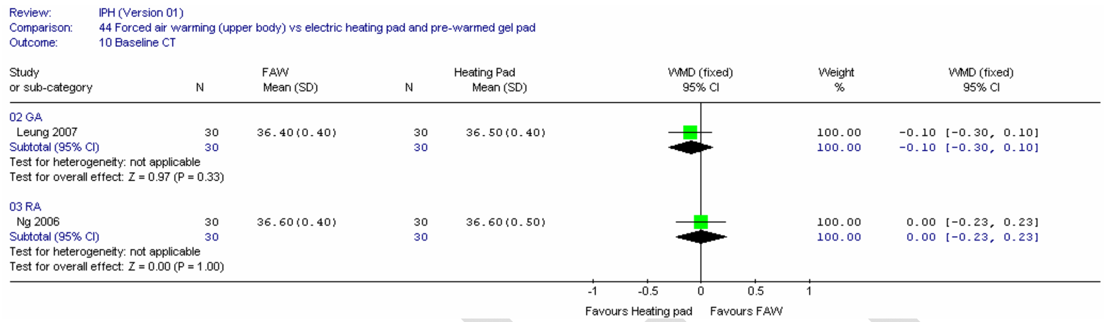
Forced air warming versus radiant heaters



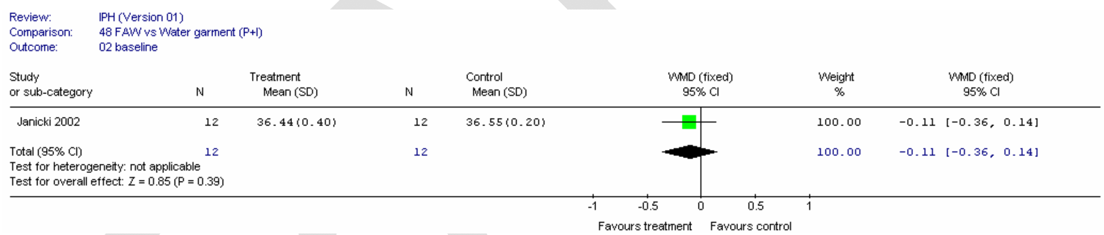
Electric blanket versus circulating water mattress



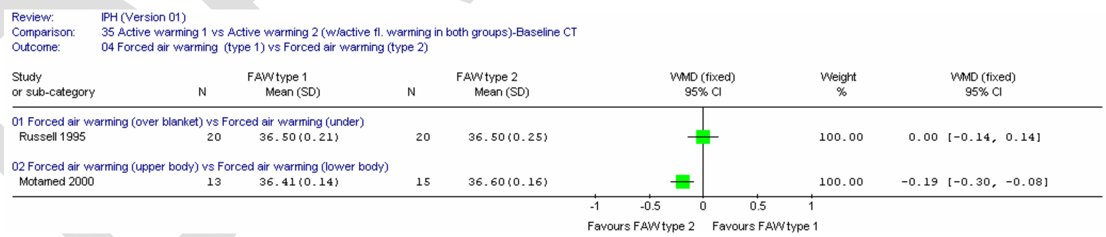
Forced air warming versus electric heating pad



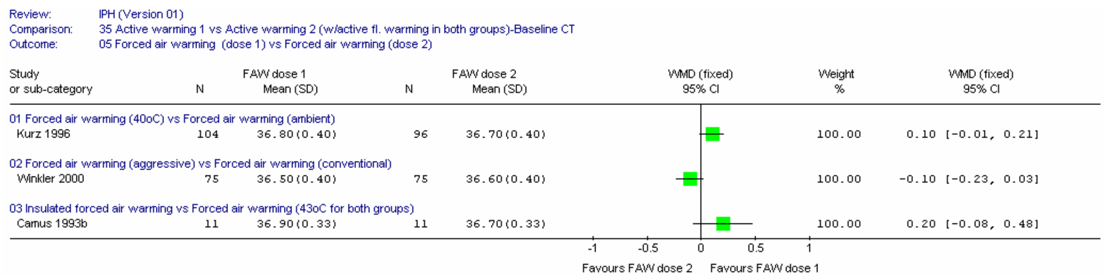
Forced air warming versus water garment



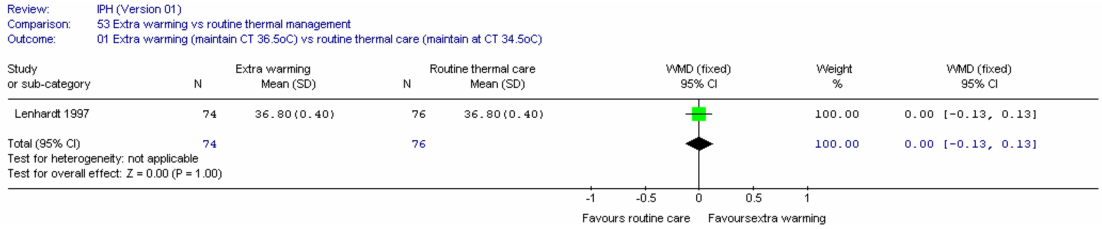
Forced air warming (type 1) versus forced air warming (type 2)



Forced air warming (dose 1) versus forced air warming (dose 2)



Extra warming versus usual care



Baseline differences in core temperature prior to induction were significantly different in four studies [five comparisons] (Kurz 1993b; Smith 1994a; Russell 1995 [2 comparisons]; Camus 1997) out of 58 studies.

Baseline temperature was significantly different in the following studies:

- 0.4°C higher for the group assigned to circulating water mattress compared with forced air warming (Kurz 1993b);
- 0.5°C higher for the group assigned to warmed cotton blanket compared with forced air warming(Smith 1994a);
- 0.20°C higher for the group assigned to forced air warming (over) compared to electric blankets (Russell 1995);
- 0.20°C higher for the group assigned to forced air warming (under) compared to electric blankets (Russell 1995);
- 0.3°C higher for group assigned to electric blanket compared with usual care (Camus 1997).

In five studies [seven comparisons] (Kurz 1993a; Müller 1995; Casati 1999; Rasmussen 1998; Negishi 2003 [3 comparisons]), there were differences in baseline core temperature, however, the standard deviations were not provided, so we cannot determine whether this difference was significant.

The differences in core temperature were as follows:

- 0.39°C higher in the group assigned to circulating water mattress group compared to the forced air warming (Kurz 1993a);
- 0.10°C higher in the group assigned to forced air warmed group compared to circulating water mattress + actively warmed fluids group (Müller 1995);
- 0.14°C higher in the group assigned to forced air warmed group compared to the thermal insulation group (Casati 1999);
- 0.20°C higher in the group assigned to forced air warmed group compared to the control group (Rasmussen 1998);
- 0.16°C higher in the group assigned to forced air warmed group compared to the electric blanket group (Negishi 2003);
- 0.22°C higher in the group assigned to circulating water mattress group compared to the forced air warming group (Negishi 2003);

- 0.41°C higher in the group assigned to circulating water mattress group compared to the electric blanket group (Negishi 2003).

In one study (Hindsholm 1992) median values were reported. The median was 36.29°C for both groups.

Eleven studies ([16 comparisons] Radford 1979; Dyer 1986; Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Hynson 1992 [2 comparisons]; Hoyt 1993; Yamakage 1995 [3 comparisons]; Berti 1997; Mason 1998; Wong 2004; Torrie 2005) did not provide baseline core temperature and it is unclear if there were significant differences between the groups. Torrie (2005) only gave oral temperatures for the baseline temperature and there was no significant difference [(36.4°C [SD 0.3] and 36.3°C [SD 0.3]; p=0.20) for the forced air warming and radiant heat groups respectively].

In four studies (Smith 1994; Smith 1994a; Mogera 1997; Wong 2004) the initial core temperatures reported were not measured pre-induction. In two studies (Smith 1994; Smith 1994a) core temperatures after induction of anaesthesia, denoted as time 0 were reported. In Smith (1994), core temperatures were above 36°C in both groups and there were no significant differences. In Smith (1994b) there was a significant difference in core temperature (0.57°C higher in the group assigned to warmed cotton blankets). In one study (Mogera 1997), at induction of anaesthesia the mean core temperature was 36.54°C (SD 0.27) and 36.56°C (SD 0.2) for the forced air warming and the usual care groups, respectively. The difference was not significant. In one study (Wong 2004) following induction, the mean core temperature was 36.1°C (SD 0.4) and 35.9°C (0.5) for the forced air warming and the radiant heat groups respectively. The difference was not significant (p=0.15).

In three studies (Bourke 1984 [1]; Bourke 1984 [2]; Smith 1994a) patients were hypothermic at induction. Results from the three studies were not considered.

Fourteen studies carried out a power calculation (Hindsholm 1992; Kurz 1996; Casati 1999; Kabbara 2000; Motamed 2000; Winkler 2000; Janicki 2001; Scott 2001; Janicki 2002; Lee 2004; Wong 2004; Torrie 2005; Ng 2006; Leung 2007).

Ten studies considered difference in core temperatures as the primary outcome.

- To detect a difference of 0.3°C in final core temperature at 5% level, it was calculated that 28 patients were required in each group (Lee 2004; Torrie 2005; Ng 2006; Leung 2007).

- To detect a change in core temperature of 1.00°C (SD 0.75) at 5% level, it was calculated that 11 patients were required in each group (Hindsholm 1992).
- To detect a 0.5°C difference in core temperature at end of surgery at 5% level, it was calculated that 20 to 25 patients were required per group (Casati 1999).
- To detect a 0.5°C in mean core temperature between the groups at 5% level (90% power), it was calculated that overall 44 patients were required (Janicki 2001).
- To detect a 0.5°C in mean core temperature between the groups at 5% level (80% power), it was calculated that overall 24 patients were required (Janicki 2002).
- To detect 0.1°C at 5% significant level 20 patients were required in each group Wong (2004).
- To detect a 0.5°C difference in final core temperature at 5% level (90% power) 40 patients were required in each group (Kabbara 2000).

One study (Motamed 2000) noted that sample size was based on detect a difference of 1.5°C (SD 1) in core temperature of from baseline, at 5% level and 80% power.

One study (Kurz 1996) calculated sample size based on incidence of wound infection in a pilot study. It was calculated 400 patients would provide a 90% chance of identifying a difference at 1% level. Scott (2001) calculated a sample size of 306, to detect a 10% reduction in the incidence of pressure ulcer, at 5% level (90% power).

In one study (Winkler 2000) estimated a sample size of 150, to provide a 90% chance of identifying a significant hypothermia-induced increase in blood loss, one-tailed at 5% level.

One study (Lenhardt 1997) calculated that 150 patients would give a 80% chance of identifying a 10-min difference in fitness to discharge at 5% level (two-tailed).

Eleven studies were industry sponsored (warming devices loaned) study (Camus 1993a; Camus 1993b; Bennett 1994; Borms 1994; Matsukawa 1994; Smith 1994; Smith 1994a; Russell 1995; Camus 1997; Baxendale 2000; Harper 2007). Seven studies reported receiving grant support from industry and/or national institutes (e.g. NIH in the USA) and private foundations (Kurz 1993a; Kurz 1993b; Lenhardt 1997; Johansson 1999; Winkler 2000; Janicki 2002; Lee 2004; Wong 2004). Three studies reported that monitoring equipment (e.g. temperature probes) were donated (Bennett 1994; Hynson 1992; Negishi 2003).

Summary

In summary, seven studies were considered to have potential for bias. Kabbara (2000) stated an inadequate method of allocation concealment. Four studies (Kurz 1993b; Smith 1994a; Russell 1995 [2 comparisons]; Camus 1997) had significant baseline differences in core temperature. Bennett (1994) showed significant shorter duration of surgery for the thermal insulation group. Where there was a difference in baseline core temperature we included these studies in the analyses only when the effect size was at least 5 times larger than the baseline difference. The other studies (Bennett 1994; Kabbara 2000) were treated with caution and examined in sensitivity analyses.

The following comparisons were reported:

I. Active warming of patients versus usual care
(Patients received general anaesthesia unless otherwise stated).

A. Active warming of patients versus usual care
Forced air warming versus usual care

- Forced air warming versus usual care:
  - Forced air warming (upper body) versus usual care (Bennett 1994);
  - Forced air warming (upper body) versus reflective blanket (Ouellette 1993) + room temperature IV fluids in both groups;
  - Forced air warming (upper body) versus usual care (Smith 1994) + warmed cotton blankets (60°C) in both arms;
  - Forced air warming (upper or lower body) versus routine thermal care (Krenzischek 1995) (general and regional).

Electric blanket versus usual care

- Electric blanket group (two blankets; upper and lower body) versus usual care (Camus 1997) + IV fluids (room temperature) infused for both groups.

B. Active warming of patients versus usual care, with warmed fluids in both groups
Forced air warming versus usual care (with warmed fluids)

- Insulated forced air warming (lower body) versus usual care (Camus 1993b) + IV fluids (ambient temperature) and warmed irrigation fluids (37°C) infused for both groups.
- Forced air warming (lower body) versus usual care (Camus 1993b) + IV fluids (ambient temperature) and warmed irrigation fluids (37°C).
- Forced air warming (lower body) versus usual care (Hynson 1992) + warmed IV fluids (37°C) infused for both groups.

- Forced air warming + warmed IV fluids versus usual care (Scott 2001)
  + warmed IV and blood products as determined by clinical need for the usual care group (general or regional anaesthesia).
- Forced air warming (upper body) versus upper body light blanket (Yamakage 1995)
  + warmed IV fluids (37°C) (regional anaesthesia).
- Forced air warming (lower body) versus upper body light blanket (Yamakage 1995)
  + warmed IV fluids (37°C).
- Forced air warming versus usual care (Lindwall 1998)
  + warmed fluids (38-39°C) infused for both groups (regional and general).
- Forced air warming (upper or lower body) versus routine thermal care (Frank 1995)
  + warmed IV and blood in both groups (general and/or regional).
- Forced air warming (upper or lower body) versus routine thermal care (Frank 1997)
  + warmed IV and blood infused for both groups (general and/or regional).

Electric blanket versus usual treatment

- Electric blanket (lower body) versus usual treatment
  + IV fluids (ambient temperature) and warmed irrigation fluids infused for both groups (37°C) (Camus 1993a).

Water blanket/mattress versus usual care

- Full-length circulating-water blanket versus usual care
  + warmed IV fluids in both groups (Hynson 1992).
- Hot-water mattress versus usual care (Joachimsson 1987).
- Warming blanket versus usual care (Tølløfsrud 1984a; Tølløfsrud1984b).

Circulating vest and cap versus insulated usual care

- Circulating fluid warming vest and cap (38°C) versus 2 cotton shirts and blankets and a cotton skull cap (Radel 1986)
  + warmed IV (37°C) fluids infused for both groups.

Circulating vest and cap versus usual care

- Circulating fluid warming vest and cap (38°C) versus two cotton blankets and gown (Radel 1986b)
  + warmed IV (37°C) fluids infused for both groups.

C. Active warming of patients versus usual care, with active patient warming 2 in both groups

- Forced air warming (upper body)+ pre-warmed gel mattress (40°C) versus pre-warmed gel mattress (40°C) (Rasmussen 1998) (general and epidural anaesthesia)
  + room temperature IV fluids infused for both groups.
- Forced air warming (upper limbs and thoracic region) + circulating blanket warming versus circulating blanket warming (Matsukawa 1994)
  + IV fluids (temperature not stated) infused for both groups.

D. Active warming of patients versus usual care, with warmed fluids + active 2 in both groups

- Forced air warming (upper body) + pre-warmed gel filled mattress versus cotton blanket + pre-warmed gel filled mattress (Johansson 1999) (spinal anaesthesia)
  + warmed fluids and blood infused for both groups.

II. Thermal insulation versus usual care

Reflective blankets versus usual care

- Metallised plastic sheeting (Thermos) versus cotton sheet (Radford 1979).
- Reflective blanket (aluminized Tyvek) versus standard operating room draping (Bourke 1984 [1]).
- Reflective blanket (aluminized Tyvek) versus standard operating room draping (Bourke 1984 [2])
  + patients in both groups placed on active heating pad.
- Reflective blanket versus usual care (Ouellette 1993).
- Metallised plastic sheet (Thermolite) versus usual care (Bennett 1994).
- Reflective blanket versus cloth blanket (Sheng 2003).
- Reflective blanket (Sun Flex aluminized plastic sheetings) versus cotton gown + standard operating room draping (three weave cotton blankets) (Hindsholm 1992) (regional anaesthesia).
- Reflective blanket versus usual care (Dyer 1986) (regional anaesthesia).

Aluminised head covers

- Insulated head covers versus usual care (Hoyt 1993)
- Aluminised head covers versus usual care (Erickson 1991).

III. Active warming of patients versus thermal insulation

- Forced air warming (upper body) versus metallised plastic sheet (Bennett 1994).

- Forced air warming (lower body) versus reflective thermoplastic aluminium composite (Borms 1994)
  + warmed (37°C) IV fluids infused for both groups.
- Forced air warming (upper body) versus reflective blanket (Ouellette 1993) + room temperature IV fluids in both groups.
- Warmed cotton blankets versus reflective blanket (Whitney 1990).
- Forced air warming (upper limbs) versus reflective blankets (Casati 1999)
  + warmed (37°C) IV lactate Ringer's solution in both groups (combined spinal-epidural anaesthesia).
- Forced air warming (upper body) versus reflective blanket (Berti 1997) (with low flow anaesthesia delivered to both groups) (combined epidural-general anaesthesia).

IV. Active patient warming 1 versus active patient warming 2

A. Active patient warming 1 versus active patient warming 2

- Forced air warming (commercial blankets) versus forced air warming (hospital blankets) (Kabbara 2002)
  + room temperature IV fluid was infused as clinically indicated.
- The GDG decided that this study should not be included as the method of warming employed is contraindicated.
- Forced air warming (lower body) versus warmed cotton blankets (Mason 1989).
- Forced air warming (intra + post) versus warmed cloth blanket (Smith 1994a).

B. Active patient warming 1 versus active patient warming 2 (with active fluid warming in both groups)

- Forced air warming versus electric blanket:
  - Forced air warming (over blanket) versus electric under blanket (full length silicone rubber pad) (Russell 1995)
    + actively warmed fluids (37°C) infused for both groups.
  - Forced air warming (upper body) versus electric blanket (Matsuzaki 2003)
    + warmed fluids (37°C) infused for both groups.
  - Forced air warming (lower body) versus electric blanket (Negishi 2003)
    + warmed fluids (37°C) infused for both groups.
  - Forced air warming (under blanket) versus electric under blanket (full length silicone rubber pad)
    + actively warmed fluids infused for both groups (37°C) (Russell 1995b).
  - Forced air warming versus electric warming mattress (Harper 2007)
    + warmed IV fluids infused for both groups.
  - Forced air warming versus electric warming mattress (Baxendale 2000)

+ warmed IV fluids infused for both groups.

- Forced air warming versus electric heating pad:
  - Forced air warming (upper body) versus pre-warmed heating pad with gel pad (Ng 2006)
    + actively warmed IV fluids infused for both groups.
  - Forced air warming (upper body) versus pre-warmed heating pad with gel pad (Leung 2007)
    + actively warmed IV fluids infused for both groups.
- Forced air warming versus circulating water mattress:
  - Forced air warming (lower body) versus circulating-water blanket (Hynson 1992) + warmed IV fluids (37°C) infused for both groups.
  - Forced air warming (lower body) versus circulating-water mattress (Kurz 1993a; Kurz 1993b)
    + warmed fluid in both groups.
  - Forced air warming (lower body) versus circulating-water mattress (full length) (Negishi 2003)
    + warmed fluids (37°C) infused for both groups.
  - Forced air warming (upper body) versus circulating-water mattress (Matsuzaki 2003)
    + warmed fluids (37°C) infused for both groups.
- Forced air warming versus radiant warming:
  - Forced air warming (upper or lower body) versus radiant warming (Lee 2004)
    + warmed IV fluid infused for both groups.
  - Forced air warming (upper body) versus radiant warming (Wong 2004)
    + pre-warmed IV fluids (42°C) infused for both groups.
  - Forced air warming (upper body) versus radiant warming (Torrie 2005)
    + actively warmed IV fluids and passively warmed irrigation fluid in both groups.
- Electric blanket versus circulating water mattress:
  - Electric blanket (upper body) + warmed fluids(37°C) versus circulating-water mattress (full length) (Matsuzaki 2003)
    + warmed fluids(37°C) infused for both groups.
  - Electric blanket (partially upper and lower body)+ warmed fluids versus circulating-water mattress (full length) (Negishi 2003)
    + warmed fluids infused for both groups.
- Forced air warming versus water garment
  - Forced air warming (upper body) versus water garment (Janicki 2001)
    + warmed intraoperative fluids in both groups

- o Forced air warming (upper and lower body) versus water garment (Janicki 2002) + warmed intraoperative fluids in both groups.

VI. Comparisons of different types of forced air warming

- Forced air warming (over blanket) versus forced air warming (under mattress) (Russell 1995)
  + actively warmed fluids (37°C) in both groups.
- Forced air warming (upper body) versus forced air warming (lower body)
  + fluid warming infused for both groups
  - o Forced air warming (upper body) versus forced air warming (lower body) (Motamed 2000)
    + warmed infusion of crystalloid (37°C) infused for both groups.
  - o Forced air warming (upper body) versus forced air warming (lower body) (Yamakage 1995)
    + warmed lactated Ringer's solution (37°C) infused for both groups.

VII. Comparisons of different settings for forced air warming (dose comparison)

- Active patient warming 1 (dose 1) versus. Active warming 1 (dose 2), with fluid warming in both groups:
  - o Aggressive forced air warming versus conventional forced air warming (Winkler 2000)
    + warmed IV fluids ((37°C) infused for both groups.
  - o Forced air warming (40°C) versus forced air warming (ambient temperature) (Kurz 1996)
    + actively warmed IV fluids infused for both groups.
  - o Extra warming versus no warming (Lenhardt 1997).
  - o Forced air warming (insulated; lower body) versus forced air warming (regular; lower body) (Camus 1993b)
    + ambient IV fluids and actively warmed irrigation fluids (37°C) infused for both groups.

VIII. Active warming 1 + active warming 2 + thermal insulation versus usual care

- Circulating water mattress + heated-humidifiers + reflective blankets versus usual care (Joachimsson 1997a) (general and/or regional anaesthesia) + warmed fluids and blood (37°C to 38°C) in both groups.

IX. Thermal insulation 1 + thermal insulation 2 versus thermal insulation 1

- Reflective blankets (head and face) and reflective blankets (lower body) versus reflective blankets (lower body) (Kamitini 1999).

RESULTS

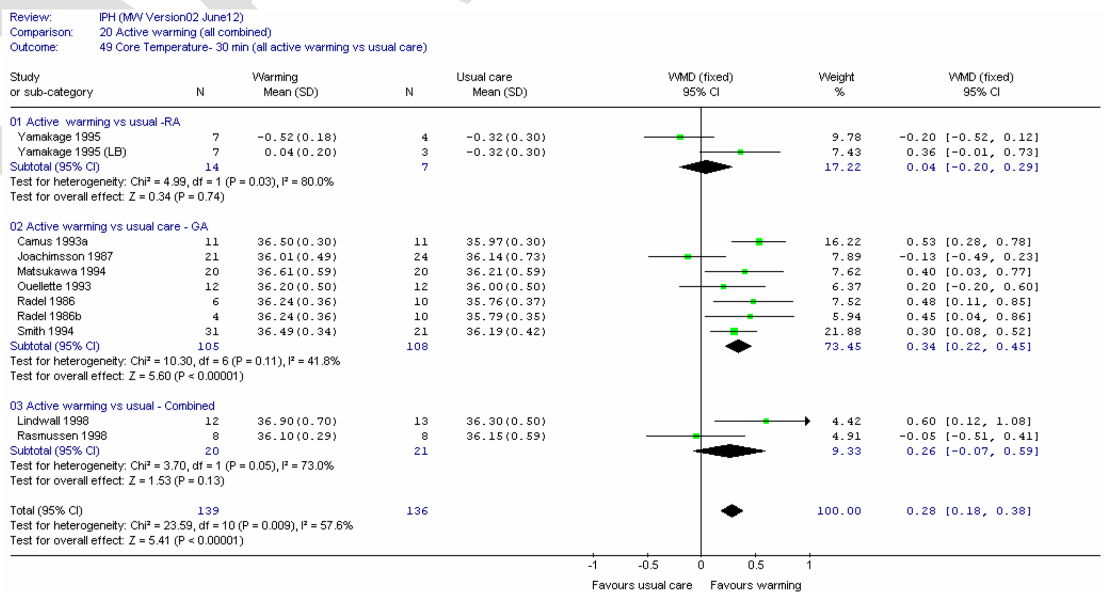
Originally, the GDG decided to stratify only by presence/absence of comorbidities, trauma, and hyperthermia. Perioperative phases were also to be considered separately. However, a post-hoc decision was made to stratify by type of anaesthesia (general; regional; combined) as these were expected to have different mechanisms of action. Otherwise all categories of active warming versus usual care were combined regardless of the type of active warming, the presence of warmed fluids or other active interventions. If there was heterogeneity, these were examined in sensitivity analyses.

Subgroup analyses by type of anaesthesia

The first set of analyses examines the effectiveness of active warming for separate subgroups by type of anaesthesia at three intraoperative times: 30 minutes (Figure 2); 60 minutes (Figure 3); and 2 hours (Figure 4).

When calculating the overall summary statistic, we split the number of patients in the control groups across comparisons in the Hynson (1992) study to avoid double counting. We note that in two other studies (Camus 1993b [2 comparisons]; Radel 1986 [2 comparisons]) the number of patients was split in the control and treatment groups respectively to avoid double counting. When subgroup analyses were carried out, if across comparison, the control group included all the patients.

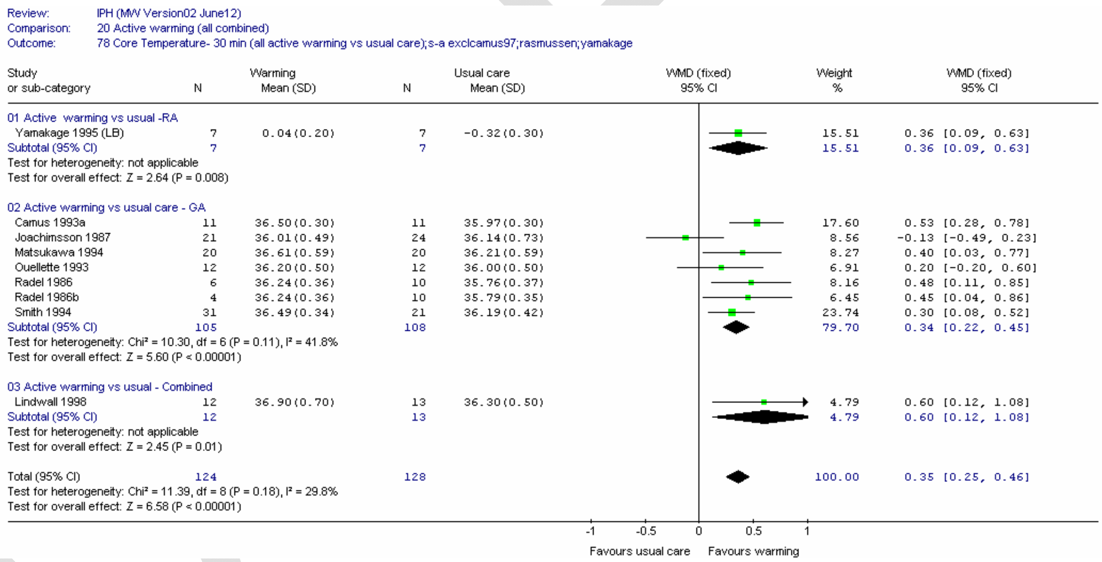
Figure 2: Core temperature: 30 minutes; active versus usual care



At 30 minutes, there is significant heterogeneity in the two subgroups that have studies in which the patients had regional anaesthesia, and there is also heterogeneity overall (I^2=57.6%, p=0.009) (Figure 2). In the regional anaesthesia subgroup, the heterogeneity was attributed to differences in site of warming. Upper body warming was much less effective which was to be expected because this area was not at risk of anaesthesia-induced thermal redistribution. In the combined general and regional anaesthesia subgroup, Rasmussen (1998) had upper body warming only and Lindwall (1998) had either upper or lower body warming. Rasmussen (1998) was less effective. A sensitivity analysis was carried out removing both the Yamakage (1995) (upper body) and Rasmussen (1998) studies (Figure 2b) which reduced the overall heterogeneity to non significant levels (I^2=29.8%, p=0.18).

We note that there was still some heterogeneity in the general anaesthesia group.

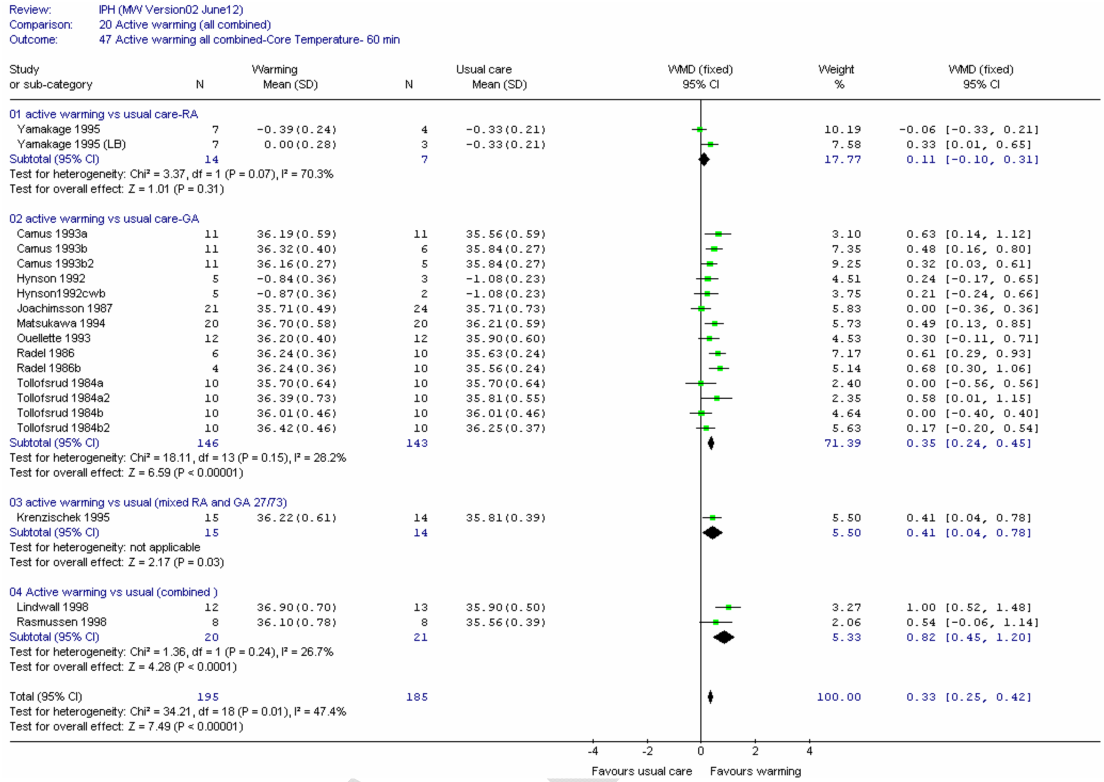
Figure 2b: Core temperature: 30 minutes; active versus usual care; sensitivity analysis



60 minutes

At 60 minutes, there was significant heterogeneity only in the regional anaesthesia subgroup and overall (I^2=70.3%, p=0.07). Overall, the heterogeneity was significant (I^2=47.4%; p=0.01) (Figure 3).

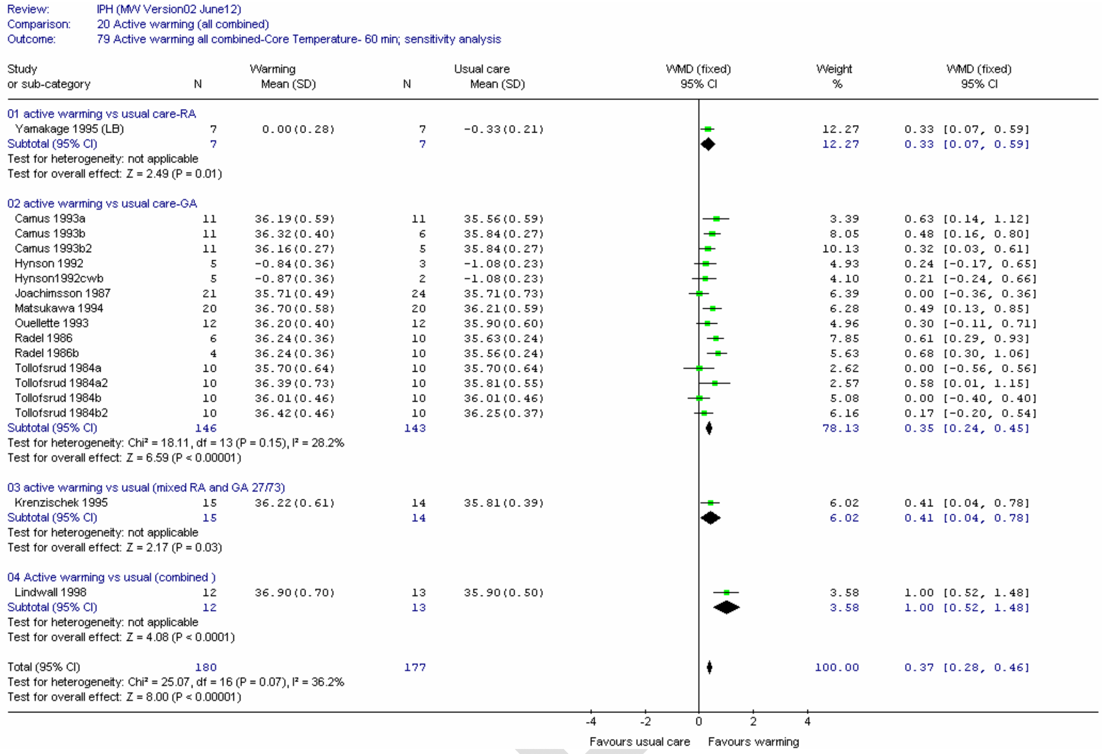
Figure 3: Core temperature: 60 minutes; active versus usual care



NB: Scale -4 to 4

Sensitivity analysis without the two studies (Rasmussen 1998; Yamakage 1995, upper body) giving upper body warming for regional anaesthesia decreased the overall heterogeneity, however, it was still significant (I^2=36.2%, p=0.07). We note that the combined anaesthesia subgroup (Lindwall 1998) showed a larger difference in mean core temperature than the other subgroups (Figure 3b).

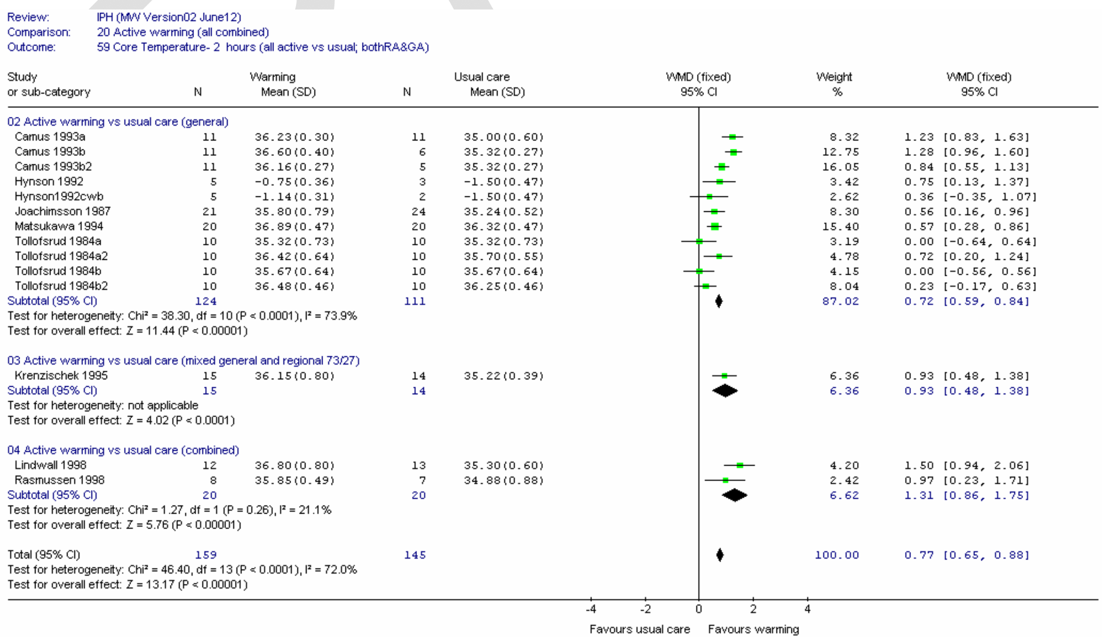
Figure 3b: Core temperature: 60 minutes; active versus usual care; sensitivity analysis



2 hours

At 2 hours, there is significant heterogeneity in the general anaesthesia subgroup (I^2 = 73.9%, p<0.0001) and overall (I^2=72.0%, p<0.0001) (Figure 4).

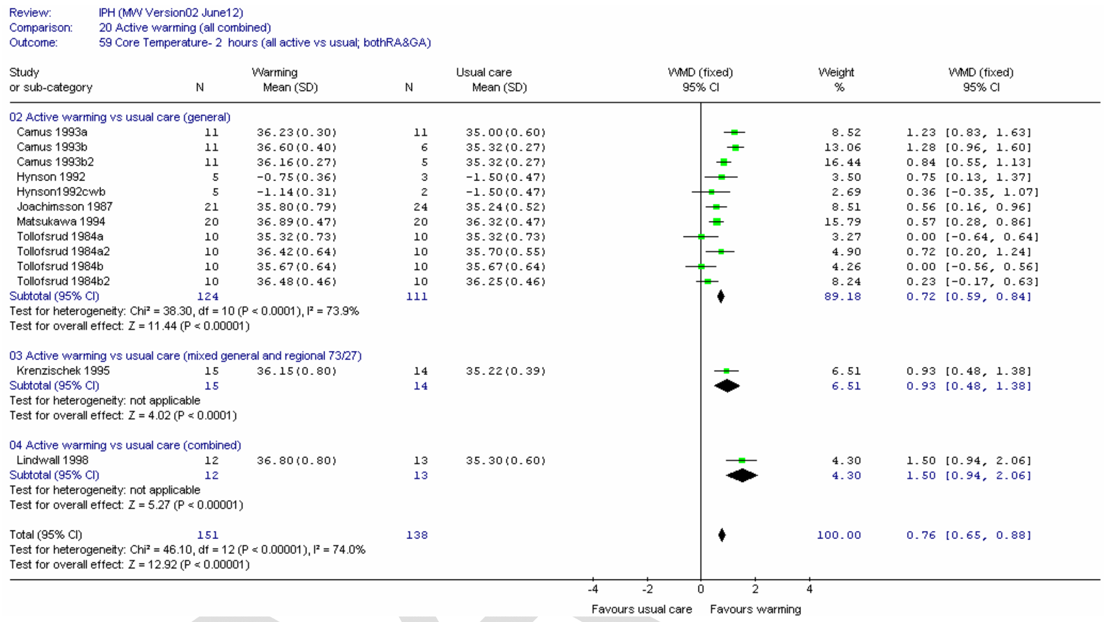
Figure 4: Core temperature: 2 hours; active versus usual care



NB: Scale -4 to 4

One study (Rasmussen 1998) with patients receiving upper body warming only for the regional anaesthesia and was removed for in the sensitivity analysis. However, the overall heterogeneity was still significant (overall I^2=74.0%, p<0.00001) (Figure 4b). We note that the study (Lindwall 1998) in the combined anaesthesia subgroup showed a larger effect of warming compared to any of the general anaesthesia studies and to their pooled results.

Figure 4b: Core temperature: 2 hours; active versus usual care; sensitivity analysis



NB: Scale -4 to 4

The above analyses suggest that studies in which only the upper body was warmed in patients receiving regional anaesthesia should be treated separately. The analyses also lend support to the post-hoc assumption of splitting the studies by type of anaesthesia, especially when separating the combined regional and general anaesthesia compared with general anaesthesia.

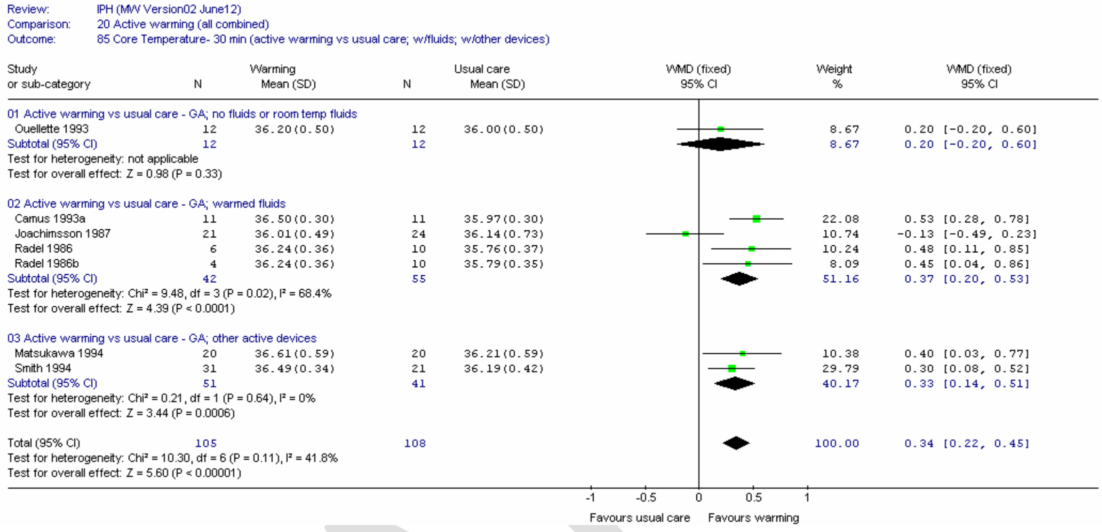
Subgroup analyses of general anaesthesia studies by presence of additional warming mechanisms

In the next sets of analyses, we tested the assumption that all active versus usual care comparisons could be combined, regardless of type of warming device and/or presence of fluids or other active warming devices.

The following sets of analyses examined the effectiveness of active warming (under general anaesthesia) for three subgroups by presence of usual care or additional warming (fluids) additional warming (devices) at three intraoperative times: 30 minutes (Figure 5); 60 minutes (Figure 6); and 2 hours (Figure 7).

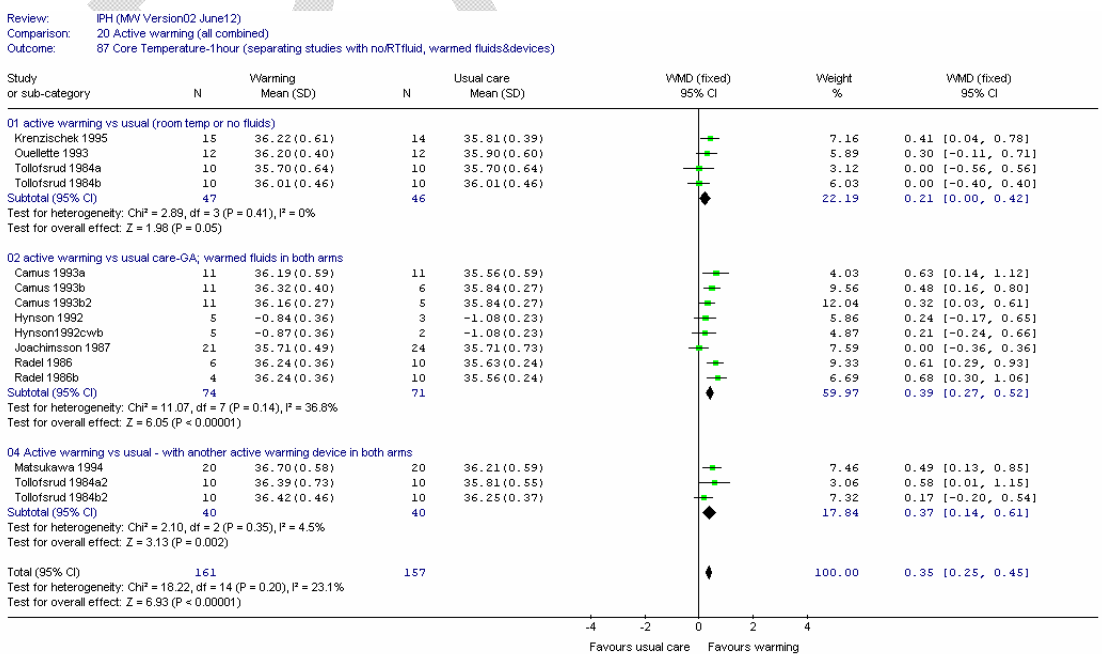
At 30 minutes, the overall heterogeneity was I^2=41.8%, p=0.11. There was significant heterogeneity within the subgroup of studies in which all patients also received warmed fluids (I^2=68.4%, p=0.02)

Figure 5: Core temperature: 30 minutes; active versus usual care; general anaesthesia



At 60 minutes the overall heterogeneity was not significant (I^2=23.1%, p=0.20).

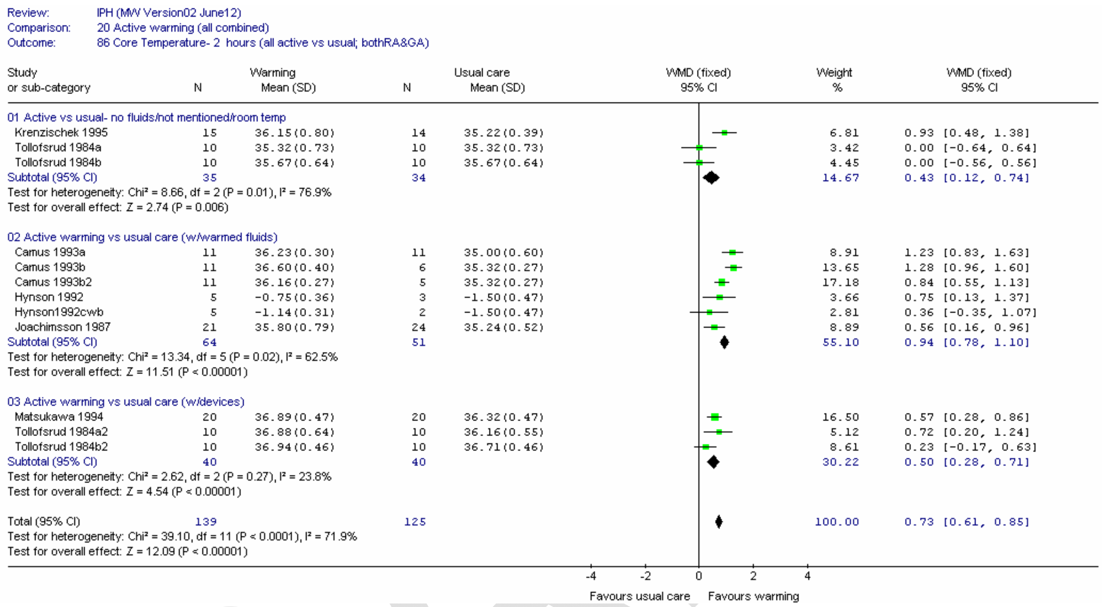
Figure 6: Core temperature: 60 minutes; active versus usual care; general anaesthesia



NB: Scale -4 to 4

At 2 hours there was significant heterogeneity overall (I^2 =71.9%, p <0.0001) and within two subgroups in which all patients also received warmed fluids (I^2=62.5%, p= 0.02) and in which no additional warming mechanisms were used (I^2 =76. 9%, p=0.01) (Figure 7).

Figure 7: Core temperature: 2 hours; active versus usual care; general anaesthesia



NB: Scale -4 to 4

The above analyses suggested that the heterogeneity was not explained by the presence of warmed fluids or additional warming devices.

The next subgroup analyses examine the importance of type of warming device.

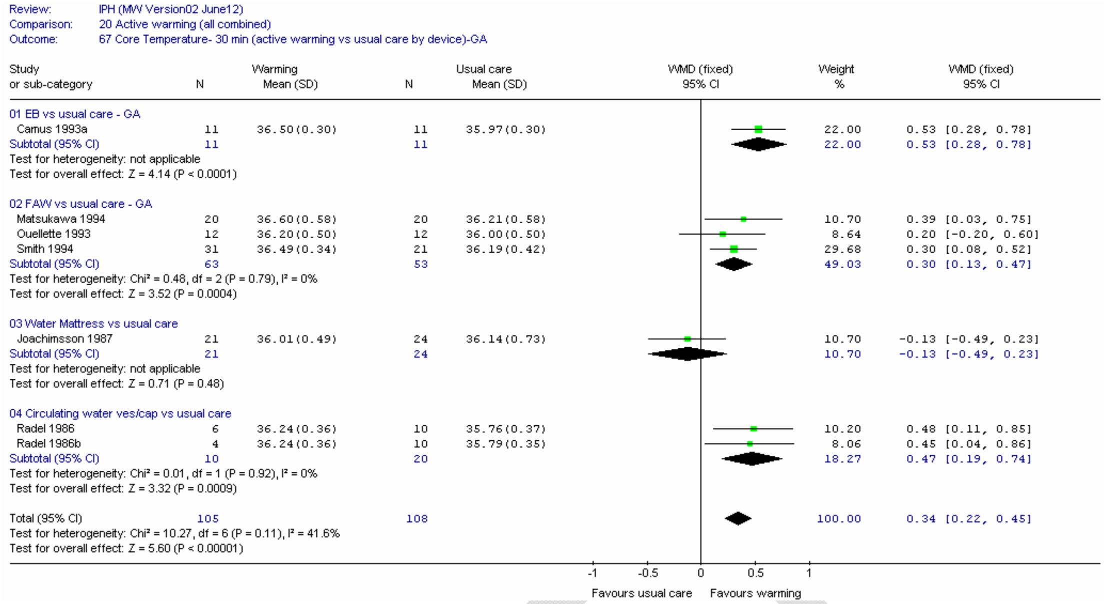
Subgroup analyses of general anaesthesia studies by type of warming device

30 minute subgroup analyses

There is some heterogeneity (I^2= 41.6%, p=0.11), however, splitting by type of warming appears to explain the heterogeneity and there was no heterogeneity within each subgroup (I^2=0%).

Subgroup analysis suggests that there is a larger effect for electric blanket and a smaller effect for circulating water mattress (Figure 8).

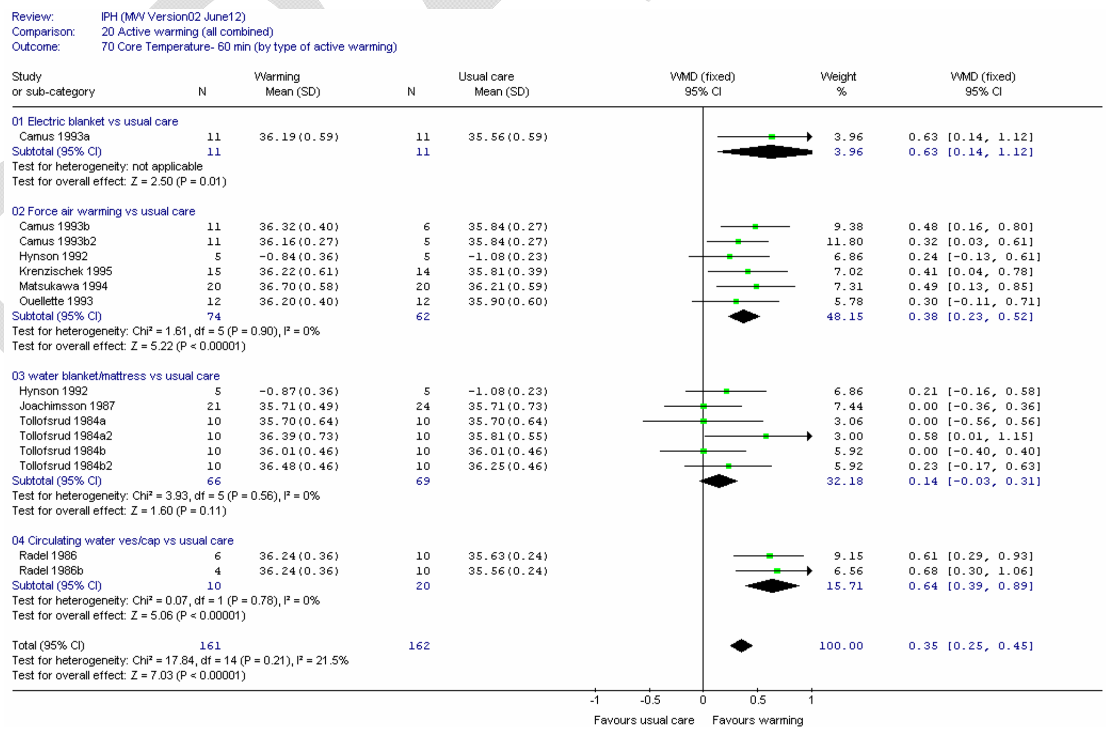
Figure 8: Core temperature: 30 minutes subgroup analyses; active versus usual care; general anaesthesia



60 minutes

At 60 minutes there was some heterogeneity overall (I^2 = 20.5%, p= 0.23), including Krenzischek (1995) which had 27% of patients receiving regional anaesthesia. There was no heterogeneity within each of the subgroups (I^2 = 0%) (Figure 9).

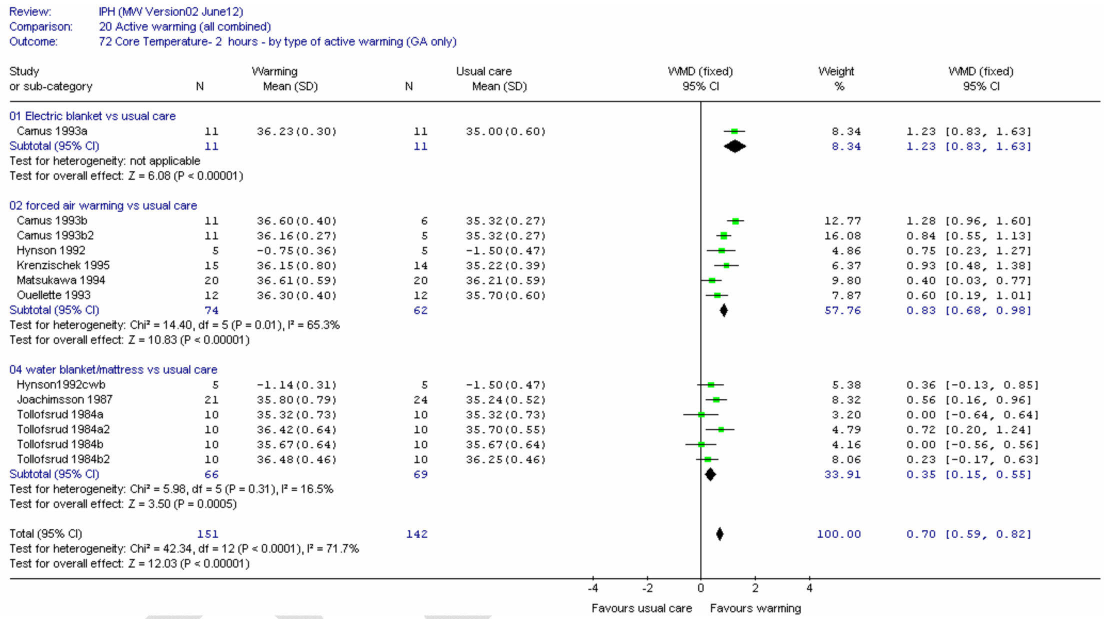
Figure 9: Core temperature: 60 minutes subgroup analyses; active versus usual care; general anaesthesia



2 hours

At 2 hours there was significant heterogeneity overall (I^2= 71.9%, p<0.0001). Splitting into subgroups indicated a similar pattern with larger effect being found for the elect blanket subgroup and smaller effect for the circulating water mattress. However, there was still significant heterogeneity within the forced air warming subgroup (I^2=65.3%, p=0.01) (Figure 10).

Figure 10: Core temperature: 2 hours; active versus usual care; general anaesthesia

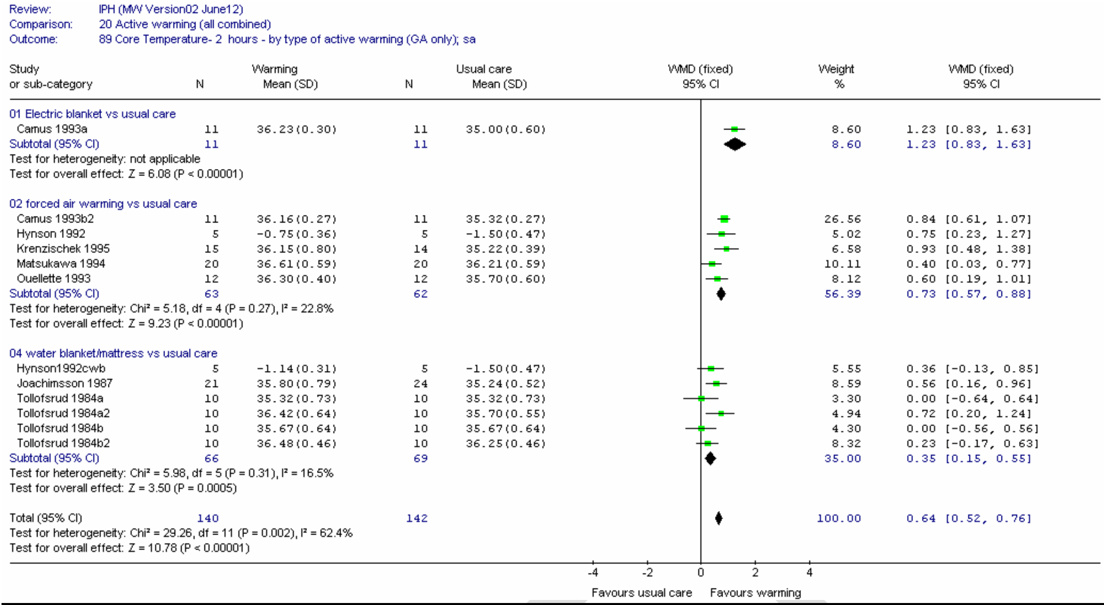


NB: Scale -4 to 4

The GDG noted that the Camus (1993b) study had two forced air warming arms, one of which

had two cotton sheets on top of the forced air warmer which the authors described as 'insulated forced air warming'. It was considered that this adaptation of forced air warming was not a standard approach and therefore a sensitivity analysis was carried out without this comparison. Excluding Camus (1993b), there was no significant heterogeneity (I^2=22.8%, p=0.27). However, there was overall heterogeneity (I^2=61.5%, p=0.003) (Figure 11).

Figure 11: Core temperature: 2 hours subgroup analyses; active versus usual care; general anaesthesia



NB: Scale -4 to 4

Discussion

The subgroup analyses of the general anaesthesia studies showed that heterogeneity was explained by the type of warming device and not by the presence of warmed fluids or additional warming devices.

The GDG decided that the following stratifications should be carried out:

- By type of anaesthesia;
- By type of warming device.

It was acceptable to combine studies regardless of the presence of warmed fluids or additional warming devices.

Studies in which patients were warmed upper body under regional anaesthesia (Yamakage 1995; Rasmussen 1998) and the study using insulated forced air warming (Camus 1993b) were not considered further.

I. Active warming of patients versus usual care

IA. General anaesthesia

Fourteen studies [18 comparisons] (Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Radel 1986 [2 comparisons]; Joachimsson 1987;Hynson 1992 [2 comparisons]; Camus 1993a; Camus 1993b2; Bennett 1994; Matsukawa 1994; Smith 1994; Frank 1995; Frank 1997; Krenzischek 1995; Scott 2001) compared active warming with usual care in the intraoperative period.

One study (Camus 1993a) with 22 patients undergoing abdominal surgery compared electric blankets with usual care. The electric blanket (42 to 43°C) covered from the legs up to the pubis, IV fluids were infused at ambient temperature and irrigation solutions were warmed to 37°C.

Ten studies (Hynson 1992; Camus 1993b2; Ouellette 1993; Bennett 1994; Matsukawa 1994; Smith 1994; Frank 1995; Krenzischek 1995; Frank 1997; Scott 2001) with 727 patients compared forced air warming with usual care.

More specifically, the comparisons were as follows:

- Forced air warming (set to 'high'- approximately 43°C) with usual care, with warmed IV fluids (37°C) for both arms (Hynson 1992).
- Forced air warming (set to high – approximately 43°C) with usual care and IV fluids were infused at ambient temperature and irrigation solutions were warmed to 37°C for both arms (Camus 1993b2).
- Forced air warming (set to 'low') with usual care and IV fluids were infused at room temperature for both arms (Ouellette 1993).
- Forced air warming (set to 'high') with usual care, with circulating water mattress and IV fluids infused (temperature not stated) both arms (Matsukawa 1994).
- Forced air warming (set to 'high' or adjusted to 'medium' to maintain core temperature at or near 37°C) with usual care and did not report any information on fluids (Krenzischek 1995).
- Forced air warming (dose not stated) and warmed fluids with usual care. Warming of IV fluids done when necessary for the usual care groups (Scott 2001).

Four studies [6 comparisons] (Joachimsson 1987; Hynson 1992; Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]) with 135 patients compared warmed water mattress/blanket with usual care.

- Circulating water mattress (set to 40°C) and all patients received warmed IV fluids (37°C) (Hynson 1992).
- Hot mattress (set to 38°C to 40°C) and blood and IV products (37°C to 38°C) were warmed (Joachimsson 1987).
- Heated circulating water blanket (set to 38°C to 39°C) covered with two layers of cotton sheet compared with usual care [patients rested on the blanket] (Tølløfsrud 1984a; Tølløfsrud 1984b).
- Circulating water blanket (set to 38°C to 39°C) covered with two layers of cotton sheet and patients in both groups received heated-humidified inspired gas [patients rested on the blanket] (Tølløfsrud 1984a2; Tølløfsrud 1984b2).

One study (Radel 1986) [3 arms] compared the effectiveness of circulating water cap and vest with usual care (patient gown and two cotton blankets) or with insulated usual care (two cotton shirts and blankets and one skull cap). Patients in all arms received warmed IV fluids warmed to 37°C.

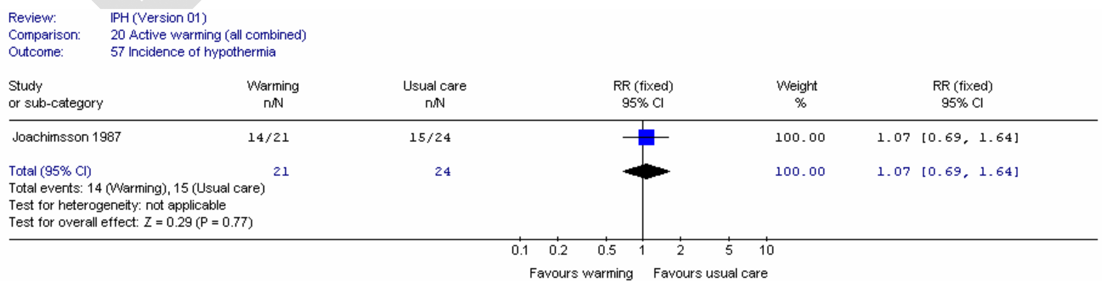
Within each subgroup, pooled results, where appropriate were reported at each of the following time periods: 20 minutes; 30 minutes; 40 minutes; 60 minutes; 120 minutes; 180 minutes; time when lowest intraoperative temperature reached; core temperature at end of surgery; blood loss (Bennett 1994); incidence of shivering (Camus 1993b; Krenzischek 1995; Frank 1997), pain scores, thermal discomfort (Krenzischek 1995); cardiac events (Frank 1997); and incidence of pressure ulcers (Scott 2001) were also reported.

We note that with the exception of Scott (2001) information on intraoperative core temperatures were extracted from graphs for all of the studies. We note that in one study (Hynson 1992) the error bars for the control group were not presented on the graph. The authors reported that the error bars were 'very similar' to those shown for another group.

1. Incidence of hypothermia

One study (Joachimsson 1987) with 45 patients comparing water mattress with usual care reported incidence of hypothermia at end of surgery. Only the results presented at the following temperature ranges: 35.9°C to 35.0°C; 34.9°C to 34.0°C; and less than 34°C were considered. It was decided to combine the events for the three temperature ranges. The study reported that 14 patients in the warmed group 15 patients in the control group had core temperature less than 36.0°C. There was no significant difference in the incidence of hypothermia [RR 1.07 (95% CI 0.69, 1.64)] (Figure 12).

Figure 12: Incidence of hypothermia; water mattress versus usual care; general anaesthesia



2. Intraoperative Core Temperature

a) Electric blanket

One study Camus (1993a) with 22 patients compared electric blankets with usual care.

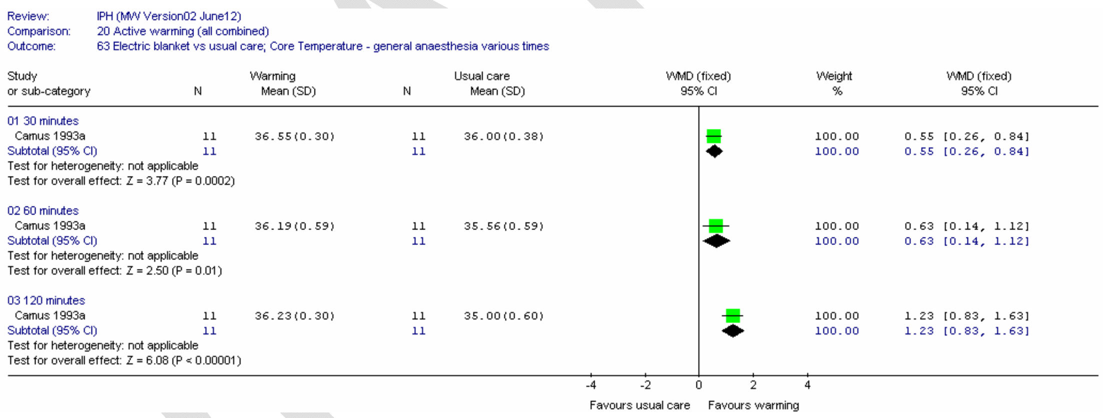
At 30 minutes, 60 minutes and 2 hours the mean core temperature was significantly higher in the electric blanket group. At all times, the difference was clinically significant (Figure 13).

At 30 minutes, MD 0.55°C (95% CI 0.26, 0.84) for a control group rate of 36.0°C; the difference was clinically significant.

At 60 minutes the mean core temperature was significantly higher in the electric blanket group: MD 0.63°C (95% CI 0.14, 1.12). The confidence interval is fairly wide.

At 2 hours, the mean core temperature was significantly higher in the electric blanket group: MD 1.23°C (95% CI 0.83, 1.63). The confidence interval is fairly wide.

Figure 13: Core temperature: intraoperative period; electric blanket versus usual care; general anaesthesia



NB: Scale -4 to 4

b) Forced air warming

Six studies (Hynson 1992; Camus 1993b2; Ouellette 1993; Matsukawa 1994; Smith 1994; Krenzischek 1995) with 177 patients comparing forced air warming with usual care reported intraoperative core temperature.

At 20 minutes and 40 minutes, one study (Hynson 1992) with 10 patients showed no significant difference (Figure 14).

At 30 minutes, meta-analysis of three studies (Ouellette 1993; Matsukawa 1994; Smith 1994) with 116 patients showed a significantly higher mean core temperature for the forced air warming group: MD 0.30°C (95% CI 0.13, 0.47) for control group temperature range 36.0°C to 36.2°C. This difference is not clinically significant. There was no heterogeneity.

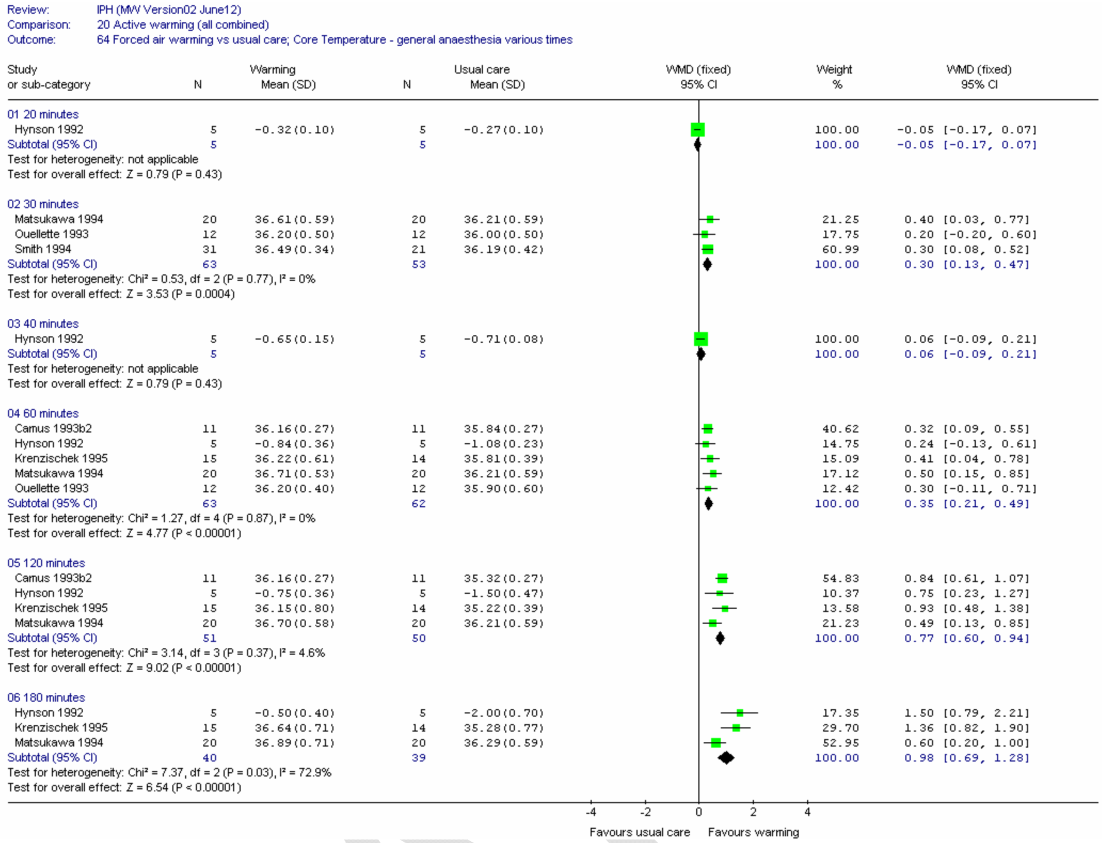
At 60 minutes, meta-analysis of five studies (Hynson 1992; Camus 1993b2; Ouellette 1993; Matsukawa 1994; Krenzischek 1995) with 125 patients showed a significantly higher mean core temperature for the forced air warmed group: MD 0.35°C (95% CI, 0.21, 0.49) for a control group temperature range 35.9°C to 36.2°C. The difference is clinically significant. There was no heterogeneity.

At 2 hours, meta-analysis of four studies (Hynson 1992; Camus 1993b2; Matsukawa 1994; Krenzischek 1995) with 101 patients showed a significantly higher mean core temperature in the forced air warming group: MD 0.77°C (95% CI 0.60, 0.94) for a control group temperature range 35.2°C to 36.2°C. This difference is clinically significant. There was no significant heterogeneity.

At 3 hours, meta-analysis of three studies (Hynson 1992; Matsukawa 1994; Krenzischek 1995) with 79 patients showed significant heterogeneity (I^2=72.9%, p= 0.03).

The significant heterogeneity was explored by a sensitivity analysis based on the device setting. Two studies (Hynson 1992; Krenzischek 1995) applied forced air warming at the ‘high’ setting and one study (Matsukawa 1994) at a ‘medium’ setting (Figure 14b).

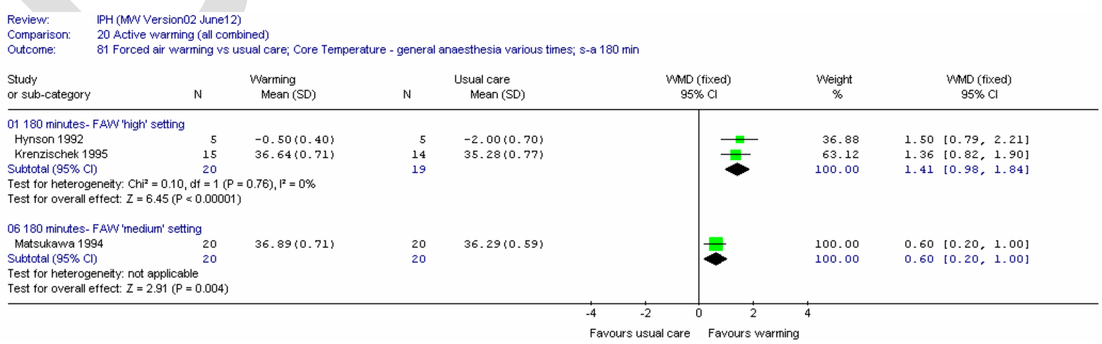
Figure 14: Core temperature: intraoperative period; forced air warming versus usual care; general anaesthesia



NB: Scale -4 to 4

Excluding Matsukawa (1994), a sensitivity analysis of the remaining two studies (Hynson 1992; Krenzischek 1995) with 39 patients receiving forced air warming at a high setting showed a significantly higher mean core temperature in the forced air warmed group: WMD 1.41°C (95% CI 0.98, 1.84) for a control group temperature of 35.2°C. The confidence interval is fairly wide. The difference is clinically significant. There was no heterogeneity (Figure 14b).

Figure 14b: Core temperature: 3 hours; forced air warming versus usual care; general anaesthesia; sensitivity analysis



NB: Scale -4 to 4

c) Circulating water mattress

Four studies [6 comparisons] (Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Joachimsson 1987; Hynson 1992) compared circulating water mattress with usual care.

At 20 minutes, meta-analysis of 3 studies [5 comparisons] (Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Hynson 1992) with 90 patients showed a small difference in core temperature for the warmed group: MD 0.10°C (95% 0.00, 0.21) for a control group temperature range 36.1°C to 36.2°C. The difference is not clinically significant. There was no heterogeneity (Figure 15).

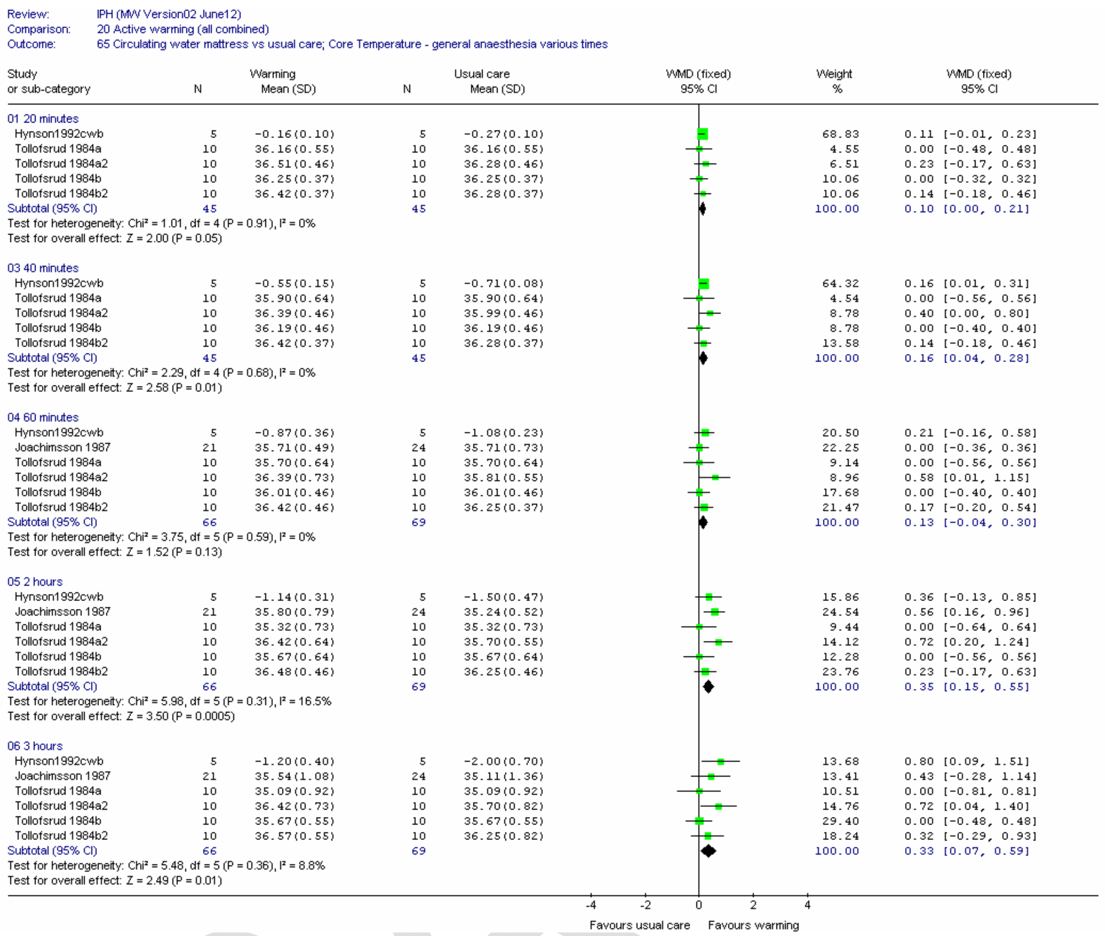
At 40 minutes, meta-analysis of 3 studies (Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Hynson 1992) with 90 patients showed a small difference in core temperature for the warmed group: WMD 0.16°C (95% CI 0.04 to 0.28) for a control group temperature range of 35.7°C to 36.2°C. The difference is not clinically significant. There was no heterogeneity.

At 1 hour, the mean difference was not significant.

At 2 hours, meta-analysis of 4 studies [6 comparisons] (Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Joachimsson 1987; Hynson 1992) with 135 patients showed significantly higher mean core temperatures for the warmed group: WMD 0.35°C (95% 0.15, 0.55) for a control group temperature range 35.2°C to 36.2°C. The difference is clinically significant. There was no significant heterogeneity.

At 3 hours, meta-analysis of 4 studies [6 comparisons] (Tølløfsrud 1984a [2 comparisons]; Tølløfsrud 1984b [2 comparisons]; Joachimsson 1987; Hynson 1992) with 135 patients showed significantly higher mean core temperatures for the water mattress group: WMD 0.33°C (95% 0.07, 0.59) for a control group temperature range 35.0°C to 36.2°C. The difference is clinically significant. There was no significant heterogeneity.

Figure 15: Core temperature: intraoperative period; water mattress versus usual care; general anaesthesia



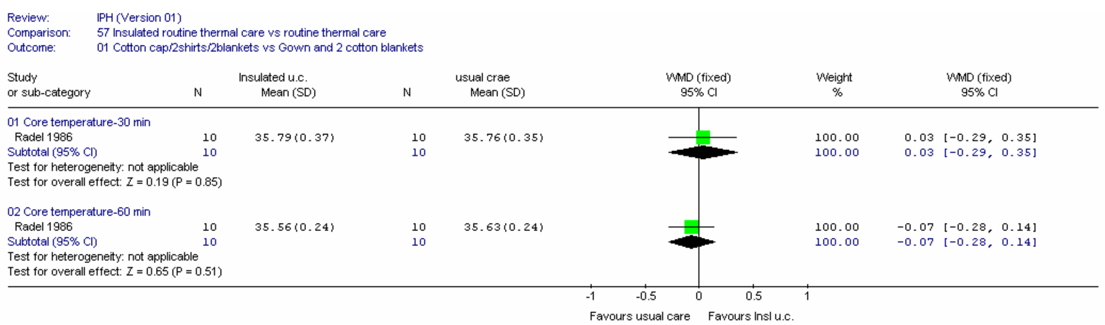
NB: Scale -4 to 4

d) Circulating water cap and vest

i. Intraoperative core temperature

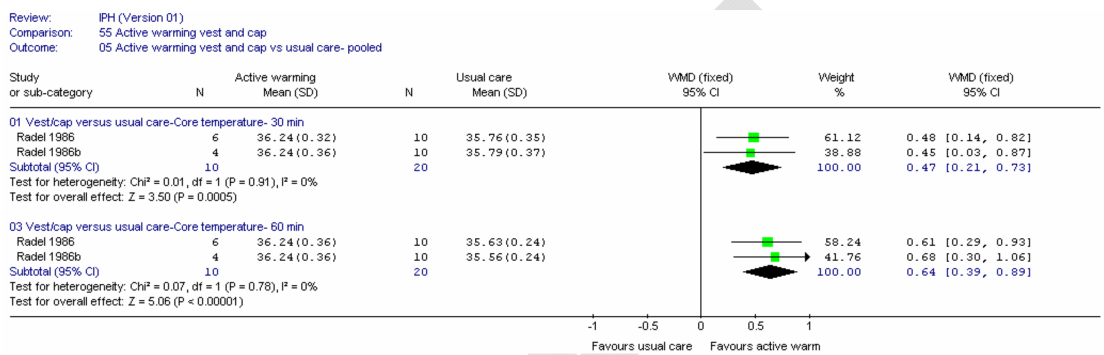
One study [2 comparisons] (Radel 1986) with 30 patients in total compared the effectiveness of circulating water hat and vest with usual care and insulated usual care in male patients undergoing orthopaedic procedures for the lower extremities under general anaesthesia. Patients in all groups received warmed IV fluids (37°C). A comparison of the usual care with the insulated usual care group showed no difference (Figure 16).

Figure 16: Core temperature; insulated usual care versus usual care; general anaesthesia



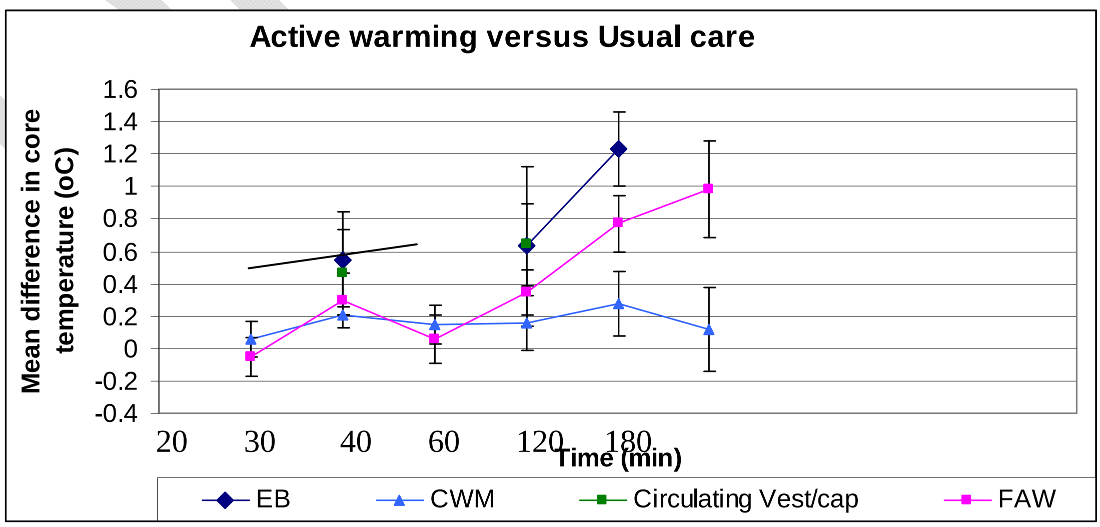
Insulated usual care was treated in the same way as ordinary usual care. Meta-analysis of the two comparisons at 30 min and 1 hour showed significantly higher mean core temperature for the circulating water vest and cap group. At 30 minutes, MD 0.47 (95% CI 0.21, 0.73); at 60 minutes, MD 0.64 (95% CI 0.39, 0.89). The confidence interval is fairly wide at both times (Figure 17).

Figure 17: Core temperature; circulating water vest and hat versus usual and insulated care; general anaesthesia



These data are reported graphically below. We note that the results for electric blanket and circulating water mattress are based on two small trials, but these subgroup analyses show an increasing effect of each warming device with time compared to usual care. The electric blanket appears to be more effective than forced air warming than circulating water mattress.

Figure 18: Intraoperative core temperature: active warming versus usual care; general anaesthesia



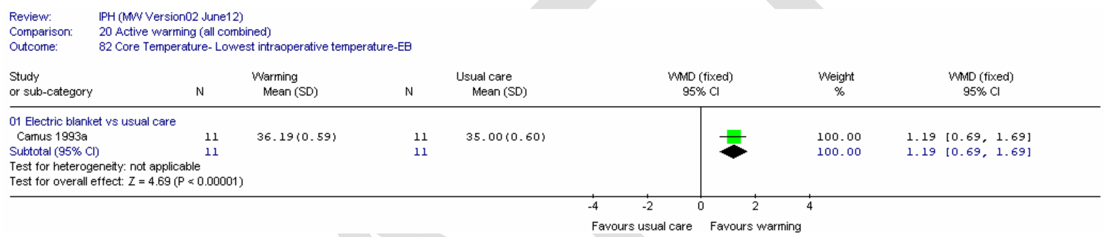
3. Core Temperature – lowest intraoperative temperature

Lowest intraoperative temperatures for the three types of active warming were extracted for five studies [6 comparisons] (Hynson 1992 [2 comparisons]; Camus 1993a; Camus 1993b2; Ouellette 1993; Matsukawa 1994; Krenzischek 1995; Scott 2001).

a) Electric blanket

One study (Camus 1993a) with 22 patients undergoing abdominal surgery compared electric blankets with usual care. The lowest intraoperative times were: at 60 minutes for the warming group and at 120 minutes for the control group (Camus 1993a): WMD 1.19°C (95% CI 0.69, 1.69). The confidence interval is wide (Figure 19).

Figure 19: Core temperature – lowest intraoperative temperature; active warming versus usual care; general anaesthesia



NB. Scale -4 to 4

b) Forced air warming

Six studies (Hynson 1992; Camus 1993b2; Ouellette 1993; Matsukawa 1994; Krenzischek 1995; Scott 2001) with 449 patients compared forced air warming with usual care.

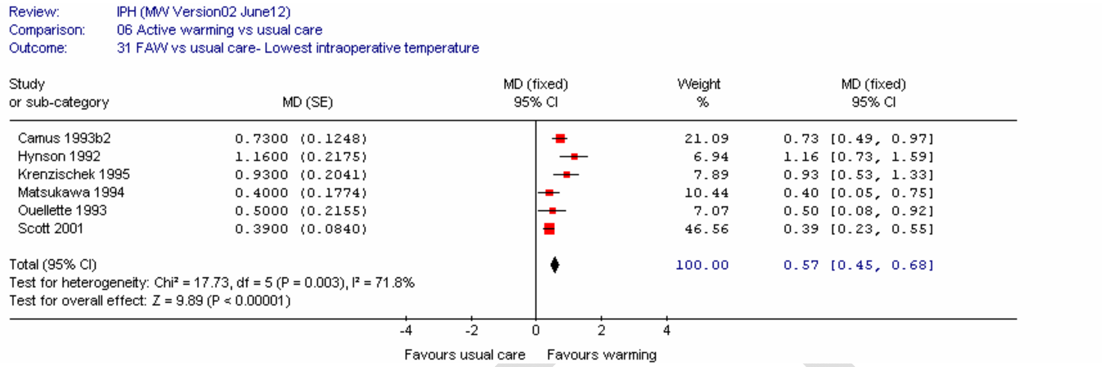
The lowest intraoperative times were reported at the following time periods:

- At 90 minutes for the forced air warming group and at end of anaesthesia for the control group (over 3 hours) (Camus 1993b2);
- At 60 minutes for the warming group and 180 minutes for the control group (Hynson 1992);
- At 30 minutes for the warming group and 90 minutes for the control group (Ouellette 1993);
- At 30 minutes for both groups (Matsukawa 1994);
- At 120 minutes for the treatment and control group (Krenzischek 1995).

Scott (2001) did not report at what time lowest core temperature was reached for each group.

The mean core temperature was significantly higher in the warmed group: WMD 0.65°C (95% CI 0.57, 0.68). There was significant heterogeneity (I^2=71.2%, p=0.003) (Figure 20).

Figure 20: Core temperature – lowest intraoperative temperature; active warming versus usual care; general anaesthesia;

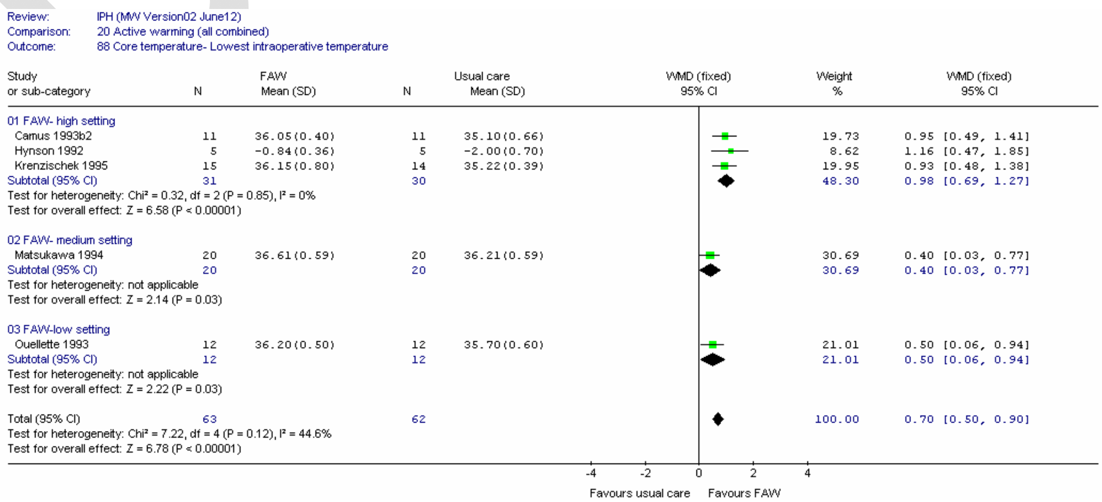


NB: Scale -4 to 4

Examining the heterogeneity we note that Scott (2001) had equal numbers of patients who were undergoing surgery under general (56%) or regional anaesthesia and the studies differed in the setting on the forced air warming device.

In three studies (Hynson 1992; Camus 1993b2; Krenzischek 1995) the forced air warmer was set to 'high'; in one study (Matsukawa 1994) the forced air warmer was set to 'medium', and in one study (Ouellette 1994) the forced air warmer was set to 'low'. One study (Scott 2001) did not state the setting on the forced air warmer. Subgroup analysis without Scott (2001) suggested that this may be an explanation for the heterogeneity (Figure 20b).

Figure 20b: Core temperature – lowest intraoperative temperature; active warming versus usual care; general anaesthesia; sensitivity analysis



NB: Scale -4 to 4

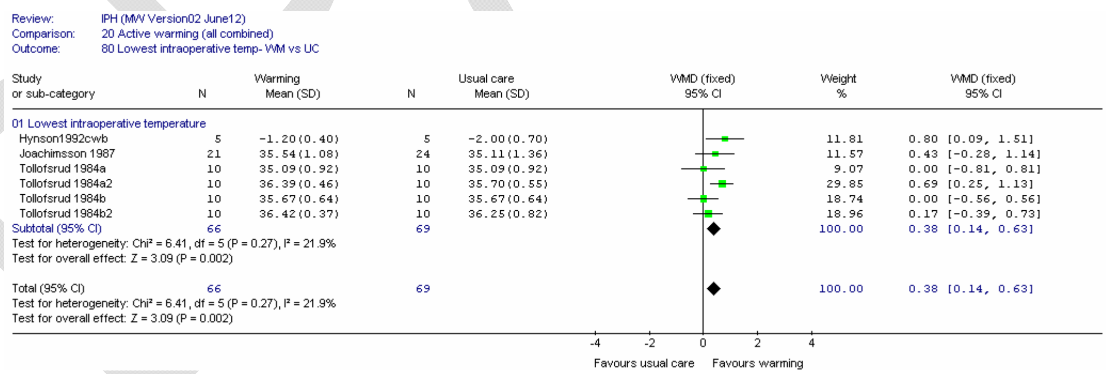
c) Circulating water mattress versus usual care

Lowest intraoperative temperature was extracted for 4 studies [6 comparisons] (Joachimsson 1987; Hynson 1992; Tølløfsurd 1984a [2 comparisons]; Tølløfsurd 1984b [2 comparisons]) with 135 patients compared circulating water blanket with usual care. Lowest intraoperative temperature was reached at the following times:

- At 20 minutes for the intervention group receiving water mattress and heated-humidifiers and at 60 minutes for the control group receiving heated-humidifiers (Tølløfsurd 1984b2);
- At 40 minutes for the intervention group receiving water mattress and heated-humidifiers and at 100 minutes for the control group receiving heated humidifiers (Tølløfsurd 1984a2);
- At 2 hours in both arms in one study (Tølløfsurd 1984b);
- At 3 hours for both arms in four studies (Joachimsson 1987; Hynson 1992; Tølløfsurd 1984a).

The mean core temperature was significantly higher in the warmed group: WMD 0.38°C (95% CI 0.14, 0.63) for a control group temperature range of 35.0°C to 36.2°C. There was no significant heterogeneity (Figure 21).

Figure 21: Core temperature – lowest intraoperative temperature; active warming versus usual care; general anaesthesia

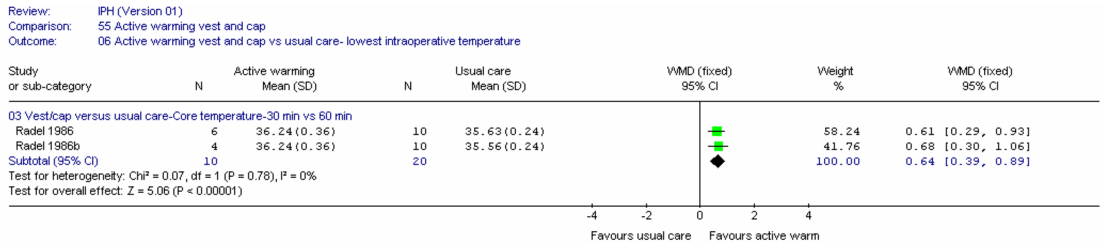


NB. Scale -4 to 4

d) Circulating water vest/cap versus usual care

In one study (Radel 1986 [2 comparisons]) with 30 patients, lowest intraoperative temperature was recorded at 30 minutes for the intervention group and at 60 minutes for the control group. The mean core temperature was significantly higher in the warmed group: MD 0.64°C (95% CI 0.39, 0.89). The confidence interval is fairly wide (Figure 22).

Figure 22: Lowest intraoperative core temperature; active warming versus usual care; general anaesthesia



NB: Scale -4 to 4

4. End of surgery

Core temperatures at the end of surgery was extracted for eight studies (Joachimsson 1987; Camus 1993a; Camus 1993b; Ouellette 1993; Bennett 1994; Frank 1995; Krenzischek 1995;_Frank 1997) (Figure 23).

One study (Camus 1993a) with 22 patients undergoing abdominal surgery compared electric blankets with usual care. Patients in the intervention group receiving an electric blanket (42°C to 43°C) were covered from the legs up to the pubis and IV fluids were infused at ambient temperature and irrigation solutions were warmed to 37°C. Duration of anaesthesia was 195 minutes (SD 14) for the warming group and 184 minutes (SD 13) in the control group. The mean core temperature was significantly higher in the electric blanket group: MD 1.8°C (95% CI 1.52, 2.08) for a control group temperature of 34.6°C. The confidence interval is fairly wide.

Six studies (Camus 1993b2; Ouellette 1993; Bennett 1994; Frank 1995; Krenzischek 1995; Frank 1997) with a total of 479 patients comparing forced air warming with usual care reported core temperature at end of surgery.

Mean duration of surgery for the forced air warming and usual care groups were as follows:

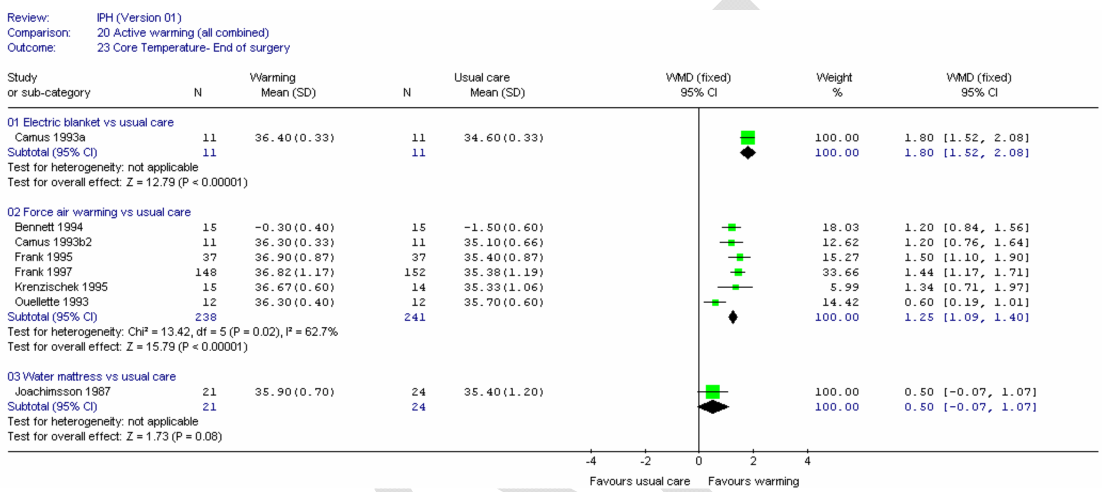
- Was over 2 hours in two studies (Ouellette 1993; Bennett 1994);
- Over 3 hours in the remaining two studies (Camus 1993b2; Krenzicheck 1995; Frank 1997);
- Not stated in one study (Frank 1995).

There was significant heterogeneity (I^2=62.7%, p=0.02).

A sensitivity analysis on the basis of different dose/settings was conducted. All of the studies applied forced air warming set at ‘high’, with the exception of one study (Ouellette 1993) where forced air warming was set at ‘low’. Meta-analysis of the remaining five studies with 455 patients showed significantly higher mean core temperature for the warmed group: MD 1.36 (95% CI 1.19, 1.53) for a control group temperature range 35.1°C to 35.4°C. The difference was clinically significant.

One study (Joachimsson 1987) with 45 patients comparing warmed water mattress with usual care reported core temperature at end of surgery. Mean duration of surgery was over 2.5 hours in both groups. The mean difference was not significant.

Figure 23: Core temperature – end of surgery; active warming versus usual care; general anaesthesia



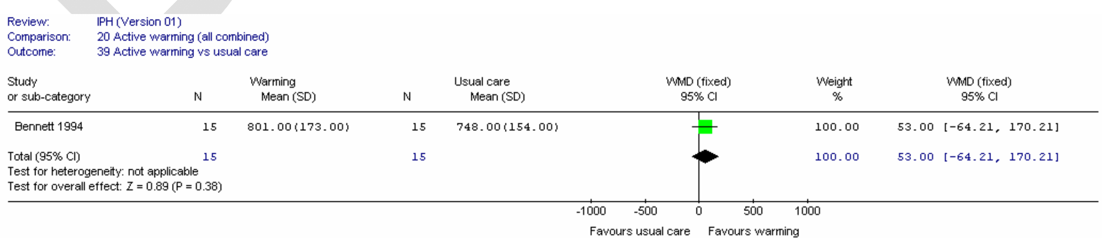
NB: Scale -4 to 4

Intraoperative Complications

5. Blood transfusion

One study (Bennett 1994) reported blood transfusion warmed to 37°C. Seven patients in the actively warmed group and 5 patients in the control group were administered blood. The difference was not significant in the volume of blood transfusion required in each group (Figure 24).

Figure 24: Volume of blood infused; active warming versus usual care; general anaesthesia



NB: Scale -1000 to 1000

Postoperative period

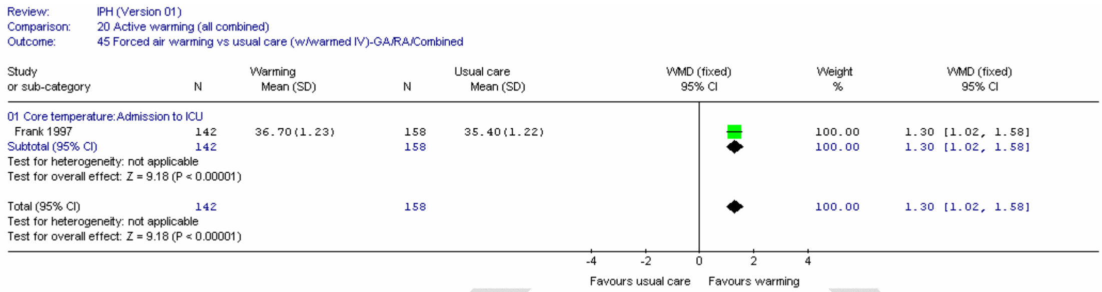
6. Primary incidence of hypothermia

No studies reported on incidence of hypothermia in the postoperative period.

7. Core temperature: ICU

One study (Frank 1997) reported core temperature upon admission into ICU. There is a significantly higher mean core temperature for the actively warmed group: MD 1.30°C (95% CI 1.02, 1.58) for a control group temperature of 35.4°C. This is clinically significant (Figure 25).

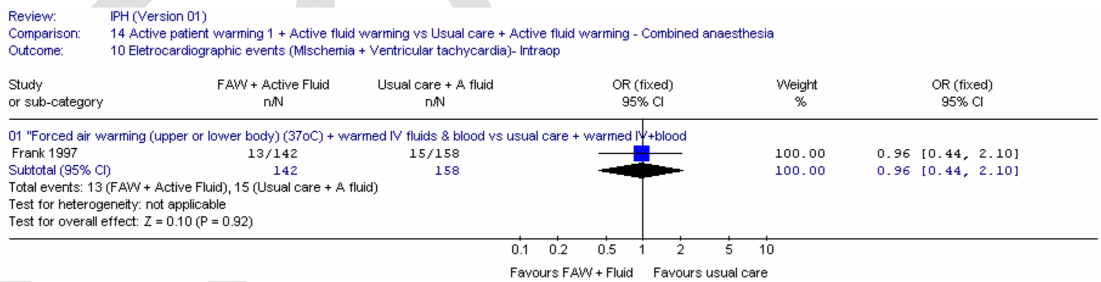
Figure 25: Core temperature: admission to ICU



8. Incidence of myocardial ischemia and ventricular tachycardia

Frank (1997) assessed the incidence of myocardial ischemia and ventricular tachycardia during the intraoperative period. The odds ratio was 0.96 (95% CI 0.44, 2.10) and was not statistically significant (Figure 26).

Figure 26: Incidence of myocardial ischemia and ventricular tachycardia – intraoperative



NB: Scale 0.1 to 10

9. Shivering

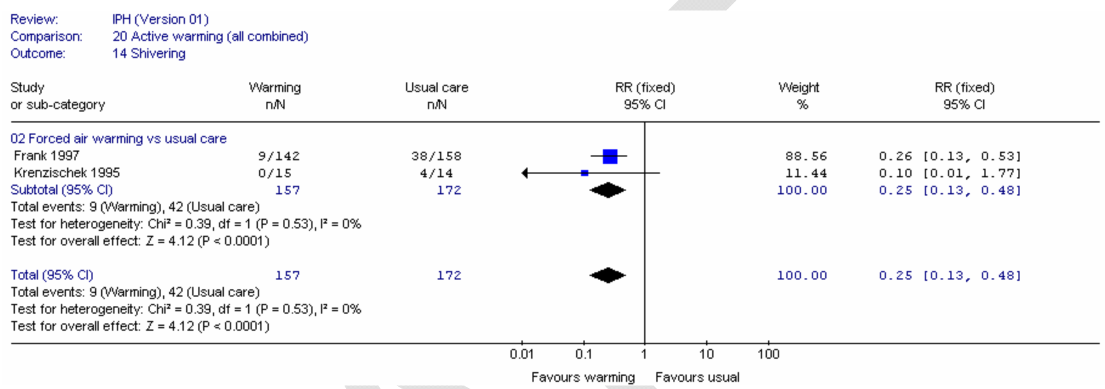
Seven studies [7 comparisons] (Camus 1993a; Camus 1993b [2 comparisons]; Matsukawa 1994; Camus 1997; Krenzicheck 1995; Frank 1997) assessed shivering during recovery. Results for two studies (Camus 1993a; Camus 1993b [2 comparisons]) will not be considered as all patients were covered with an electric blanket in the PACU until core temperature had reached 37°C (Figure 27).

In one study (Krenzicheck 1995) shivering was assessed in the postoperative period and recorded as either 'absent' or 'present'. Two studies (Matsukawa 1994; Frank

1997) did not provide details on how shivering was assessed. One study (Matsukawa 1994) reported no incidence of shivering for either group.

Meta-analysis of the two studies (Krenzicheck 1995; Frank 1997) showed a significantly lower incidence of shivering (RR 0.25 [95% CI 0.13, 0.48]) (Figure 27). The NNT is 6 (95% CI 4, 9) for a control group rate of (24 to 29%).

Figure 27: Shivering (recovery); active warming versus usual care; general anaesthesia

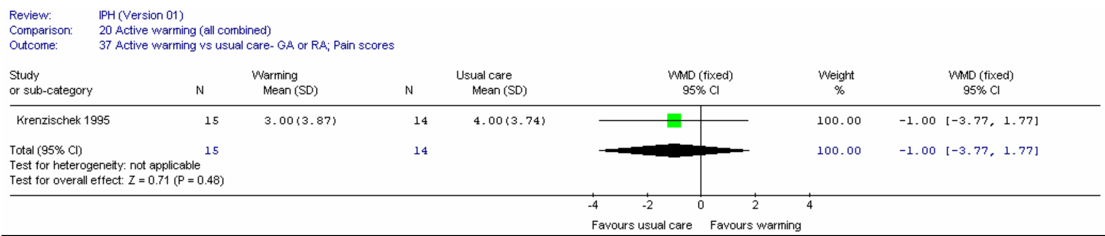


NB: Scale 0.01 to 100

10. Pain (admission to PACU)

One study (Krenzischek 1995) reported pain scores after admission to PACU. Duration of warming was over 3 hours in the intraoperative period. There was no significant difference and the confidence interval is fairly wide (Figure 28). The study also reported pain scores at 1 hour and 2 hours postoperatively. However, results at these time periods were not considered as patients in the intervention group continued to receive forced air warming and patients in the control group received warmed cotton blankets at the discretion of nursing staff. It was unclear how many patients in the control group received the warmed cotton blankets in the postoperative period.

Figure 28: Pain scores; active versus usual care; regional or general anaesthesia



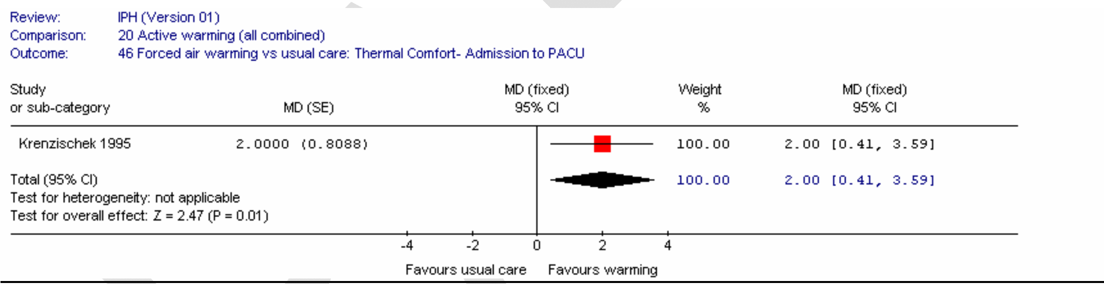
NB: Scale -4 to 4

11. Thermal comfort (admission to PACU)

One study (Krenzischek 1995) assessed thermal comfort after admission into the PACU. Thermal comfort was assessed (although it was unclear whether the observer was blinded to treatment in the intraoperative period) in the PACU on an oral analog scale, with a score of 0 representing very cold; 5 neutral thermal comfort; and 10 representing very warm. The mean thermal comfort score for the warmed group was 5 compared with 3 for the unwarmed group (Figure 29).

The study also reported thermal comfort scores at 1 hour and 2 hours postoperatively. However, results at these time periods were not considered as patients in the intervention group continued to receive forced air warming for that duration and patients in the control group received warmed cotton blankets at the nurse's discretion. It was unclear how many patients in the control group received the warmed cotton blankets in the postoperative period.

Figure 29: Thermal comfort; active versus usual care; regional or general anaesthesia

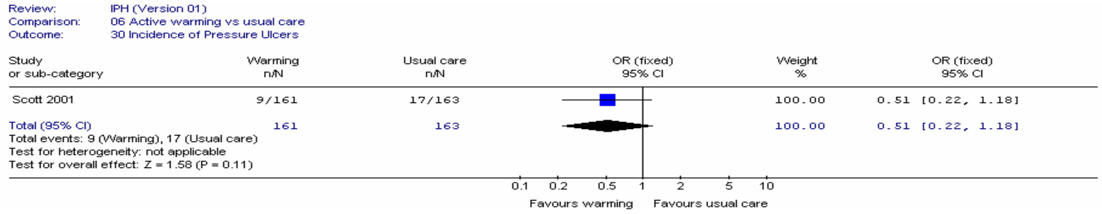


NB: Scale -4 to 4

12. Incidence of Pressure Ulcers

One study (Scott 2001) compared forced air warming with usual care in 324 patients and reported on incidence of pressure ulcers in the post operative period. Pressure ulcers were defined as 'persistent (i.e. longer than 24 hours) non blanching hyperaemia or break in the skin'. Pressure ulcers were assessed by researcher blinded to treatment and was assessed at postoperative days one, three and five or at discharge. There was no statistically significant difference in incidence of pressure ulcers, although the confidence interval is fairly wide (Figure 30).

Figure 30: Incidence of pressure ulcers; active versus usual care; regional or general anaesthesia



IB. Regional anaesthesia

Two studies (Yamakage 1995 Johansson 1999) with patients undergoing surgery under regional anaesthesia compared forced air warming with usual care.

In one study (Yamakage 1995) with 14 patients undergoing surgery on the lower extremity, received either upper or lower body forced air warming compared with usual care. There was limited information on baseline demographics for the three groups.

One study (Johansson 1999) with 50 patients compared the effectiveness of upper body forced air warming in comparison to cotton blankets in patients undergoing spinal anaesthesia during total hip arthroplasty. Patients in both groups rested on pre-warmed gel-filled mattress and IV fluids and blood were warmed. Forced air warming was continued for 2 hours after the surgery.

Intraoperative core temperatures was reported in one study (Yamakage 1995; Johansson 1995), end of surgery (Johansson 1999) and thermal comfort (Yamakage 1995) were reported.

1. Core temperature: 30 minutes

One study (Yamakage 1995) with 14 patients compared upper body forced air warming (setting: approximately 37°C) with usual care reported intraoperative temperature at 30 minutes and 60 minutes (Figure 31).

At 30 minutes, the mean core temperature was significantly higher for the lower body warmed group: MD 36°C (95% CI 0.09, 0.63) for a change in core temperature of -0.3°C for the control group.

At 60 minutes, the mean core temperature was significantly higher for the lower body warmed group: MD 0.33°C (95%CI 0.07, 0.75) for a change in core temperature of -0.3°C for the control group.

Final intraoperative core temperature was reported at 90 minutes in one study (Yamakage 1995), and was significantly higher in the lower body warmed group: MD

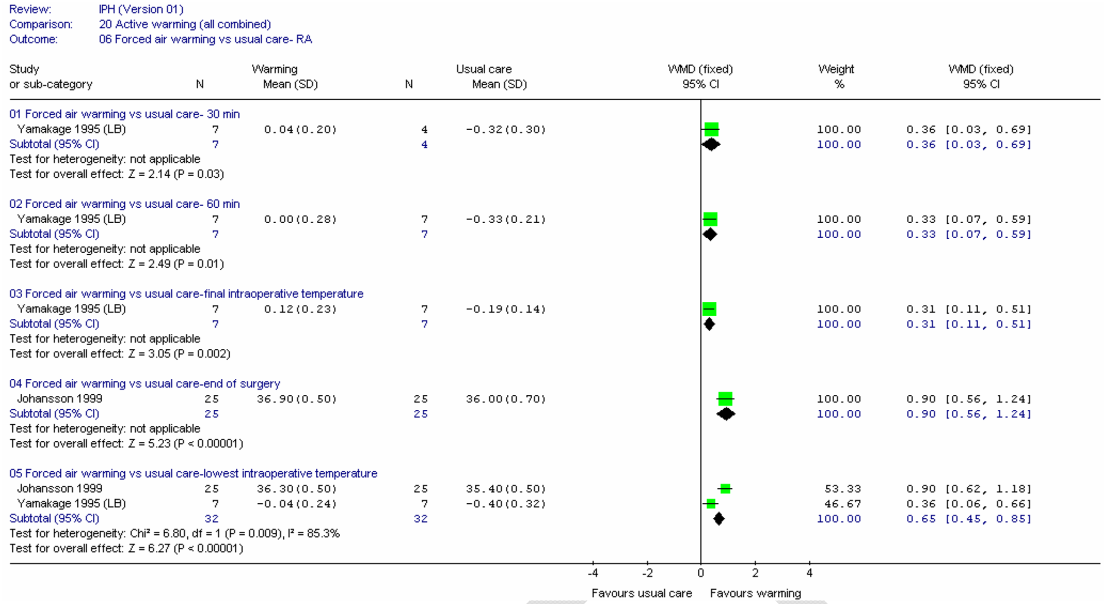
0.31°C (95% CI 0.11, 0.51) for a change in core temperature of -0.1°C for the control group.

Two studies (Yamakage 1995; Johansson 1999) recorded lowest intraoperative temperature. In one study (Yamakage 1995) lowest intraoperative temperature was reached at 40 minutes for both groups and not stated in the other study (Johansson 1999). Pooled estimate showed significant heterogeneity (I^2=85.3%, p=0.009). Examining heterogeneity by the proposed subgroup analysis: the mean age of patients differed (below 60 years in Yamakage 1995; above 65 in Johansson 1999); type of surgery (elective in both studies); duration of anaesthesia (more than 1 hour in both studies). One study (Yamakage 1995) reported ASA status (I and II). We note patients received forced air warming at a 'medium' setting in one study (Yamakage 1995) and setting was not stated in the other study.

Considering these results separately, one study (Yamakage 1995) with 14 patients showed significantly higher mean core temperatures at 40 minutes: MD 0.36°C (95% CI 0.06, 0.66) for a change in control group temperature 0.4°C. One study (Johansson 1999) with 50 patients showed significantly higher mean core temperature for the forced air warmed group: MD 0.90°C (95% CI 0.62, 1.18) for a control group temperature of 35.0°C. The confidence interval is fairly wide

One study (Johansson 1999) reported core temperature at end of surgery. Mean duration of surgery was over 100 minutes. The mean core temperature was significantly higher for the forced air warmed group: MD 0.90°C (95% CI 0.56, 1.24) for a control group temperature of 35.0°C. The confidence interval is fairly wide.

Figure 31: Core temperature; active warming versus usual care; regional anaesthesia



NB: Scale -4 to 4

2. Lowest intraoperative temperature

Two studies (Yamakage 1995; Johansson 1999) recorded lowest intraoperative temperature. In one study (Yamakage 1995) lowest intraoperative temperature was reached at 40 minutes for both groups and not stated in the other study (Johansson 1999). The pooled estimate showed significant heterogeneity (I^2=85.3%, p=0.009) (Figure 31).

Examining heterogeneity by the proposed subgroup analysis: the mean age of patients differed (below 60 years Yamakage 1995; above 65 in Johansson 1999); type of surgery (elective in both studies); duration of anaesthesia (more than 1 hour in both studies). One study (Yamakage 1995) reported ASA status (I and II). We note patients received forced air warming at a ‘medium’ setting in one study (Yamakage 1995) and setting was not stated in the other study.

Considering these results separately, one study (Yamakage 1995) with 14 patients showed significantly higher mean core temperatures at 40 minutes: MD 0.36°C (95% CI 0.06, 0.66) for a change in control group temperature 0.4°C. One study (Johansson 1999) with 50 patients showed significantly higher mean core temperature for the forced air warmed group: MD 0.90°C (95% CI 0.62, 1.18) for a control group temperature of 35.0°C. The confidence interval is fairly wide.

3. End of surgery

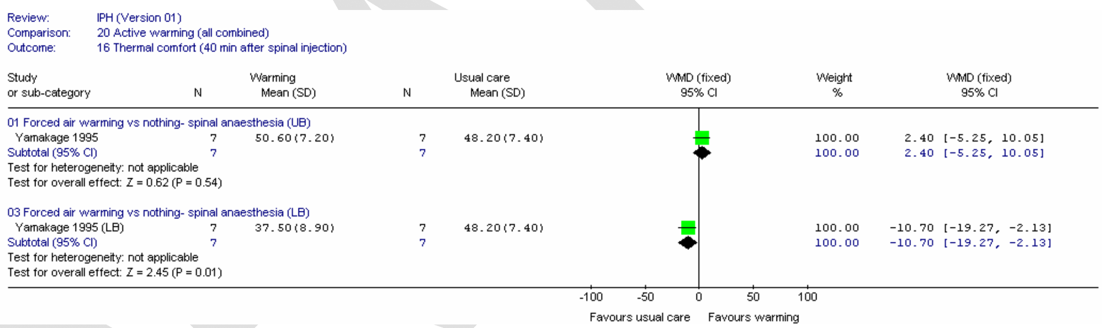
One study (Johansson 1999) reported core temperature at end of surgery. Mean duration of surgery was over 100 minutes. The mean core temperature was significantly higher for the forced air warmed group: MD 0.90°C (95% CI 0.56, 1.24) for a control group temperature of 35.0°C. The confidence interval is fairly wide. The difference was clinically significant (Figure 31).

4. Thermal discomfort

One study with three arms (Yamakage 1998) evaluated thermal discomfort 40 minutes after induction, with a 100-mm visual analog scale (VAS) , where 0 was defined as the *worst imaginable cold*, 50mm as *thermally neutral*, and 100mm as *insufferably hot*.

When the studies are considered separately due to difference in site of warming, there is a significant difference in thermal comfort (-10.70mm [95% CI-19.27, -2.13]) with patients in the control group reporting neutral thermal comfort in comparison to patients in the lower body warmed group, who reported feeling cold. There was no significant difference in thermal comfort between the upper body warmed group and the unwarmed group (2.40mm [95% CI -5.25, 10.05]) (Figure 32).

Figure 32: Thermal discomfort (intraoperative period); active warming versus usual care; regional anaesthesia



NB: Scale -100 to 100

IC. Combined General and Regional Anaesthesia

One study (Lindwall 1998) with 25 patients undergoing thoracoabdominal operations under general and regional anaesthesia compared the added effect of forced air warming (43°C) versus usual care, with warmed fluids (38°C to 39°C) in both groups. Core temperatures in the intraoperative and PACU period were reported.

1. Intraoperative core temperature

The mean difference was significant in favour of the warmed group throughout the intraoperative period. The confidence interval was fairly wide at all times (Figure 33).

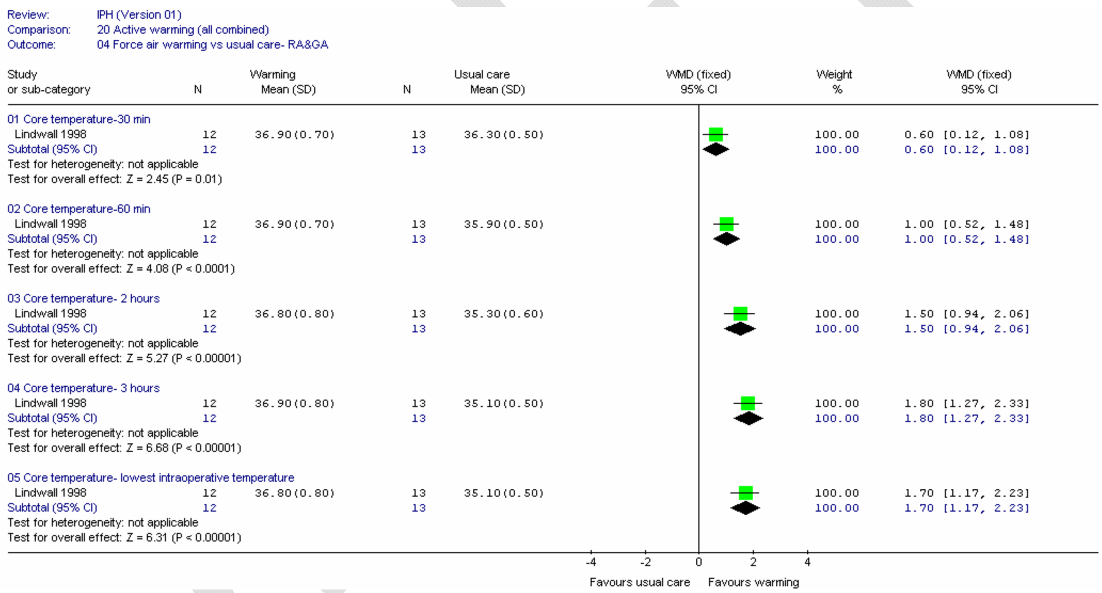
At 30 minutes the mean core temperature was significantly higher for the warmed group: MD 0.60°C (95% CI 0.12, 1.08) for a control group temperature of 36.3°C. The confidence interval is wide.

At 60 minutes the mean core temperature was significantly higher for the warmed group: MD 1.00°C (95% CI 0.52, 1.48) for a control group temperature of 35.9°C. The confidence interval is fairly wide. The difference is clinically significant.

At 2 hours the mean core temperature was significantly higher for the warmed group: MD 1.50°C (95% CI 0.94, 2.06) for a control group temperature of 35.3°C. The confidence interval is wide.

At 3 hours the mean core temperature was significantly higher for the warmed group: MD 1.80°C (95% CI 1.27, 2.33) for a control group temperature of 35.1°C. The confidence interval is wide.

Figure 33: Intraoperative core temperature – 30min 3hours; active warming versus usual care; regional and general anaesthesia



NB: Scale -4 to 4

2. Lowest intraoperative temperature

The lowest intraoperative temperature was reported at 2 hours in the warmed group and at 3 hours in the control group. The mean core temperature was significantly higher in the warmed group: MD 1.70 (95% CI 1.17, 2.28) for a control group temperature of 35.10°C. The confidence interval is wide. The difference was clinically significant (Figure 33).

3. Postoperative core temperatures

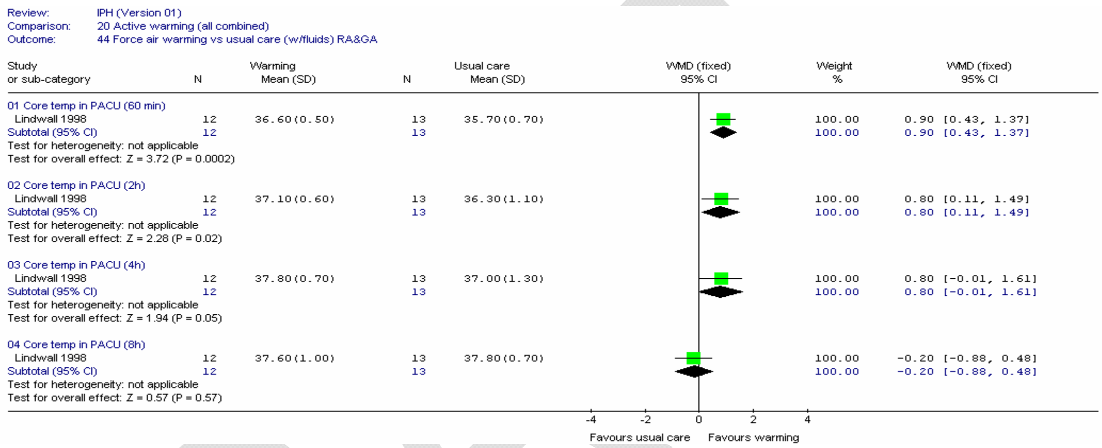
Core temperature – PACU (60 minutes, 2 hours, 4 hours and 8 hours).

One study (Lindwall 1998) reported core temperature during the postoperative period.

After 60 minutes in PACU, the mean core temperature was significantly higher in the warmed group: MD 0.90°C (95% CI 0.43, 1.37) for a control group temperature of 35.7°C. The confidence interval is fairly wide (Figure 34).

After 2 hours, the mean core temperature was significantly higher in the warmed group: MD 0.90°C (95% CI 0.43, 1.37) for a control group temperature of 35.7°C. The confidence interval is wide. There were no significant differences in core temperature 4 hours and 8 hours in the postoperative period.

Figure 34: Core temperature – PACU; active warming versus usual care; regional/general anaesthesia



NB: Scale -4 to 4

II. Thermal insulation versus usual care

Ten studies (Radford 1979; Bourke 1984(1); Bourke 1984(2); Dyer 1986; Erickson 1992; Hoyt 1993; Ouellette 1993; Bennett 1994; Hindsholm 1992; Sheng 2003) studies examined the effectiveness of thermal insulation compared to usual care in preventing IPH during the intraoperative period.

Nine studies examined the effectiveness of reflective blankets during the intraoperative period. (Radford 1979; Dyer 1986; Bourke 1984(1); Bourke 1984(2); Erickson 1991; Hindsholm,1992; Ouellette 1993; Bennett 1994; Sheng 2003). General anaesthesia was used in six studies (Radford 1979; Bourke 1984(1); Bourke 1984(2); Erickson 1991; Ouellette 1993; Bennett 1994), regional anaesthesia in two studies (Dyer 1986; Hindsholm 1992) and type of anaesthesia was unclear in one study (Sheng 2003). We assumed the type of anaesthesia for two studies (Bourke 1984 [1]; Bourke 1984 [2]). Results for Dyer (1986) and Hindsholm (1992) are presented separately as the type of anaesthesia differed and the unclear studies were grouped with general anaesthesia.

Some studies had methodological limitations. As noted earlier, the type of reflective material used has changed over the years (PatentStorm 1998). Radford (1979) suggested that the effectiveness of the blanket was reduced or lost by condensed perspiration. We decided to disregard the results from the Radford (1979) study because its effectiveness was probably impaired by moisture retention.

Both the Bourke (1984 [1]) and Bourke (1984 [2]) studies were not included in the analysis because either the intervention group or both groups were hypothermic at baseline. In addition, the material used was non conducting.

The Sheng (2003) study did not state whether the graphs recorded standard deviations or standard errors of the confidence intervals. The study gave p values for the differences between interventions at different times and this allowed us to deduce that the graph was recording standard errors.

We also note that in Sheng (2003), patients were randomised to hats and jackets or usual care during the preoperative period and that all patients were re-randomised to the reflective blanket or cloth blanket in the intraoperative period. It is unclear if the two intraoperative groups had equal distributions of reflective hats and jackets and usual care. Overall, the Sheng (2003) study was treated with caution.

One study (Hoyt 1993) with 30 patients compared the effectiveness of insulated head covers with non insulated covers in patients undergoing abdominal surgery under general anaesthesia. Patients in both arms received blanket warmers, fluid warmers and anaesthesia circuit humidifiers.

IIA. General Anaesthesia

1. Core temperature: intraoperative period

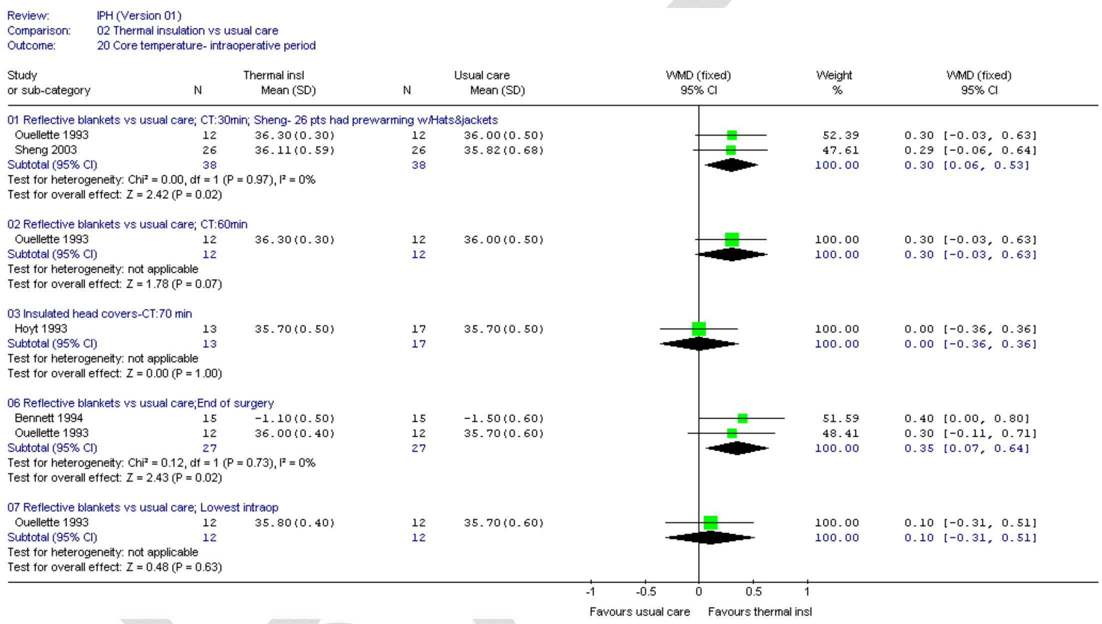
At 30 minutes, meta-analysis of two studies (Ouellette 1993; Sheng 2003) with 76 patients showed a significantly higher mean core temperature for the thermal insulation group: WMD 0.32°C (0.24,0.40) for a control group temperature range 35.8°C to 36.0°C. This is a clinically significant difference (Figure 35).

In one study (Ouellette 1993) intraoperative temperature was recorded at 60 minutes and at 90 minutes. There were no significant differences in core temperatures at both times. The confidence intervals are fairly wide.

At 70 minutes, one study (Hoyt 1993) with 30 patients showed no significant difference in core temperature between insulated head covers and usual care group.

Two studies (Ouellette 1993; Bennett 1994) with 54 patients reported core temperatures at the end of surgery. Duration of surgery was over 2 hours in both studies. In one study (Bennett 1994), we note the duration of surgery was significantly shorter for the usual care group (thermal insulation: 2.5 hours; usual care: 2.0 hours; p=0.006) and is likely to confound the results. Considering only the Ouellette (1993) study, the mean difference in core temperature at end of surgery was not significant (Figure 35).

Figure 35: Core temperature: thermal insulation versus usual care; general anaesthesia



2. Lowest intraoperative temperature

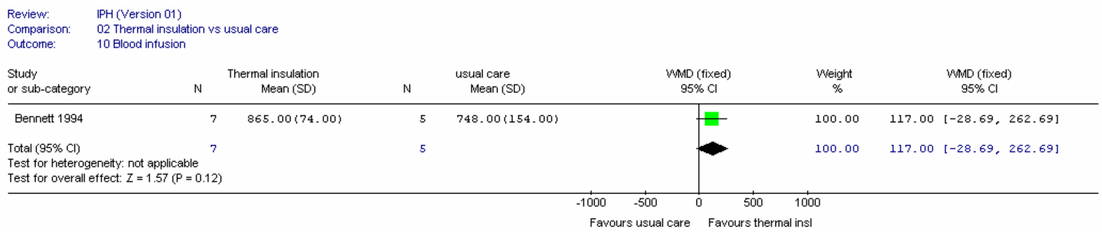
In one study (Ouellette 1993) the lowest intraoperative temperature was recorded at 60 min and at 90 min for the thermal insulation and the usual care groups, respectively. There were no significant differences in core temperatures (Figure 35).

Intraoperative complications

3. Blood transfusion

One study (Bennett 1994) reported blood transfusion (warmed to 37°C) intraoperatively. Seven patients in the thermal insulation group and 5 patients in the control group were administered blood. The volume of blood transfused was significantly less for the warmed group by 117.00ml (Figure 36).

Figure 36: Volume of blood infused (intraoperative); thermal insulation versus usual care; general anaesthesia



NB: Scale -1000 to 1000

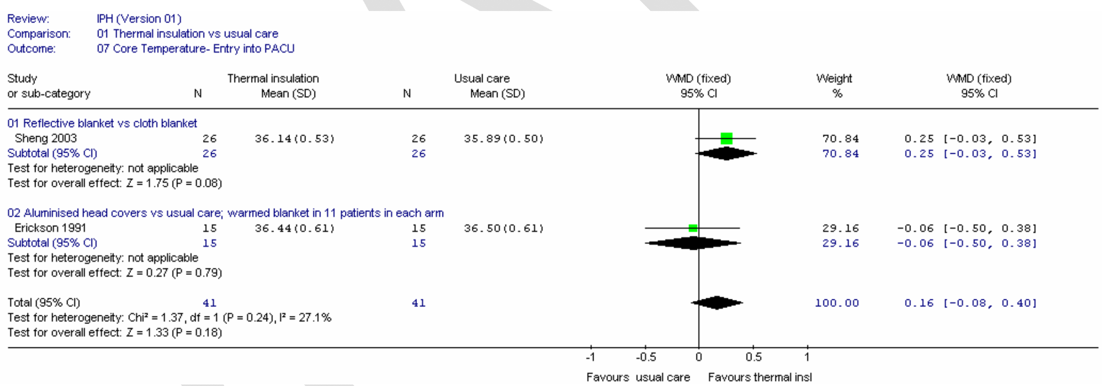
Postoperative outcomes

4. Core temperature: PACU

Two studies (Erickson 1991; Sheng 2003) reported core temperatures in PACU. One study (Erickson 1991) with 30 patients compared aluminised head covers with usual care. Eleven patients in each group received warmed blankets during the intraoperative period.

Meta-analysis of two studies (Erickson 1991; Sheng 2003) with 82 patients showed no significant difference in core temperature on arrival into PACU (Figure 37).

Figure 37: Core temperature: PACU; thermal insulation versus usual care; general anaesthesia



IIB. Regional anaesthesia

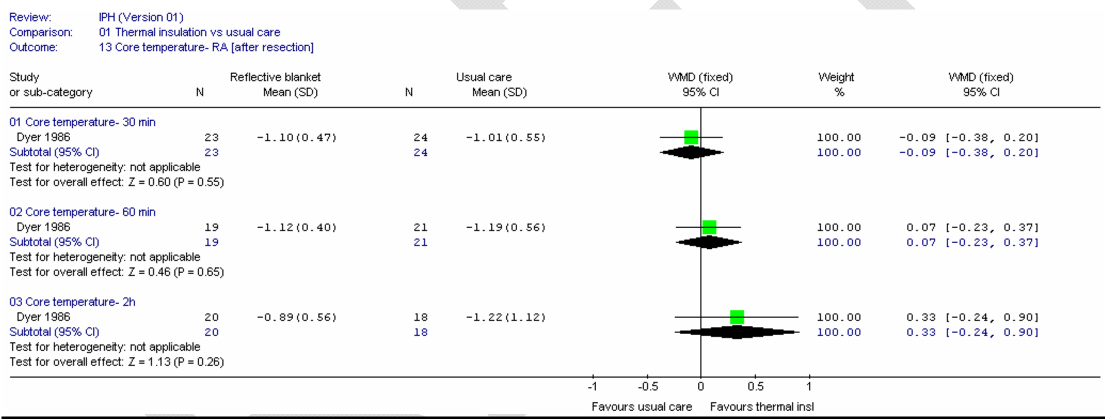
Two studies (Dyer 1986; Hindsholm 1992) compared the effectiveness of thermal insulation versus usual care and reported intraoperative core temperatures for patients undergoing regional anaesthesia. One study (Hindsholm 1992) reported median values for the mean core temperature; therefore results for the two studies cannot be combined.

In one study (Hindsholm 1992) the median core temperature was extracted from a graph at various time points. At 30 minutes, it was 36.0°C and 35.8°C for the thermal insulation and usual care groups respectively. At 60 minutes the mean core temperature was reported at 35.9°C and 35.6°C for the reflective blanket and usual groups respectively. Lowest intraoperative temperature was reported at 2 hours in both groups. The mean core temperature was 35.6°C and 35.1°C for the reflective blanket and usual care groups respectively.

One study (Dyer 1986) with 47 patients compared reflective blankets with usual care. The reflective blankets were placed over cotton blankets before induction. Patients in both groups were covered at the abdomen, chest and arms. Change in core temperatures from baseline were reported at 30 minutes, 60 minutes and 2 hours after resection. We note that durations of resection was 24.4 minutes and 32.4 minutes for the thermal insulation and usual care groups respectively.

There was no significant difference at any time, although the confidence interval was wide at 2 hours (Figure 38).

Figure 38: Intraoperative core temperature; thermal insulation versus usual care; regional anaesthesia



III. Active warming patients versus thermal insulation

Six studies (Whitney 1990; Ouellette 1993; Borms 1994; Bennett 1994; Berti 1997; Casati 1999) compared the effectiveness of active warming mechanisms with thermal insulation during the intraoperative period.

The types of active warming mechanism included forced air warming and warmed cotton blankets; the comparators were reflective blankets. Four studies used non conducting reflective blankets (Whitney 1990; Ouellette 1993; Bennett 1994; Borms 1994). One study (Casati 1999) did not describe the type of reflective blankets.

In two studies (Borms 1994; Casati 1999), patients in both groups received actively warmed (37°C) IV fluids. More specifically, in one study (Casati 1999) patients received infusion of lactate Ringer's solution (8ml/kg/h) throughout surgery, and 3ml of the solution were infused for every 1ml of blood loss. In one study (Bennett 1994) patients received an IV infusion of Hartmann's solution (at ambient temperature) at a rate of 6ml/kg/h and blood was warmed to 37°C before infusion. In two studies (Whitney 1990; Borms 1994) heat and moisture exchangers were utilised.

In three studies patients underwent surgery under general anaesthesia (Ouellette 1993; Borms 1994; Bennett 1994), combined anaesthesia (epidural-general) (Berti 1997) and combined spinal-epidural anaesthesia (Casati 1999). Results are presented separately for the types of anaesthesia. Type of anaesthesia was unclear in one study (Whitney 1990); this study was included under the general anaesthesia section.

Pooled results, where appropriate, are reported at each of the following time periods: 30 minutes; 60 minutes; 90 minutes; 120 minutes; time when lowest intraoperative temperature was reached; and core temperature at end of surgery. One study (Bennett 1994) reported volume of blood infused during the intraoperative period and one study (Casati 1999) reported incidence of shivering, time to fulfil discharge criteria and length of hospital stay.

Baseline core temperature was comparable in three studies (Ouellette 1993; Bennett 1994; Borms 1994) and not stated in one study (Berti 1997). In one study (Casati 1999), we note that core temperature was 0.14°C higher in the group assigned to forced air warmed group compared to the thermal insulation group. Standard deviations were not reported and we cannot comment whether this is a significant difference.

We note that in one study (Bennett 1992) duration of surgery was significantly longer in the active warming group compared with thermal insulation group (0.3 hours; p= 0.006). Findings from this study should be treated with caution. We also note that in four studies (Ouellette 1993; Bennett 1994; Borms 1994; Whitney 1999) there were 20 patients or fewer in each arm and these should be treated with caution.

The two studies comparing forced air warming with reflective blanket (Ouellette 1993; Borms 1994) were not combined with the Whitney (1990) study due to differences in types of active warming. Results for Casati (1999) are presented separately under the regional anaesthesia section and for Berti (1997) under the combined regional and general anaesthesia section.

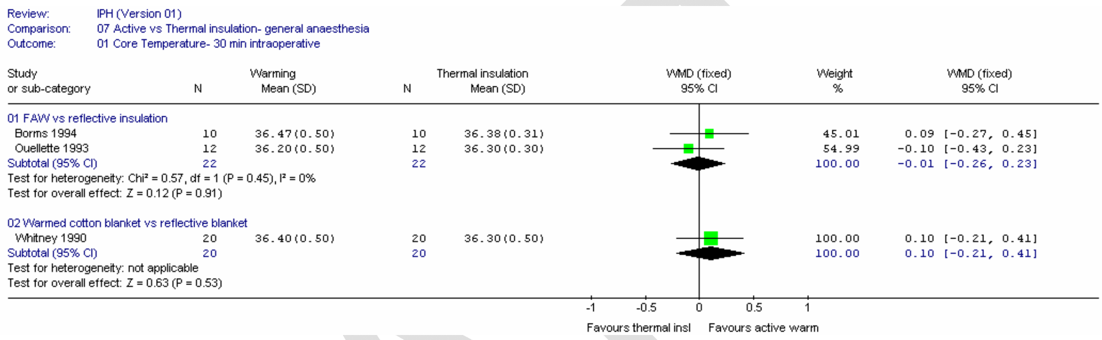
We note that information on core temperature, with the exception of three studies (Whitney 1990; Ouellette 1993; Bennett 1994) was extracted from graphs.

IIIA. General anaesthesia

1. Core Temperature at 30 minutes intraoperative period

Three studies (Whitney 1990; Ouellette 1993; Borms 1994) reported core temperature at 30 minutes. Two studies (Ouellette 1993; Borms 1994) with 44 patients compared the effectiveness of forced air warming in comparison to reflective blankets and one study (Whitney 1990) with 40 patients compared warmed cotton blankets to reflective blankets. The mean difference in core temperature was not significant for either comparison. We note that the temperatures were greater than 36.0°C for the treatment and control groups in all three studies (Figure 39).

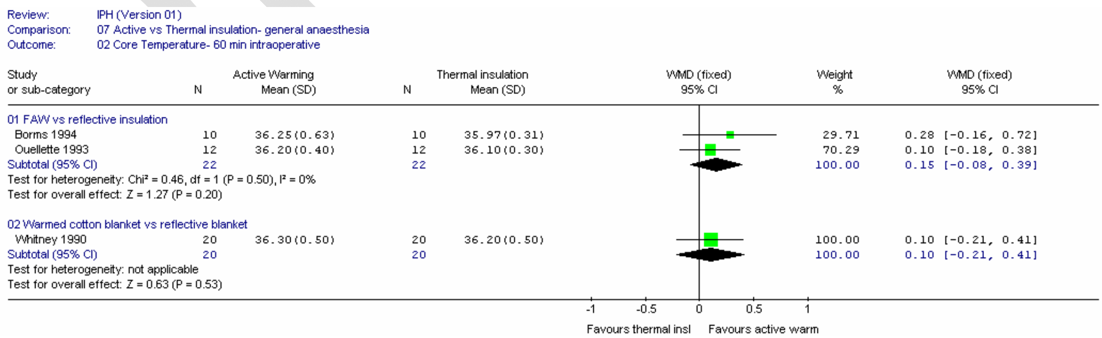
Figure 39: Core temperature at 30 minutes; active versus thermal insulation; general anaesthesia



2. Core Temperature at 60 minutes intraoperative period

Three studies (Whitney 1990; Ouellette 1993; Borms 1994) reported core temperatures at 60 minutes. The mean difference in core temperature was not significant for either comparison (Figure 40).

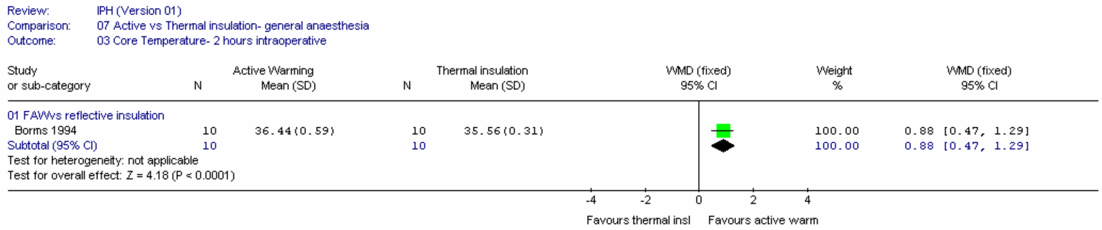
Figure 40: Core temperature at 60 minutes; active versus thermal insulation; general anaesthesia



3. Core Temperature – 2 hours intraoperative period

One study (Borms 1994) with 20 patients reported core temperatures at 2 hours. The mean core temperature was significantly higher for the forced air warmed group: MD 0.88°C (95% CI 0.47, 1.29) for a core temperature of 35.5°C for the reflective blanket group. The difference is clinically significant. The confidence interval is fairly wide (Figure 41).

Figure 41: Core temperature – 2 hours; active versus thermal insulation; general anaesthesia



NB: Scale -4 to 4

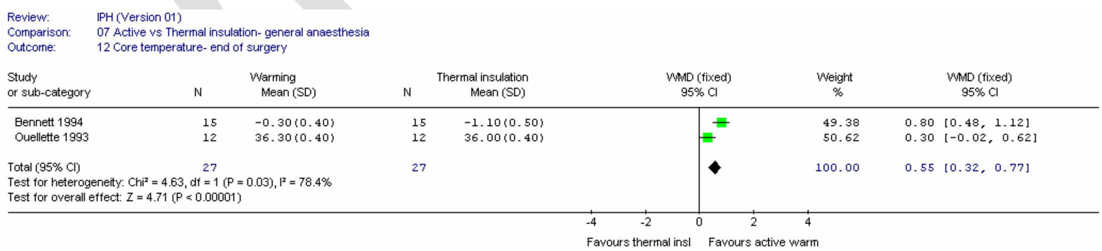
5. Core Temperature- End of surgery

Two studies (Ouellette 1993; Bennett 1994) with 54 patients reported core temperature at the end of surgery. In one study (Bennett 1994) mean duration of surgery was 2.3 hours (SD 0.3) in the actively warmed group and 2 hours (SD 0.3) in the thermal insulation group; one study (Ouellette 1993) reported mean anaesthesia time as 117min (SD 27) and 127min (SD 27) for the actively warmed and thermal insulation groups respectively.

Meta-analysis of the two studies (Ouellette 1993; Bennett 1994) with 54 patients showed significant heterogeneity. There was a significant difference in duration of surgery in one study (Bennett 1994) which was likely to confound the results.

Considering only the Ouellette (1993) study, there was no significant difference between the groups in mean core temperature at the end of surgery (Figure 42).

Figure 42: Core temperature- end of surgery; active versus thermal insulation; general anaesthesia



NB: Scale -4 to 4

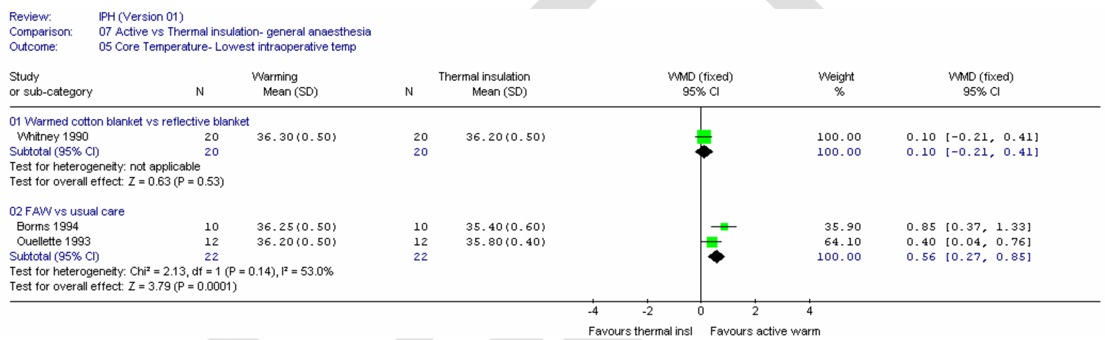
6. Lowest intraoperative temperature

The lowest intraoperative temperature was recorded at 45 minutes for both groups in one study (Whitney 1990), at 45 minutes for the forced air warmed group and at 135 minutes for one study (Borms 1994), and 30 minutes for the warmed groups and 90 minutes in the reflective blanket in one study (Ouellette 1993).

In Whitney (1990), the lowest intraoperative temperature was recorded at 45 minutes for both the warmed blanket and reflective blanket groups and the mean core temperature is not significantly different.

Meta-analysis of two studies (Ouellette 1993; Borms 1994) with 44 patients showed a significantly higher mean core temperature for the active warming group: MD 0.64°C (95% CI 0.33, 0.96), for a core temperature range of 35.4°C to 35.8°C for the reflective blanket group. There is some heterogeneity (I^2=53.0%, p=0.14) (Figure 43).

Figure 43: Core temperature – lowest intraoperative temperature; active versus thermal insulation; general anaesthesia



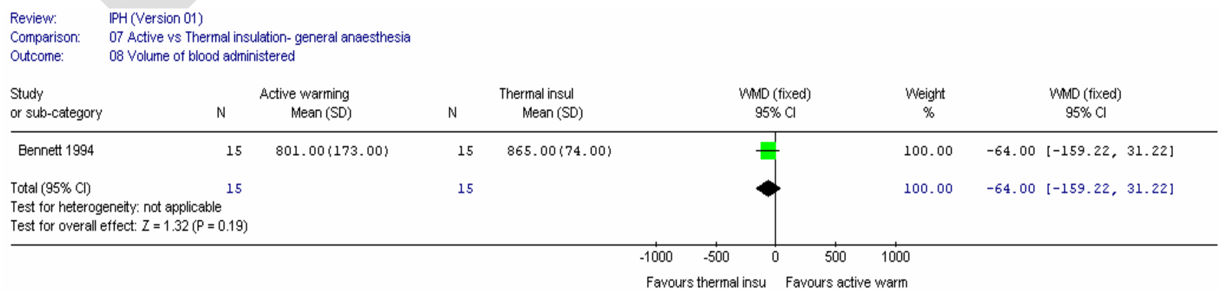
NB: Scale -4 to 4

Intraoperative complications

7. Blood infusion

One study (Bennett 1994) reported on the volume of blood administered during the intraoperative period. The mean difference in volume of infusion (ml) was not statistically significant despite the difference in duration of warming (Figure 44).

Figure 44: Volume of blood administered; active warming versus thermal insulation



NB: Scale -1000 to 1000

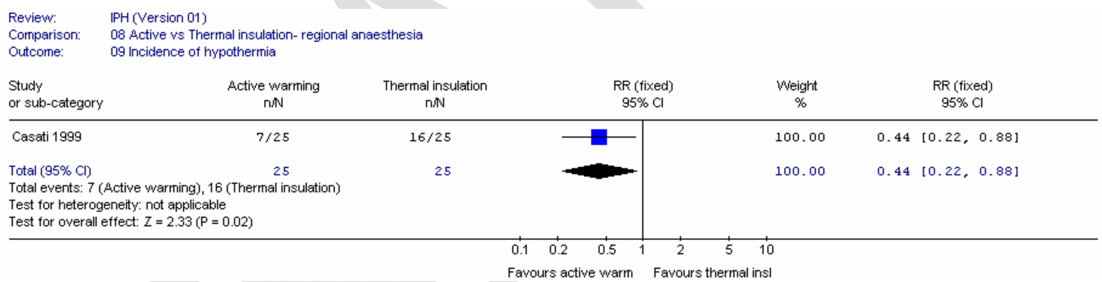
IIIB. Regional anaesthesia

One study (Casati 1999) compared the effectiveness of forced air warming of the upper limbs with reflective blankets in 50 patients undergoing elective total hip arthroplasty under combined spinal/epidural anaesthesia. Patients in both groups received an actively warmed (37°C) IV infusion of lactate Ringer's solution (8ml/kg/h) throughout surgery, and 3ml of the solution were infused for every 1ml of blood loss. We note the baseline core temperature was 0.14°C higher in the group assigned to forced air warmed compared to the thermal insulation group. However, it is unclear whether this difference was significant as standard deviations were not reported.

1. Outcome: Incidence of hypothermia

Casati (1999) reported the number of patients arriving into recovery room with a core temperature less than 36°C. The incidence of hypothermia was statistically significantly lower in the actively warmed group (RR 0.44 [95% CI 0.22, 0.88]). This corresponds to an NNT of 3 (95% CI 2, 10) for a control group rate of 16/25 (64%). The confidence interval is fairly wide (Figure 45).

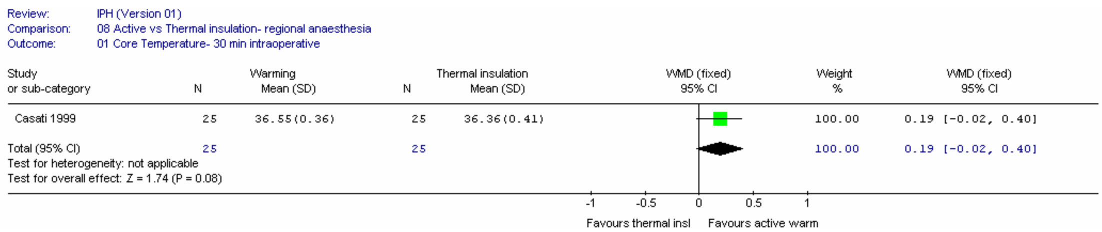
Figure 45: Incidence of hypothermia; active versus thermal insulation; regional anaesthesia



2. Core temperature – 30 minutes

One study (Casati 1999) in 50 patients compared forced air warming of the upper limbs with a reflective blanket, and reported core temperature at 30 minutes. The mean difference was not significant (MD 0.19°C [95% CI -0.02, 0.40]) (Figure 46).

Figure 46: Core temperature at 30 minutes; active versus thermal insulation; regional anaesthesia

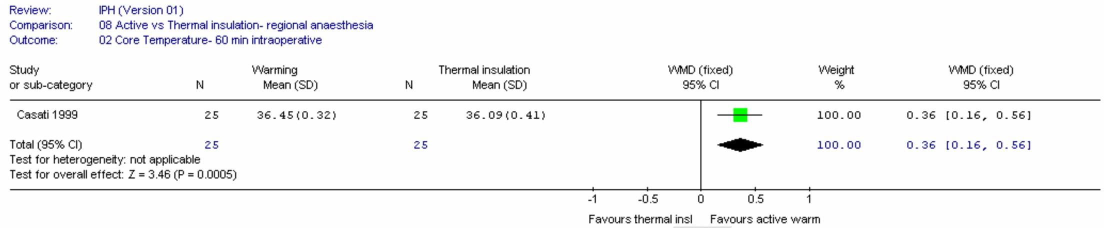


3. Core temperature – 60 minutes

One study (Casati 1999) with 50 patients at 60 minutes intraoperatively showed a significantly higher mean core temperature for the forced air warmed group: MD

0.36°C (95% CI 0.16, 0.56) for a core temperature of 36.0°C for the reflective blanket group; this is not clinically significant (Figure 47).

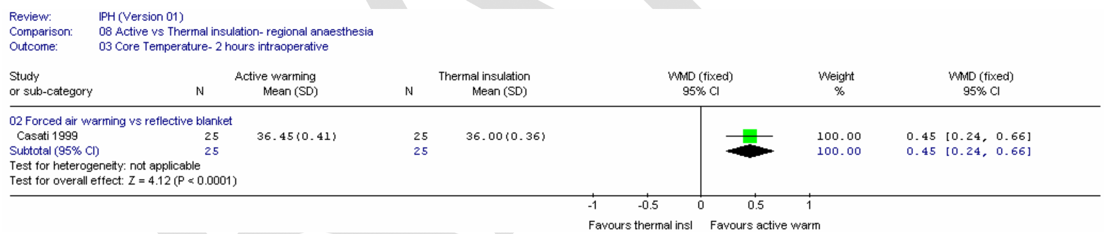
Figure 47: Core temperature – 60 minutes; active versus thermal insulation; regional anaesthesia



4. Core temperature – 2 hours

One study (Casati 1999) with 50 patients reported core temperature at 2 hours into the intraoperative period. The mean core temperature was significantly higher for the forced air warmed group: MD 0.45°C (95% CI 0.24, 0.66) for a core temperature of 36.0°C for the reflective blanket group; this is not clinically significant (Figure 48).

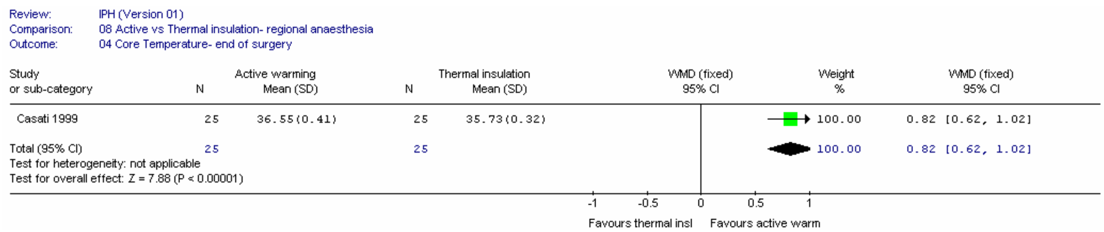
Figure 48: Core temperature – 2 hours; active versus thermal insulation; regional anaesthesia



5. Core temperature – End of surgery

One study (Casati 1999) with 50 patients reported core temperature at end of surgery. Mean duration of surgery was 102 minutes. The mean core temperature was significantly higher in the forced air warmed group: 0.82°C (95% CI 0.62, 1.02) for a core temperature of 35.7°C for the reflective blanket group (Figure 49).

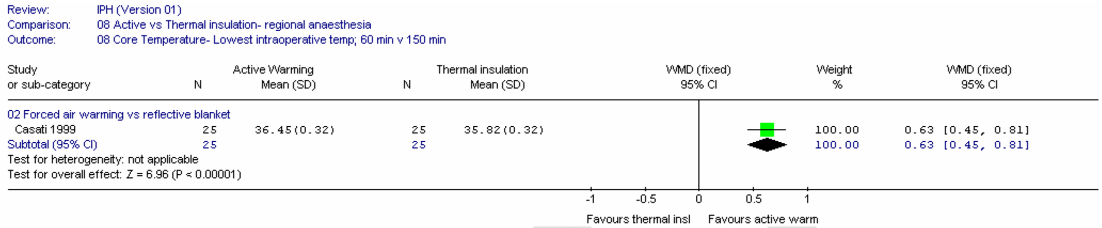
Figure 49: Core temperature – end of surgery; active versus thermal insulation; regional anaesthesia



6. Core Temperature – lowest intraoperative temperature

The lowest intraoperative temperature was recorded at 60 minutes for the actively warmed group and at 150 minutes for the thermal insulation group in Casati (1999). The mean core temperature was significantly higher for the actively warmed group: MD 0.63°C (95%CI 0.26, 0.64), for a core temperature of 35.8°C in the reflective blanket group (Figure 50).

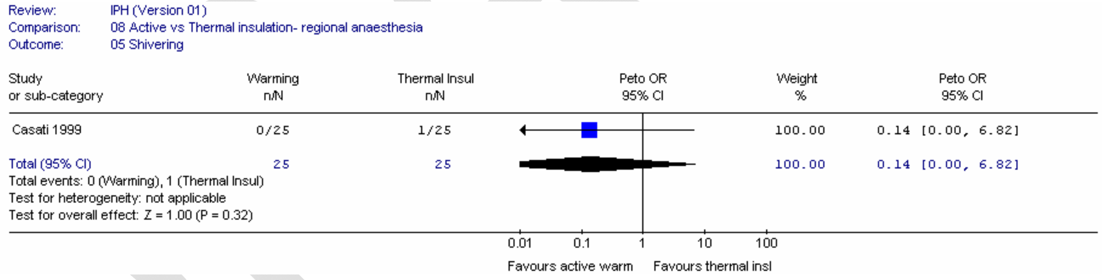
Figure 50: Core temperature – lowest intraoperative temperature; active versus thermal insulation; regional anaesthesia



7. Incidence of Shivering

One study (Casati 1999) reported on shivering. There were too few events to determine if there was a difference between groups (Figure 51).

Figure 51: Incidence of shivering; active versus thermal insulation; regional anaesthesia

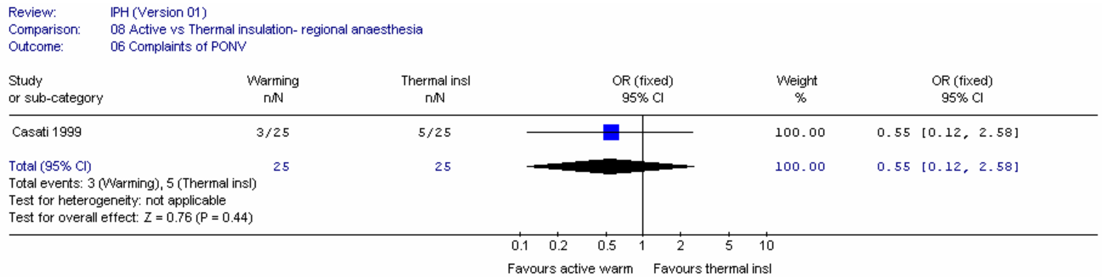


NB: Scale 0.01 to 100

8. Postoperative nausea and vomiting (PONV)

One study (Casati 1999) reported complaints of PONV. The confidence interval was too wide to determine if there was a difference between groups (Figure 52).

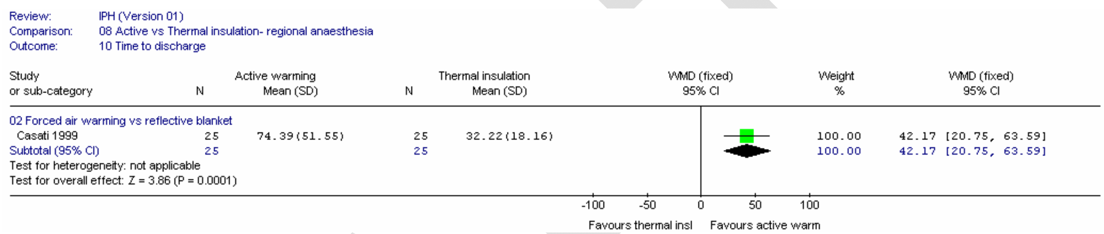
Figure 52: Complaints of PONV; active versus thermal insulation; regional anaesthesia



9. Time to discharge from the recovery area

One study (Casati 1999) reported the time required to achieve readiness for discharge from the recovery area. Criteria for discharge included: core temperature at least 36°C; patient alert and responsive with controlled pain and nausea, stable vital signs; stable haemoglobin concentrations in the absence of blood transfusions. The difference in time to fulfil clinical discharging criteria and reach a temperature above 36.0°C, was significantly shorter for the actively warmed group: MD 42.17 minutes (95% CI 20.75, 63.59) for a thermal insulation time of 32.2 minutes (Figure 53).

Figure 53: Time to discharge; active versus thermal insulation; regional anaesthesia

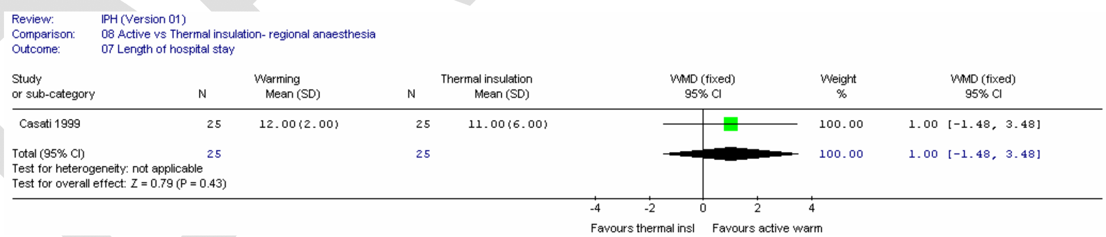


NB: Scale -100 to 100

10. Length of hospital stay

One study (Casati 1999) reported on length of hospital stay. There was no significant difference between the groups (Figure 54).

Figure 54: Length of hospital stay; active versus thermal insulation; regional anaesthesia



NB: Scale -4 to 4

IIIC. Combined anaesthesia

One study (Berti 1997) with 30 patients undergoing elective hip or knee arthroplasty under combined epidural-general anaesthesia compared the effectiveness of forced air warming (38°C) with reflective blankets; both groups received low-flow anaesthesia.

Core temperature was recorded after induction with epidural and general anaesthesia at various time points: 30 minutes, 60 minutes, 2 hours and end of surgery.

1. Core temperature during intraoperative period

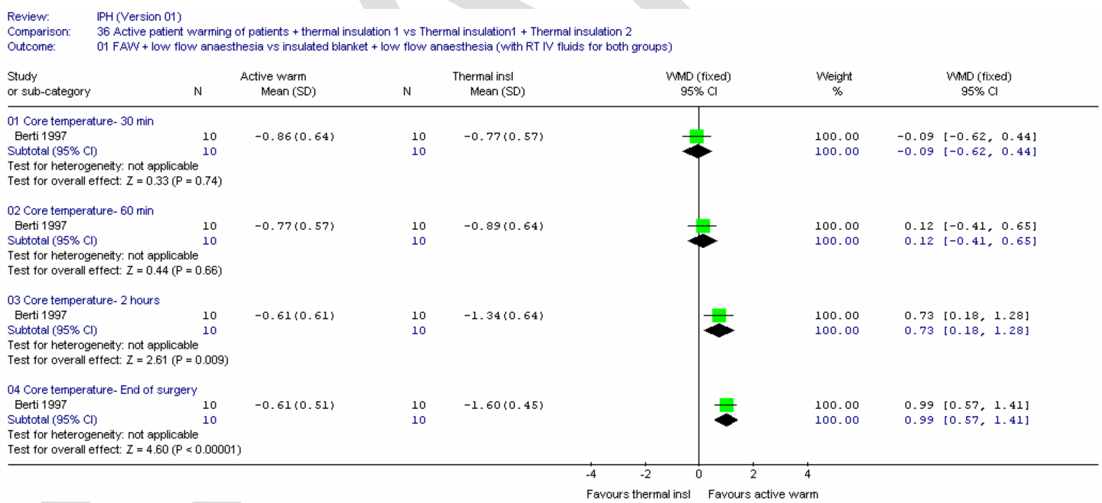
One study (Berti 1997) with 10 patients in each arm reported core temperature at 30 minutes, 60 minutes, 2 hours and the end of surgery. Mean duration of surgery was 2.6 hours (SD 0.3) for the forced air warmed group compared to 2.4 hours (SD 0.4).

At 30 minutes and 60 minutes the mean difference was not statistically significant.

At 2 hours and at the end of surgery, the mean core temperature was significantly higher for the actively warmed group. At 2 hours: MD 0.73°C (95% CI 0.18, 1.28) for a change in control group temperature of -1.3°C for the reflective blanket group. The confidence interval is wide.

At the end of surgery: MD 0.99°C (95% CI 0.57, 1.41) for a change in core temperature of -1.6°C for the reflective blanket group. The confidence interval is fairly wide (Figure 55).

Figure 55: Core temperature during the intraoperative period; active versus thermal; combined epidural-general anaesthesia

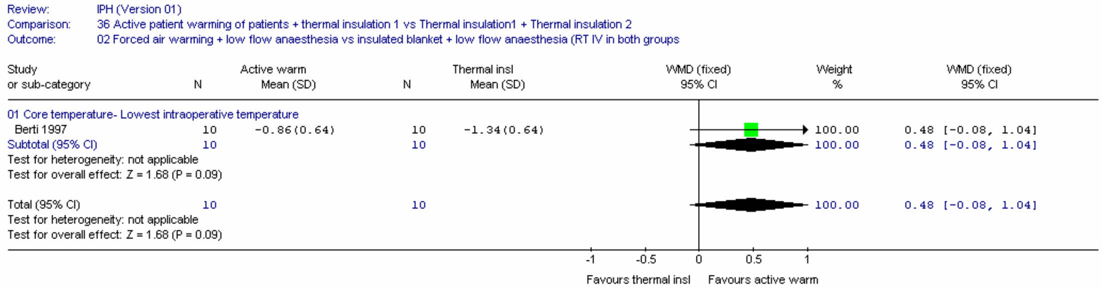


NB: Scale -4 to 4

2. Lowest intraoperative temperature

One study (Berti 1997) reported the minimal temperature at 30 minutes for the actively warmed group and at 2 hours for the thermal insulation group. The confidence interval is fairly wide 0.48°C (95% CI -0.08, 1.04) for a change in control group temperature of -1.34°C. The mean difference is not significant (Figure 56).

Figure 56: Core temperature: lowest intraoperative temperature; active versus thermal; combined epidural-general anaesthesia



IV. Active patient warming 1 versus Active patient warming 2

IVa. Forced air warming versus warmed cotton blankets

One study (Mason 1989) with 64 patients compared the effectiveness of forced air warming with warmed cotton blankets in obese patients undergoing Roux-en-Y gastric bypass under general anaesthesia. Patients received forced air warming at a medium setting (38°C) compared with warmed blankets (temperature not stated).

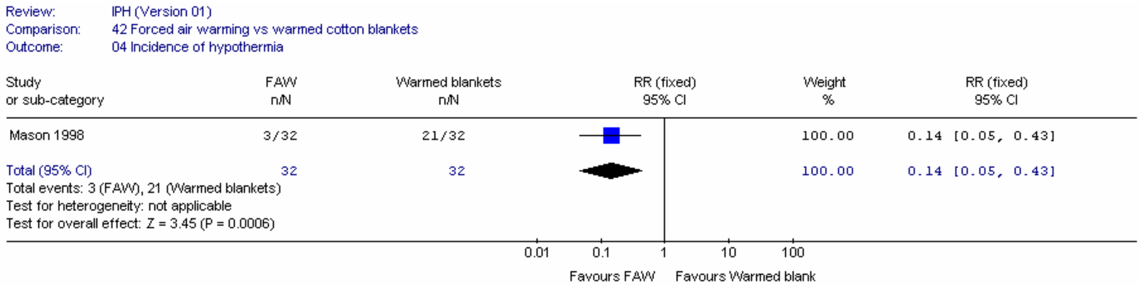
Baseline core temperature extracted from graph was 36.0°C in both groups. However, no standard deviations were recorded. There were significantly more women to men (55:9) overall, and we note that there was a significant difference in mean length of incision: 40.5cm (SD 4.7) and 43.3cm (SD 5.4) for the forced air warming and warmed blanket groups respectively.

Results are reported at each of the following time periods: 60 minutes; 120 minutes; core temperature at admission into PACU. The study also reported on the incidence of hypothermia on arrival into and on discharge from PACU, volume of blood loss, time in PACU and incidence of shivering in PACU.

1. Incidence of hypothermia

One study (Mason 1998) with 64 patients reported core temperature less than 36°C upon arrival into PACU. Incidence of hypothermia was significantly less in the forced air warming group (RR 0.14 [95% CI 0.05, 0.43]). This corresponds to an NNT of 2 (95% CI 1, 3) for a control group rate of 21/32 (66%) (Figure 57).

Figure 57: Incidence of hypothermia; forced air warming versus warmed cotton blankets; general anaesthesia



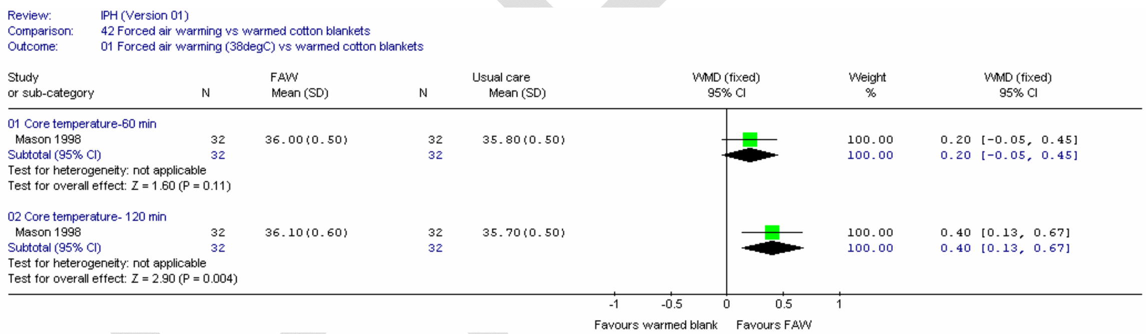
NB: Scale 0.01 to 100

2. Core temperature – intraoperative period

One study (Mason 1998) with 64 patients reported core temperature at 60 minutes and 120 minutes. At 60 minutes, the mean difference in core temperature was not significant. At 120 minutes, the mean core temperature was significantly higher in the forced air warmed group: MD 0.40°C (95% CI 0.13, 0.67) for a core temperature of 35.70°C for the warmed cotton blanket group. The confidence interval is fairly wide (Figure 58).

We note the study reported that at 60 minutes the difference in core temperature was significant at $p<0.05$ and at 120 minutes the difference was significant at $p<0.001$. However, this did not agree with our analysis of the data reported in the text.

Figure 58: Core temperature: 60 minutes and 120 minutes; forced air warming versus warmed cotton blankets; general anaesthesia

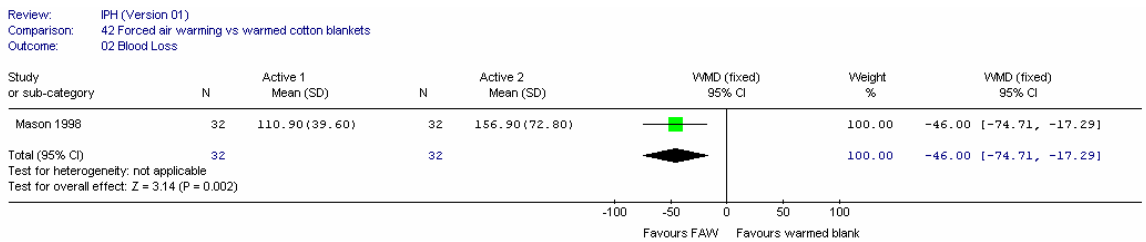


Intraoperative complications

3. Volume of blood loss

One study (Mason 1998) with 64 patients reported volume of blood loss at end of the intraoperative period. There was a significant lower volume of blood loss (46ml) in the forced air warming group (Figure 59).

Figure 59: Volume of blood loss; forced air warming versus warmed cotton blankets ; general anaesthesia



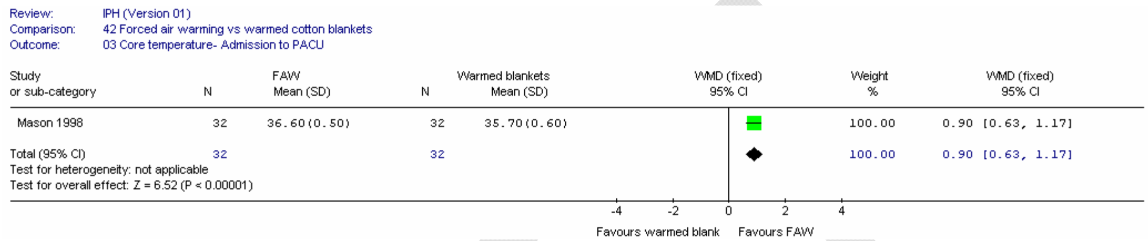
NB: Scale -100 to 100

Postoperative outcomes

4. Core temperature – Admission into PACU

One study (Mason 1998) with 64 patients reported core temperature at admission into PACU. The mean core temperature was significantly higher for the forced air warmed group: MD 0.90°C (95% CI 0.63, 1.17) for a core temperature of 35.7°C for the warmed cotton blanket group. The confidence interval is fairly wide (Figure 60).

Figure 60: Core temperature: admission into PACU; forced air warming versus warmed cotton blankets; general anaesthesia

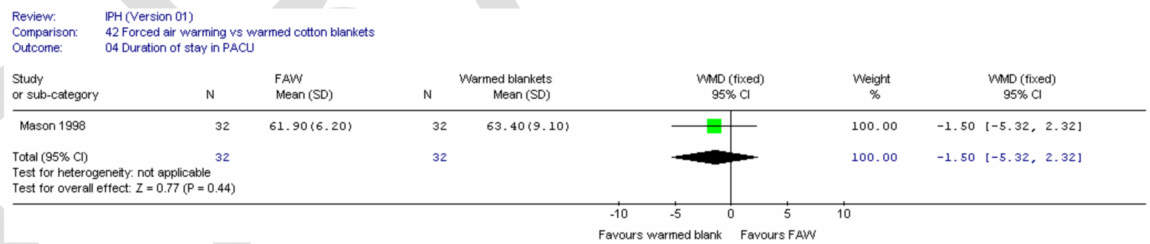


NB Scale -4 to 4

5. Duration of stay in PACU

One study (Mason 1998) with 64 patients reported duration of stay in PACU. There was no significant difference in time spent in PACU between the forced air warming and the warmed blanket group (Figure 61).

Figure 62: Duration of stay in PACU; forced air warming versus warmed cotton blankets; general anaesthesia

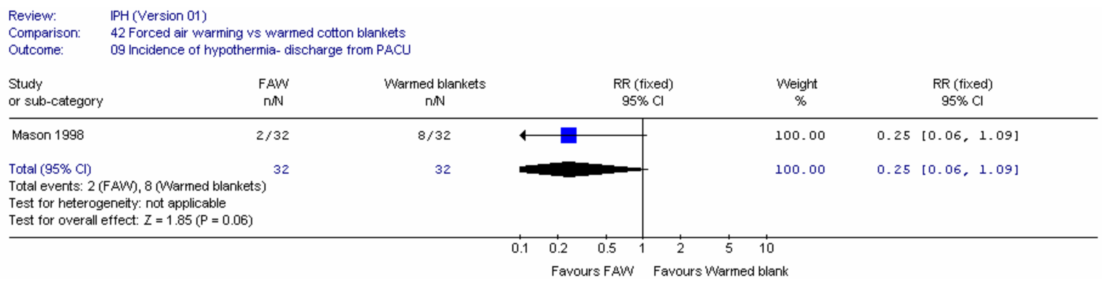


NB: Scale -10 to 10

6. Incidence of hypothermia – discharge from PACU

Mason (1998) reported number of patients with bladder temperature less than 36°C upon discharge from PACU. The difference was not significant (Figure 63).

Figure 63: Incidence of hypothermia – discharge from PACU; forced air warming versus warmed cotton blankets; general anaesthesia



IVb. Forced air warming versus electric blanket

Two studies (Matsuzaki 2003; Negishi 2003) compared the effectiveness of forced air warming with electric blankets.

More specifically the comparisons were:

- In Matsuzaki (2003), 16 patients undergoing laparoscopic cholecystectomy under general anaesthesia received either upper body forced air warming (medium setting) or electric blankets (38°C).
- In Negishi (2003), 16 patients undergoing open abdominal surgery under combined regional and general anaesthesia received either forced air warming (high setting) or electric blankets (42°C).

In one study (Negishi 2003) there was a difference in baseline core temperature of 0.17°C higher in the group assigned to forced air warming group. Standard deviations were not reported so it was unclear whether this difference is significant.

Results for these two studies are presented separately due to differences in type of anaesthesia.

A. General anaesthesia

One study (Matsuzaki 2003) with 16 patients undergoing laparoscopic cholecystectomy under general anaesthesia received either upper body forced air warming (medium setting) or electric blankets (38°C). Both groups received warmed IV fluids (37°C). There were no baseline differences in core temperature.

Results for core temperature are presented at the following time periods: lowest intraoperative core temperature; 30 minutes; 60 minutes; and final intraoperative core temperature.

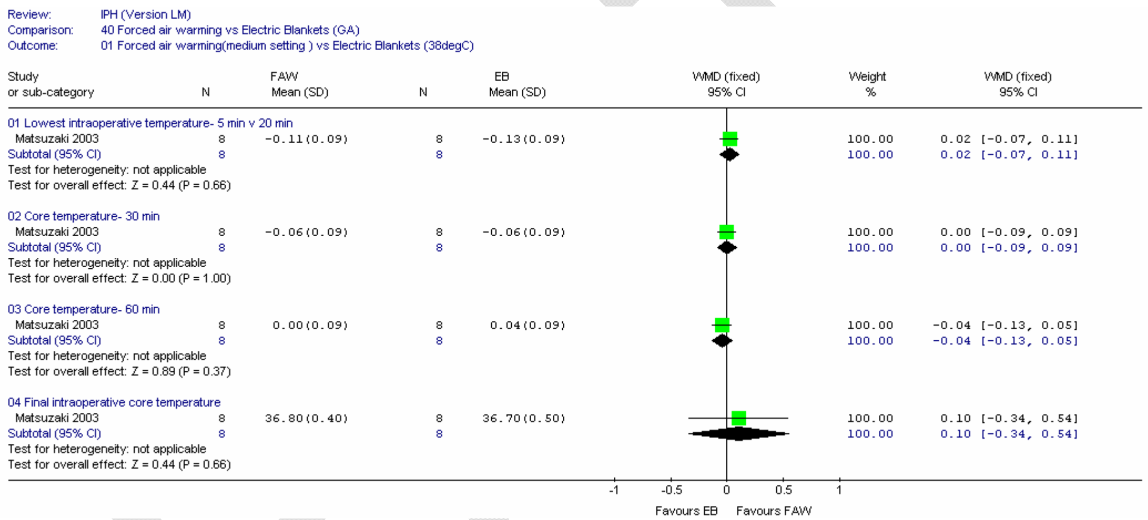
1. Core temperature: intraoperative period

One study (Matsuzaki 2003) with 16 patients reported core temperature during the intraoperative period. At 30 minutes, 60 minutes, and final intraoperative period (approximately 90 minutes) the mean difference was not statistically significant (Figure 64).

Lowest core temperature was reported at 5 minutes for the forced air warming group and at 20 minutes for the electric blanket group. The mean difference in core temperature was not significant.

We note that the standard deviations for the change scores extracted from the graphs were considerably smaller than those reported in the text for the absolute values.

Figure 64: Core temperature: intraoperative period; forced air warming versus electric blankets; general anaesthesia

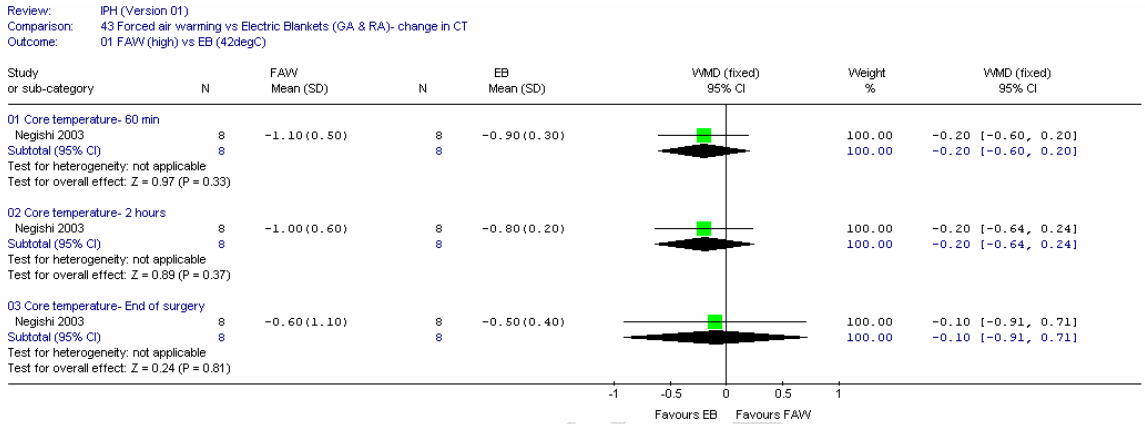


B. Combined regional and general anaesthesia

In Negishi (2003), 16 patients undergoing open abdominal surgery under regional and general anaesthesia received either forced air warming (high setting) or electric blankets (42°C). Patients in both groups received warmed (37°C) IV fluids. The baseline core temperature was 0.17°C higher in the forced air warming group. It is unclear whether this difference is statistically significant as standard deviations were not provided.

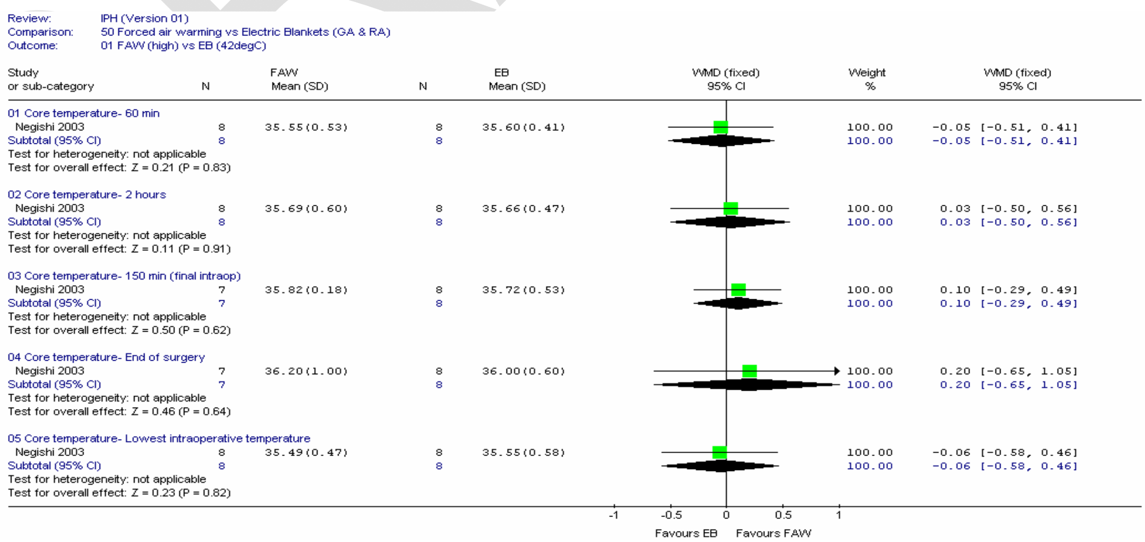
Change in core temperature was reported at 60 minutes, 2 hours and end of surgery (Figure 65). Mean duration of surgery was 248 minutes and 253 minutes for the forced air warming and electric blanket group respectively. The mean difference was not significant throughout the intraoperative period, although the confidence intervals are wide or fairly wide.

Figure 65: Change in core temperature: intraoperative period; forced air warming versus electric blankets; general anaesthesia; regional and general anaesthesia



Core temperature was also extracted from the graph for 60 minutes, 2 hours, and final intraoperative period (150 minutes). Core temperature at end of surgery was reported in the text. Lowest intraoperative period was reported at 45 minutes for the forced air warming group and 75 minutes for the electric blanket group. The standard deviation was not reported for the forced air warming group at 45 minutes; therefore the standard deviation for the electric blanket group was used instead (Figure 65b). The mean difference was not significant at any of the time periods, although the confidence intervals are wide or fairly wide.

Figure 65b: Core temperature: intraoperative period; forced air warming versus electric blankets; regional and general anaesthesia



IVc. Forced air warming versus electric under blanket

A. General anaesthesia

Three studies [four comparisons] (Russell 1995 [two comparisons]; Baxendale 2003; Harper 2007) compared the effectiveness of forced air warming with electric under blanket. More specifically, the comparisons were as follows:

- Forced air warming (over blanket) versus electric under blanket (full length silicone rubber pad) (Russell 1995) + actively warmed fluids (37°C) in both groups;
- Forced air warming (under blanket) versus electric under blanket (full length silicone rubber pad) + actively warmed fluids in both groups (37°C) (Russell 1995b);
  - The GDG subgroup advised that this comparison should not be considered as forced air warming (under mattress) is not practised and does not adhere to manufacturer's instructions. This study has not been considered further for analysis;
  - Forced air warming (set to maximum) versus electric warming mattress (full length; set to 37°C) + actively warmed fluids in both groups (Harper 2007);
  - Forced air warming (set to 43°C) versus electric warming mattress(37°C) (Baxendale 2003) + actively warmed fluids in both groups (via Bair Hugger® hose).

Russell (1995) reported the forced air over blanket was modified by cutting a hole to expose the abdomen from the area of the femoral vessels upwards and the thorax, and was secured to the patient's skin. Therefore, both legs, one arm and the sides of thorax and abdomen were covered by the blanket.

In Russell (1995) there was a significant difference in baseline core temperature; 0.20°C higher in the forced air warming group. If the baseline difference is not less than 20% of the effect size this outcome will not be considered. There was no significant difference in baseline core temperature in one study (Harper 2007).

One study (Harper 2007) reported that there was a significant difference in BMI: 31.6kg/m^2 (SD 7.8) and 25.7kg/m^2 (SD 4.0) for the forced air warming and the electric mattress groups respectively.

In one study (Harper 2007) 11 patients (5 in the forced air warming group; 6 in electric warming mattress) received regional anaesthesia in addition to general anaesthesia.

In one study (Baxendale 2003) only the change in core temperature from induction was reported and standard deviations were not provided. Baseline core temperatures were not reported as well. Data extracted from a graph showed the following changes in core temperatures for the forced air warming and electric warming mattress groups, respectively:

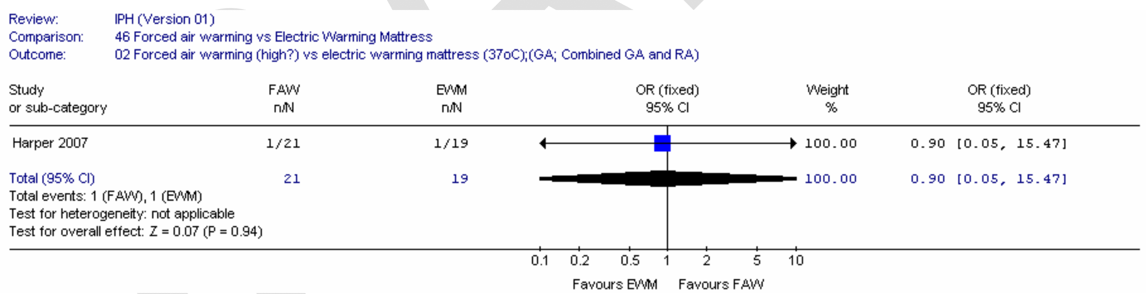
- At 30 minutes: -0.3°C and -0.3°C
- At 60 minutes: -0.3°C for both groups
- At 120 minutes: -0.2°C for both groups.

The Russell (1995) study reported times of temperature measurements in relation to states in the liver transplant procedures. It was not possible to determine times from induction as the duration of preanhepatic stage can vary. The authors noted that duration of preanhepatic stage can last 1 to 3 hours. Therefore, the results for the two studies (Russell 1995; Harper 2007) were not combined.

1. Incidence of hypothermia

One study (Harper 2007) with 40 patients reported incidence of hypothermia (defined as core temperature less than 36°C) upon arrival into the PACU. The confidence interval was too wide to determine if there was a difference between interventions (Figure 66).

Figure 66: Incidence of hypothermia; forced air warming versus electric blankets; mixed anaesthesia



2. Core temperature – intraoperative period

Two studies (Russell 1995; Harper 2007) compared the effectiveness of forced air warming with an electric mattress/heating pad. In one study (Harper 2007) 40 patients received either whole body forced air warming (set to 'maximum') with electric mattress (37°C) in patients undergoing surgery (mixed specialities under mixed anaesthesia). In one study (Russell 1995) 40 patients underwent liver transplant under general anaesthesia.

Core temperature was reported at the following periods: 30 minutes after anhepatic state; 60 minutes after postanhepatic state; 30 minutes following reperfusion; 2 hours following reperfusion, and at skin closure. In one study (Harper 2007) there were few patients (in both arms) to give reliable results; therefore results at 60 minutes were not considered.

At 30 minutes the Harper (2007) study showed no significant difference.

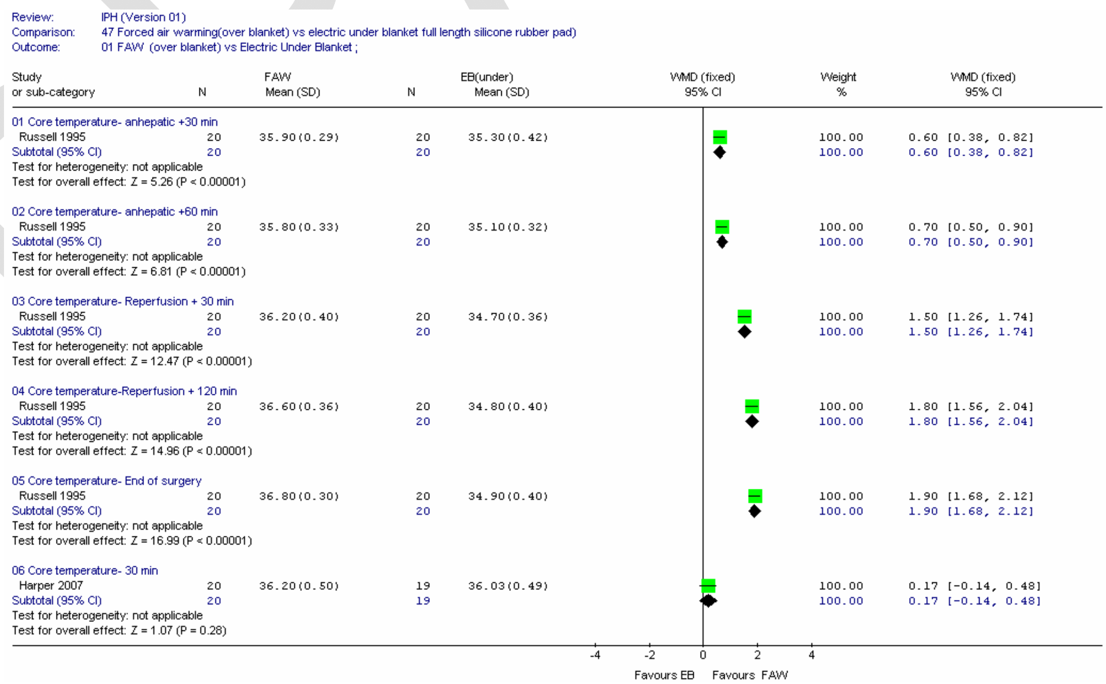
The effect size for Russell (1995) at 30 minutes postanhepatic stage and 60 minutes postanhepatic stage was large in relation to the baseline differences (0.20°C) in core temperature. Therefore these outcome measures were not included.

At 2 hours following reperfusion, the mean core temperature was significantly higher in the forced air warming group: MD1.50°C (95%CI 1.26, 1.74) for a core temperature of 34.7°C in the electric blanket group. This is clinically significant.

At 4 hours, the mean core temperature was significantly higher in the forced air warming group: MD 1.80°C (95% CI 1.56, 2.04) for a core temperature of 34.80°C in the electric blanket group. The confidence interval is fairly wide.

At end of surgery the mean core temperature was significantly higher in the forced air warming group: MD 1.90°C (95% CI 1.68, 2.12) for a core temperature of 34.90°C in the electric blanket group. This is clinically significant. Mean duration of surgery was 315 minutes (SD 58) versus 324 minutes (SD 49) for the forced air warming and electric blankets groups respectively (Figure 67).

Figure 67: Core temperature; intraoperative period; forced air warming versus electric blankets; general anaesthesia

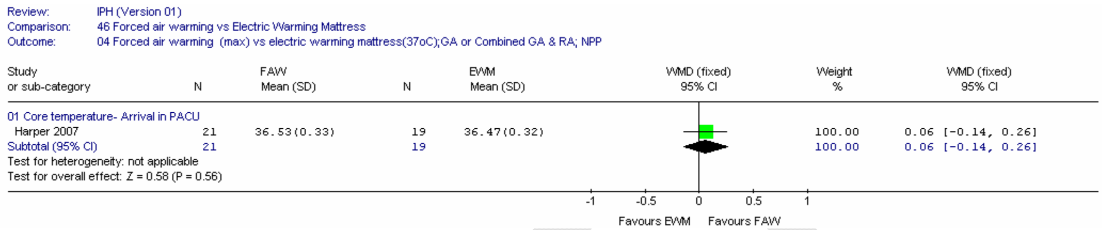


NB: Scale -4 to 4

3. Core temperature – arrival into PACU

One study (Harper 2007) reported core temperature at arrival in PACU. Mean duration of surgery was 84.6 minutes and 88.7 minutes for the forced air warming and electric warming mattress groups respectively. The mean difference in core temperature was not significant upon arrival into PACU (Figure 68).

Figure 68: Core temperature; intraoperative period; forced air warming versus electric blankets; mixed anaesthesia



IVd. Forced air warming versus circulating water mattress

Five studies (Hynson 1992; Kurz 1993a; Kurz 1993b; Matsuzaki 2003; Negishi 2003) compared the effectiveness of forced air warming with that of a circulating water mattress. More specifically the comparisons were:

- Forced air warming (lower body) versus circulating-water blanket (Hynson 1992);
- Forced air warming (lower body) versus circulating-water mattress (Kurz 1993a);
- Forced air warming (upper body) versus circulating-water mattress (Kurz 1993b);
  Forced air warming (upper body) versus circulating-water mattress (Matsuzaki 2003);
- Forced air warming (lower body) versus circulating-water mattress (full length) + warmed fluids in both groups (combined general and regional anaesthesia) (Negishi 2003).

The Hynson (1992) study reported that the temperature at induction did not differ significantly among groups. However, there were baseline differences in core temperature for the following studies:

- In one study (Kurz 1993a) the baseline core temperature (extracted from a graph) was 0.39°C higher in the group warmed with circulating-water mattress. However, as standard deviations were not provided at baseline we were unable to ascertain whether this difference is significant.
  - o The Kurz (1993a) study reported the results on a graph, but we were uncertain if the size of the standard deviation was accurate, particularly since the study stated that the difference was not significant until 5 hours, but the results obtained using the graph's standard deviations suggested it was significant at 1 hour. It was agreed with the GDG subgroup that the results for this study would not be included.

- Kurz (1993b) had a 0.40°C difference in baseline, which was significantly higher for the group warmed with circulating-water mattress.
  - o Core temperature and standard deviations were extracted from a graph, although it was thought the graph was similarly not to scale. Only the result at 4 hours (the change in core temperature reported in the text) was considered for this study. At this time the effect size was not 5 times more than the baseline difference; this outcome was therefore not included.
- Negishi (2003) had a 0.23°C higher temperature in the group warmed with circulating-water mattress. As standard deviations were not provided we are unable to check whether this difference was significant.

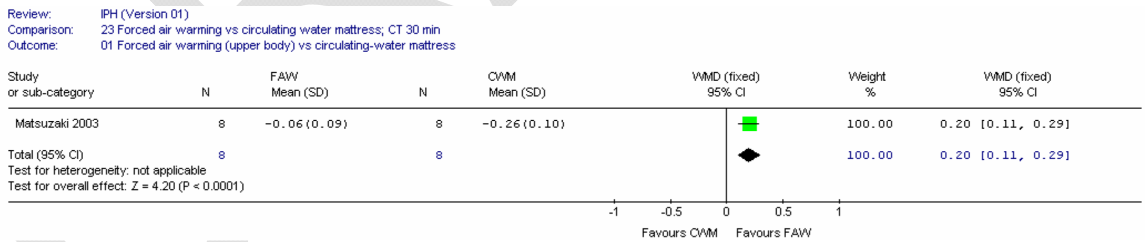
With the exception of Negishi (2003) all studies included patients undergoing surgery under general anaesthesia. Results for Negishi (2003) are considered separately under the heading of regional anaesthesia.

A. General Anaesthesia

1. Core temperature: 30 minutes

One small study (Matsuzaki 2003) with 16 patients reported core temperature at 30 minutes. The mean core temperature was significantly higher in the forced air warming group: MD 0.20°C (95% 0.11, 0.29) for a change in core temperature of -0.2 in the circulating water mattress group (Figure 69).

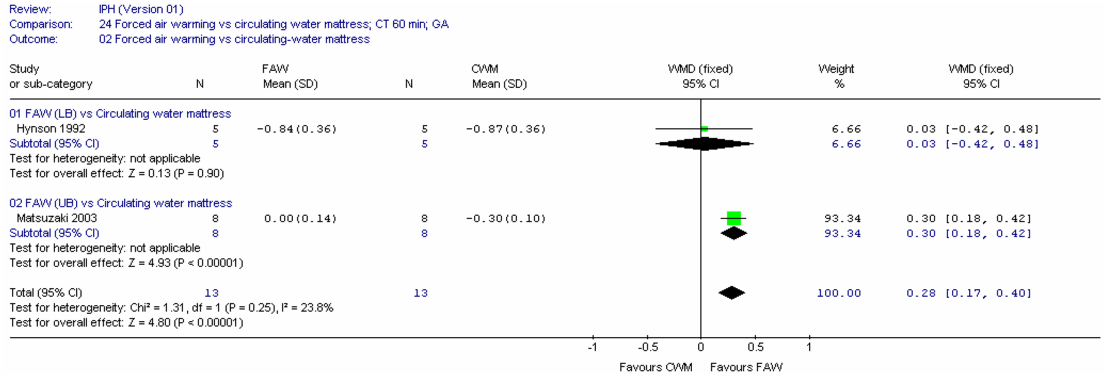
Figure 69: Core temperature: 30 minutes; forced air warming versus circulating water mattress; general anaesthesia



2. Core temperature: 60 minutes

Meta-analysis of two small studies (Hynson 1993; Matsuzaki 2003) with a total of 26 patients compared forced air warming with circulating water mattress showed a significant higher mean core temperature for the forced air warmed group: WMD 0.28°C(95% 0.17, 0.40) for a change in core temperature -0.3°C to -0.8°C for the circulating water mattress group. There was no significant heterogeneity (Figure 70).

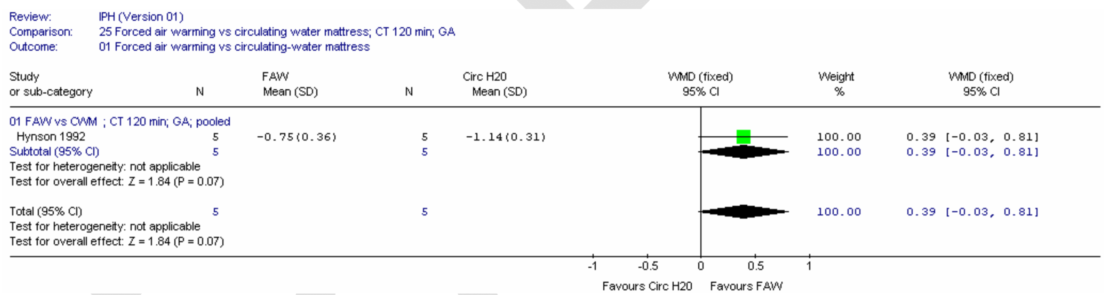
Figure 70: Core temperature: 60 minutes; forced air warming versus circulating water mattress; general anaesthesia



3. Core temperature: 2 hours

One small study (Hynson 1992) with 10 patients compared effectiveness of forced air warming with circulating water mattress. The mean difference was not significant: MD 0.39°C (95% CI -0.03, 0.81). The confidence interval is fairly wide (Figure 71).

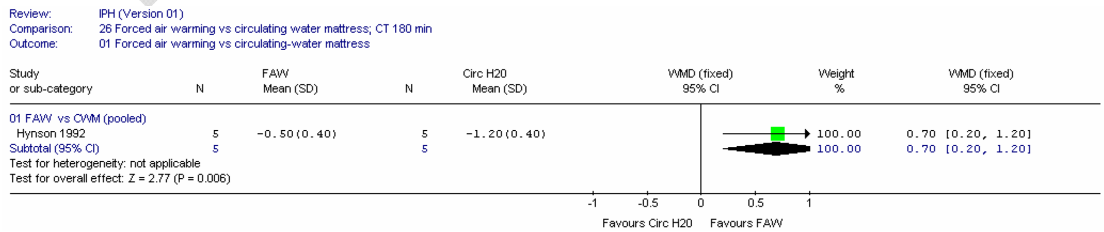
Figure 71: Core temperature: 2 hours; forced air warming versus circulating water mattress; general anaesthesia



4. Core temperature: 3 hours

One small study (Hynson 1992) with 10 patients showed a significantly higher mean core temperature in favour of the forced air warmed group: MD 0.70°C (95% CI 0.20, 1.20) for a change in core temperature -1.2°C for the circulating water mattress group. The confidence interval is wide (Figure 72).

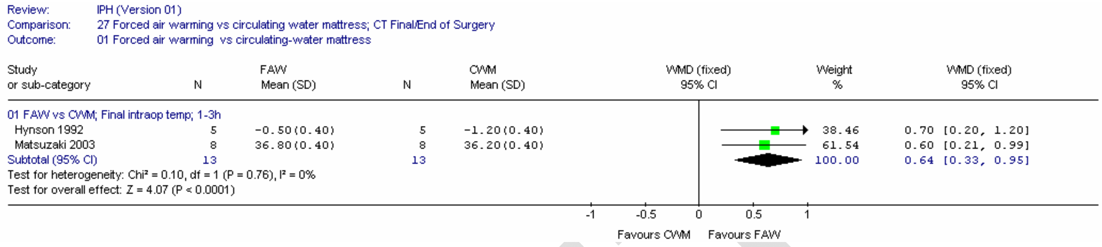
Figure 72: Core temperature: 3 hours; forced air warming versus circulating water mattress; general anaesthesia



5. Core temperature: final intraoperative temperature/end of surgery

Meta-analysis of two small studies (Hynson 1992; Matsuzaki 2003) with 26 patients showed significantly higher mean core temperature for the forced air warmed group: WMD 0.64°C (95% CI 0.33, 0.95) for a core temperature of 36.2°C for the circulating water mattress group. There was no heterogeneity (Figure 73).

Figure 73: Final intraoperative temperature; forced air warming versus circulating water mattress; general anaesthesia



B. Combined general and regional anaesthesia

In Negishi (2003), 16 patients undergoing open abdominal surgery under combined general and regional anaesthesia received either lower body forced air warming (high setting) or full length circulating-water mattress (42°C). Patients in both groups received warmed (37°C) IV fluids. The baseline core temperature was 0.23°C higher in the circulating-water mattress group. It is unclear whether this difference is statistically significant, as standard deviations were not provided.

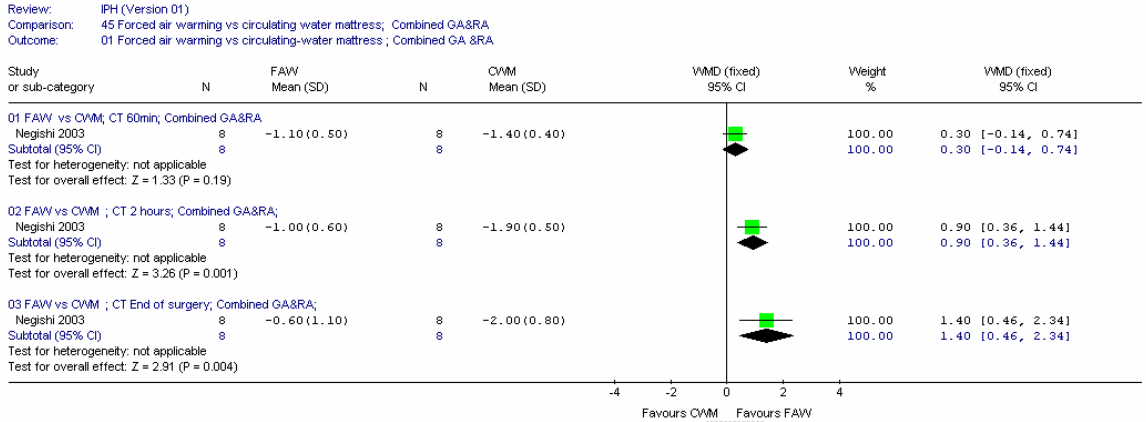
1. Change in core temperature: intraoperative period and end of surgery

One study (Negishi 2003) with 16 patients reported change in core temperature at 60 minutes, 2 hours and upon completion of surgery. Mean duration of surgery was 248 minutes and 208 minutes for the forced air warming and circulating-water mattress groups respectively. The mean difference was not significant at 60 minutes.

At 2 hours, the mean core temperature was significantly higher for the forced air warmed group: MD 0.90°C (95% CI 0.36, 1.44) for a change in core temperature -1.9°C (SD 0.5) for the circulating water mattress group. The confidence interval is wide.

At end of surgery, the mean core temperature was significantly higher for the forced air warmed group: MD 1.40°C (95% CI 0.46, 2.34) for a change in core temperature -2.0°C (SD 0.80) for the circulating water mattress group. The confidence interval is wide (Figure 74).

Figure 74: Change in core temperature during intraoperative period; forced air warming versus circulating water mattress; combined anaesthesia



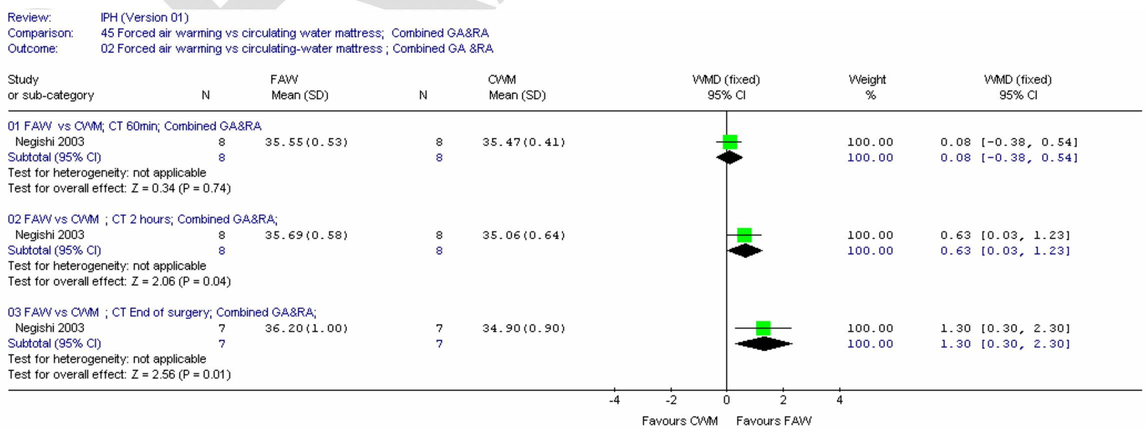
NB: Scale -4 to 4

We also extracted the mean core temperatures from the graph. The mean difference was not significant at 60 minutes.

At 2 hours, the mean core temperature was significantly higher for the forced air warming group: MD 0.63°C (95% CI 0.36, 1.44) for a core temperature of 35.0°C in the circulating water mattress group. The confidence interval is wide.

At end of surgery, the mean core temperature was significantly higher for the forced air warming group: MD 1.30°C (95% CI 0.46, 2.34) for a core temperature of 34.9°C in the circulating water mattress group. The confidence interval is wide (Figure 74b).

Figure 74b: Core temperature during intraoperative period; forced air warming versus circulating water mattress; combined anaesthesia



There was some inconsistency in the results from the change scores as reported in the text and the absolute value extracted from the graph.

IVe. Forced air warming versus radiant warming

Three studies (Lee 2004; Wong 2004; Torrie 2005) compared the effectiveness of forced air warming with radiant warming. More specifically the comparisons were as follows:

- Forced air warming (upper or lower body) versus radiant warming of the hand (Lee 2004);
- Forced air warming (upper body) versus radiant warming of the face (Wong 2004);
- Forced air warming (upper body) versus radiant warming of the palm (Torrie 2005).

Patients in both arms received warmed IV fluids (41°C) and warmed irrigation fluid (42°C) in one study (Torrie 2005).

In 2 studies (Lee 2004; Wong 2004) patients underwent combined general and regional anaesthesia. Results for the Torrie (2005) study will be presented separately under the regional anaesthesia heading.

There were no significant differences in baseline temperature in two studies (Lee 2004; Torrie 2005). We note that in Torrie (2005) oral temperatures were provided for baseline and there was no significant difference. In one study (Wong 2004) initial core temperature following induction was provided and there were no significant differences.

In one study (Wong 2004), patients in the radiant heat group had a significantly higher BMI (31.3kg/m^2 SD 5.3) compared with the forced air warming group (28.1kg/m^2 SD 3.9).

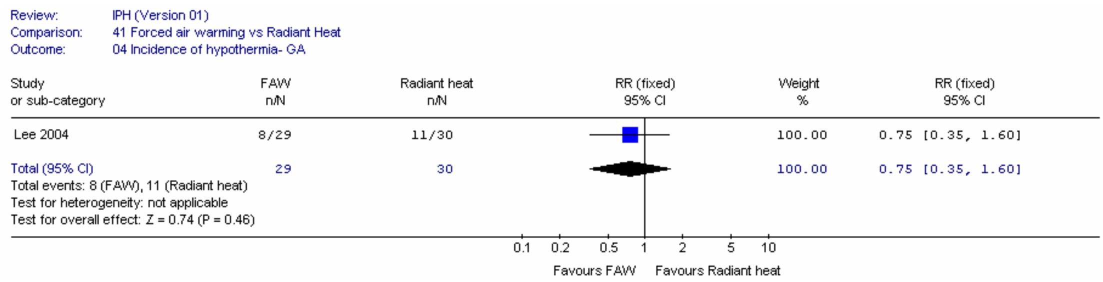
We note that information on core temperature in two studies (Lee 2004; Torrie 2005) were extracted from graphs.

A. General anaesthesia

1. Incidence of hypothermia

One study (Lee 2004) reported the incidence of hypothermia (core temperature less than 36°C) at end of surgery. There was no significant difference in the number of events although the confidence interval is very wide. The study reported duration of rewarming to a core temperature greater than 36°C was 35 minutes (5 to 140 minutes) and there was no significant difference in the duration of rewarming between the two groups (p=0.87) (Figure 75).

Figure 75: Incidence of hypothermia; forced air warming versus radiant heat; general anaesthesia



2. Core temperature – intraoperative period

One study (Lee 2004) with 59 patients undergoing elective or emergency non-cardiac surgery with duration of anaesthesia for longer than 2 hours compared the effectiveness of upper or lower body forced air warming with radiant warming directed at the palm of the hand (Figure 76). At 60 minutes, we included end of surgery results from Wong (2004) (mean duration of surgery slightly over 60 minutes) which compared the effectiveness of upper body forced air warming with radiant warming directed to the face in 42 patients undergoing laparoscopic cholecystectomy.

The lowest intraoperative temperature for Lee (2004) was extracted from a graph for 36.0°C and 35.8°C, at 35 minutes and 75 minutes for the forced air warming and radiant heat groups respectively. As standard deviations were not reported, we cannot determine the significance and the results are not presented.

The study reported intraoperative core temperature at 30 minutes, 60 minutes, 2 hours, 3 hours and 4 hours (Figure 76).

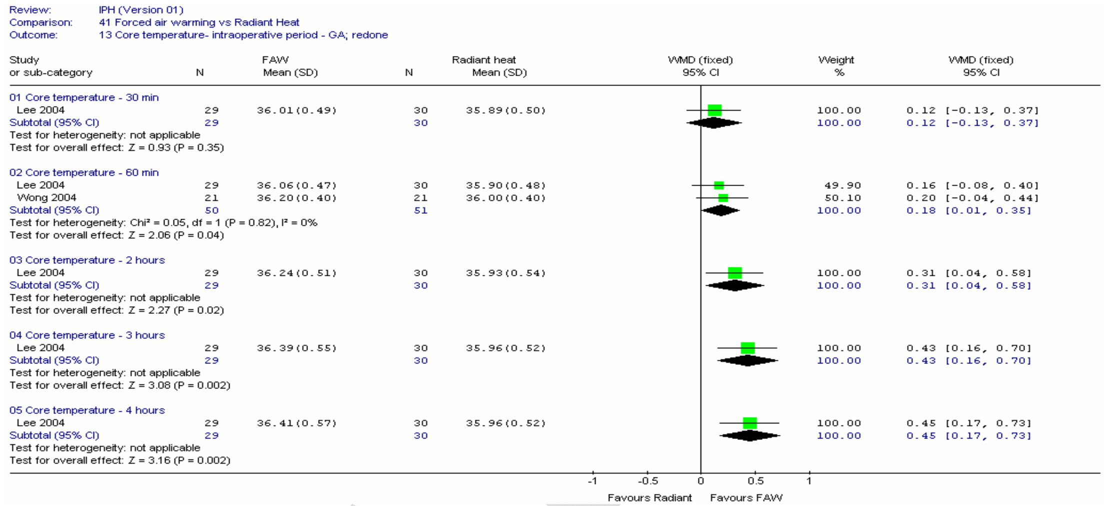
The mean difference was not significant at 30 minutes and 60 minutes in one study (Lee 2004).

At 2 hours, meta-analysis of two studies (Lee 2004; Wong 2004) with 101 patients showed a significantly higher mean core temperature for the forced air warming group: WMD 0.18°C (95% CI 0.01, 0.35) for a core temperature range of 35.9°C to 36.0°C in the radiant heat group. This is not clinically significant. There was no heterogeneity.

At 3 hours, the mean core temperature was significantly higher in the forced air warming: MD 0.43°C (95% CI 0.16, 0.70) for a core temperature of 35.9°C in the radiant heat group. The confidence interval is fairly wide.

At 4 hours, the mean core temperature was significantly higher in the forced air warming: MD 0.45°C (95% CI 0.17, 0.73) for a core temperature of 35.9°C in the radiant heat group. The confidence interval is fairly wide.

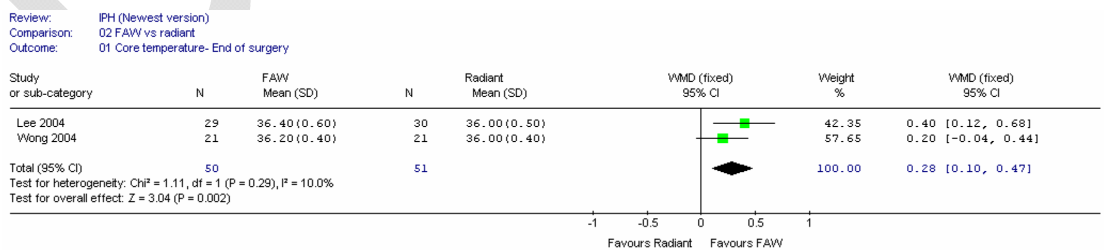
Figure 76: Core temperature during intraoperative period; forced air warming versus radiant heat; general anaesthesia



3. Core temperature: end of surgery

Two studies (Lee 2004; Wong 2004) with 101 patients reported core temperature at end of surgery. In one study (Lee 2004) duration of surgery was greater than 2 hours. In the other study (Wong 2004) mean duration of surgery was 64 minutes (SD 17) and 66 minutes (SD 18) for the forced air warming and radiant heat groups respectively. The mean core temperature was significantly higher in the forced air warming group: MD 0.28°C (95% CI 0.10, 0.47) for a control group temperature 36.0°C. This is not clinically significant (Figure 77).

Figure 77: Core temperature – end of surgery; forced air warming versus radiant heat; general anaesthesia

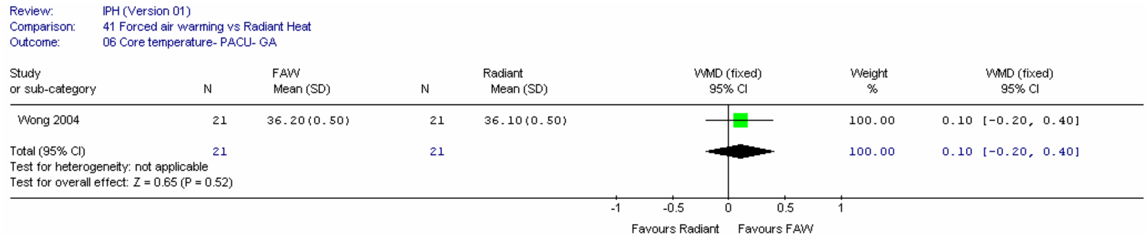


Postoperative Outcomes

4. Core temperature – PACU

One study (Wong 2004) with 42 patients reported axillary temperature after transfer to the recovery room. There was no significant difference (Figure 78).

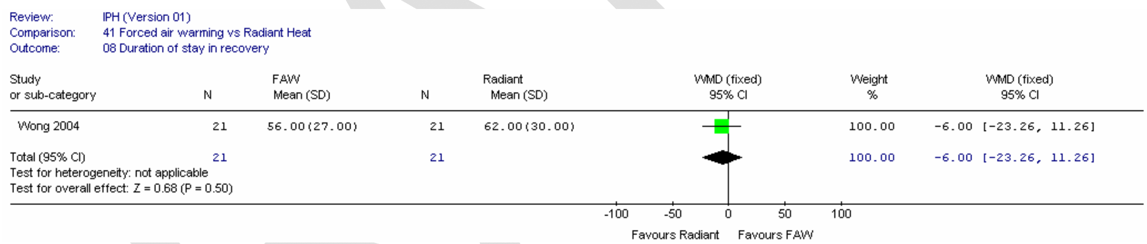
Figure 78: Axillary temperature – PACU; forced air warming versus radiant heat; general anaesthesia



5. Duration of stay in recovery

One study (Wong 2004) with 42 patients reported time in recovery (min). Duration of stay in recovery was not significant (Figure 79). The median and range for time to reach modified Aldrete score of 9 on five items (activity, respiration, circulation, conscious state, O_2 saturation) were also reported. Time to achieve the Aldrete score was 15 minutes (0-50) and 12 minutes (1-90) for the forced air warming and radiant heat groups respectively. The difference was not significant.

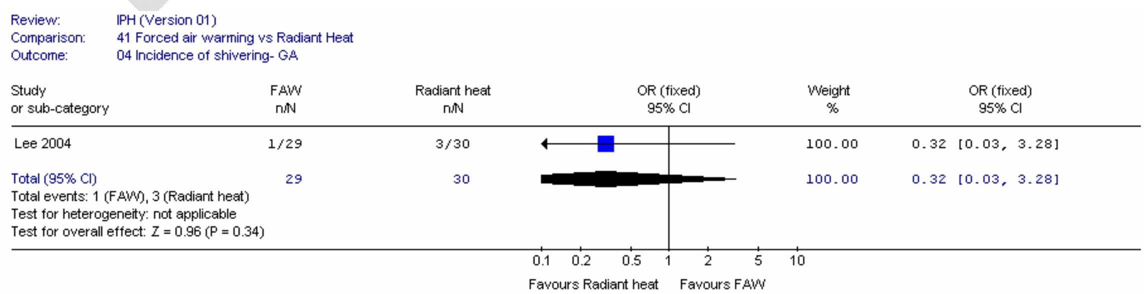
Figure 79: Duration of stay in recovery; forced air warming versus radiant heat; general anaesthesia



6. Incidence of shivering

One study (Lee 2004) reported shivering in the postoperative period. The study did not provide details on criteria for shivering and how it was assessed. The confidence interval is too wide (Figure 80).

Figure 80: Incidence of shivering; forced air warming versus radiant heat; general anaesthesia

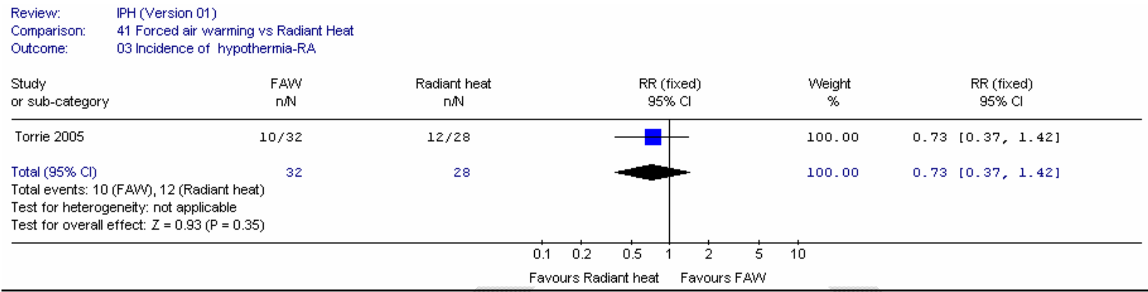


B. Regional Anaesthesia

1. Incidence of hypothermia

One study (Torrie 2005) with 60 patients undergoing transurethral prostatic resection under spinal anaesthesia reported number of patients with rectal temperature less than 36°C on arrival in PACU. The difference was not significant (RR 0.73 [95% CI 0.37, 1.42]) (Figure 81).

Figure 81: Incidence of hypothermia; forced air warming versus radiant heat; regional anaesthesia



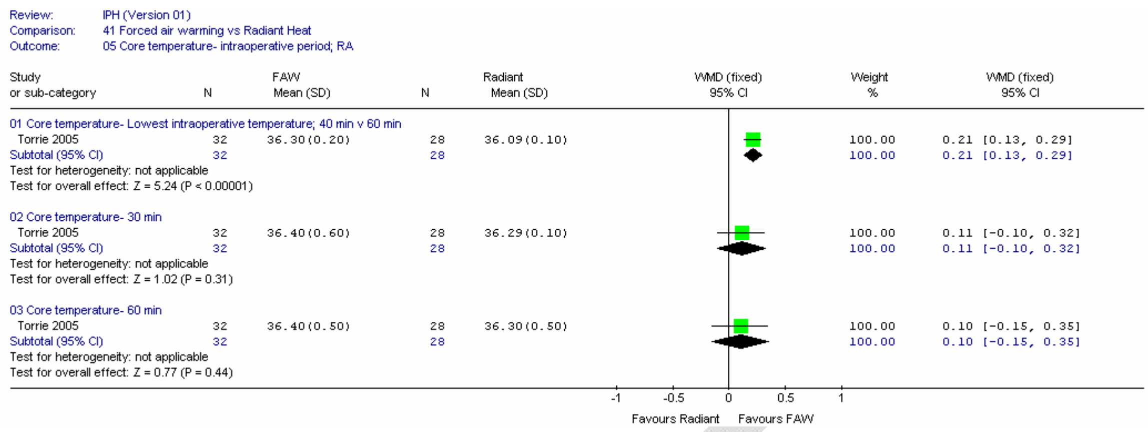
2. Core temperature – Intraoperative period

One study (Torrie 2005) with 60 patients undergoing transurethral prostatic resection under spinal anaesthesia reported core temperature (rectal) at various times in intraoperative period and end of surgery (Figure 82).

The mean difference was not significant at 30 minutes (0.11°C [95% CI -0.10, 0.32]) and at 60 minutes (0.10°C [95% CI -0.15, 0.35]). We note that the mean core temperature for the both groups was above 36°C during the entire intraoperative period.

Lowest core temperature was recorded at 40 minutes and 60 minutes for the forced air warming and radiant heat group respectively. The mean core temperature was significantly higher in the forced air warming group: MD 0.21°C (95% CI 0.13, 0.29) for a core temperature of 36.0°C in the radiant heat group.

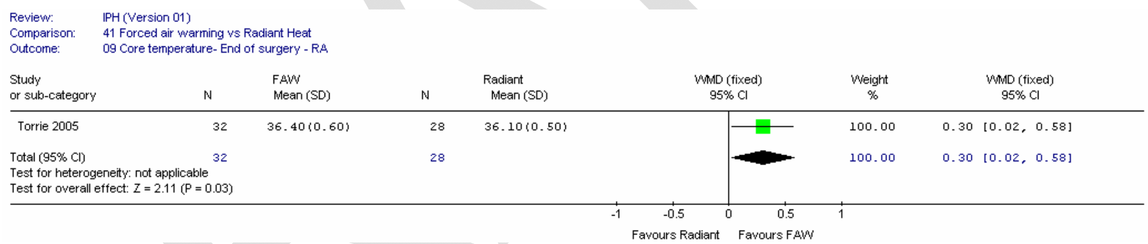
Figure 82: Core temperature intraoperative period; forced air warming versus radiant heat; regional anaesthesia



3. Core temperature – end of surgery

One study (Torrie 2005) with 60 patients reported core temperature at end of surgery. The duration of surgery was not given. Mean duration of anaesthesia was 50 minutes and 56 minutes for the forced air warming and the radiant heat group. The mean difference was statistically significant in favour of forced air warming. The confidence interval is fairly wide (0.30°C [95% CI 0.02, 0.58]) (Figure 83).

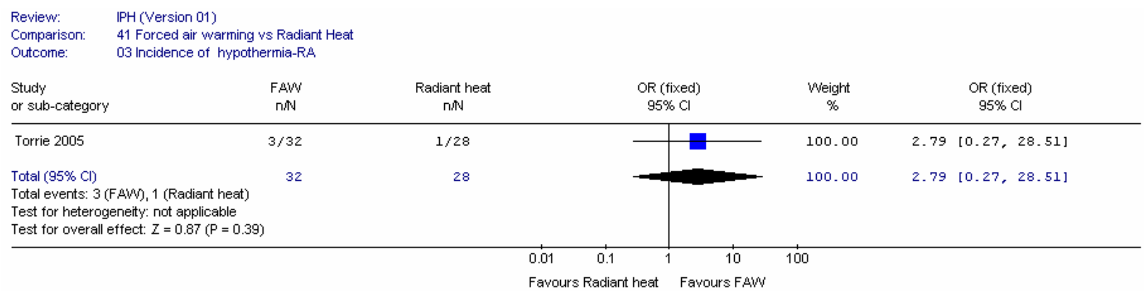
Figure 83: Core temperature – end of surgery; forced air warming versus radiant heat; regional anaesthesia



8. Incidence of shivering

One study (Torrie 2005) reported shivering in the recovery room, but this may have been confounded because some patients were rewarmed during their stay in PACU. Criteria on how shivering was assessed was not provided. There was no significant difference in the incidence of shivering (Figure 84).

Figure 84: Incidence of shivering; forced air warming versus radiant heat; regional anaesthesia



NB: Scale 0.01 to 100

IVf. Electric blanket versus circulating water mattress

Two studies (Matsuzaki 2003; Negishi 2003) compared the effectiveness of electric blanket with circulating water mattress. More specifically:

- In one study 16 patients undergoing laparoscopic cholecystectomy under general anaesthesia patients received either upper body forced air warming (medium setting) or electric blankets (38°C) (Matsuzaki 2003).
- In one study 16 patients undergoing open abdominal surgery under combined regional and general anaesthesia received either forced air warming (high setting) or electric blankets (42°C) (Negishi 2003).

There was no difference in baseline core temperature in one study (Matsuzaki 2003). In one study (Negishi 2003) there was a difference of 0.39°C (higher for the circulating water mattress group) in the baseline core temperature. As standard deviations were not provided we are not able to comment on whether this difference is statistically significant.

Results for these two studies are presented separately due to differences in type of anaesthesia.

A. General Anaesthesia

One study (Matsuzaki 2003) with 16 patients undergoing laparoscopic cholecystectomy under general anaesthesia received either electric blankets (38°C) or circulating water mattresses (38°C). Both groups received warmed IV fluids (37°C).

Results for core temperature are present for the following: lowest intraoperative core temperature; 30 minutes; 60 minutes; and final intraoperative core temperature (Figure 85).

1. Core temperature - intraoperative

At 30 minutes, the mean core temperature was significantly higher for the electric blanket group: MD 0.20°C (95% 0.11, 0.29) for a change in core temperature of -0.2°C in the circulating water mattress group.

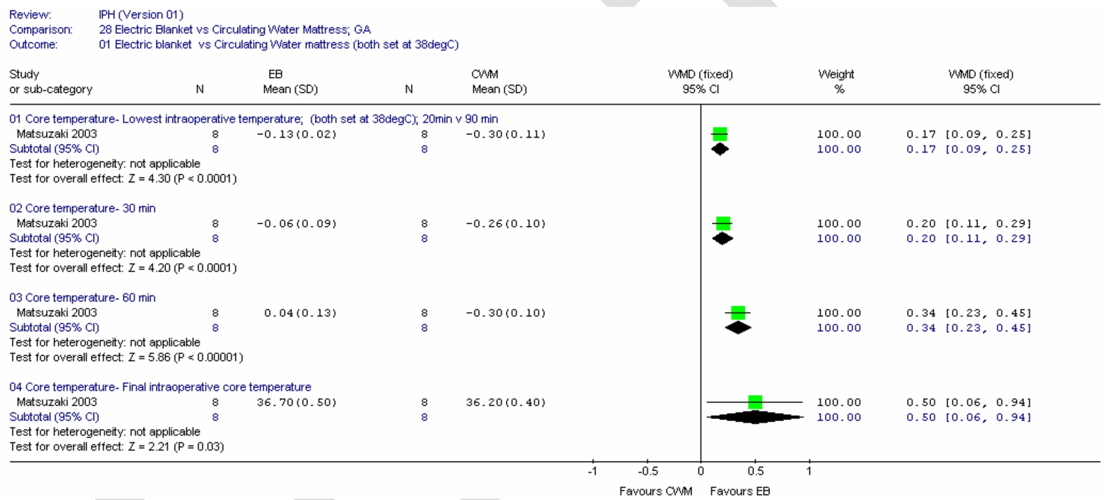
At 60 minutes, the mean core temperature was significantly higher for the electric blanket group: MD 0.34°C (95% 0.22, 0.45) for a change in core temperature of -0.30°C in the circulating water mattress group.

The final intraoperative core temperature was significantly higher for the electric blanket group (1 hour 30 minutes): MD 0.50°C (95% CI 0.06, 0.94) for a core temperature of 36.20°C in the circulating water mattress group. The confidence interval is fairly wide.

2. Lowest intraoperative temperature

The lowest intraopertive temperature was reported at 20 minutes and 90 minutes for the electric blanket and circulating water mattress respectively. The mean core temperature was significantly higher in the electric blanket group: MD 0.17°C (95% 0.09, 0.25) for a change in core temperature of -0.30°C in the circulating water mattress group (Figure 86).

Figure 86: Core temperature during intraoperative period; electric blanket versus circulating water mattress; general anaesthesia



B. Combined General and Regional anaesthesia

In Negishi (2003), 16 patients undergoing open abdominal surgery under combined general and regional anaesthesia received either electric blanket (42°C) or full length circulating water mattress (42°C). Patients in both groups received warmed (37°C) IV fluids. The baseline core temperature was 0.39°C higher in the circulating water mattress group. It is unclear whether this difference is statistically significant, as standard deviations were not provided.

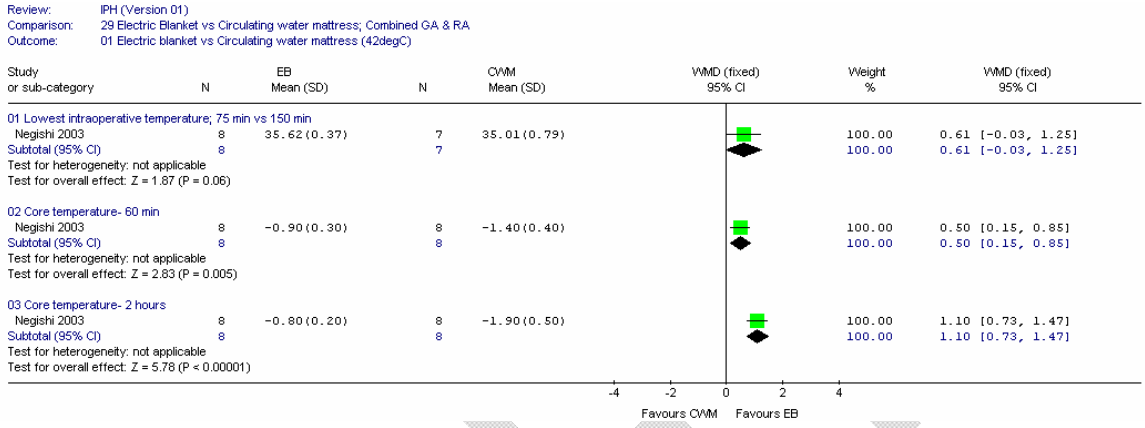
1. Change in core temperature: intraoperative period and end of surgery

One study (Negishi 2003) with 16 patients reported change in core temperature at 60 minutes, 2 hours and upon completion of surgery (Figure 87).

At 60 minutes, the mean core temperature was significantly higher for the electric blanket group: MD 0.50°C (95% CI 0.15, 0.85) for a change in core temperature of -1.40°C in the circulating water mattress group. The confidence interval is fairly wide.

At 2 hours, the mean core temperature was significantly higher for the electric blanket group: MD 1.10°C (95% CI 0.73, 1.47) for a change in core temperature -1.9°C (SD 0.5) for the circulating water mattress group. The confidence interval is fairly wide.

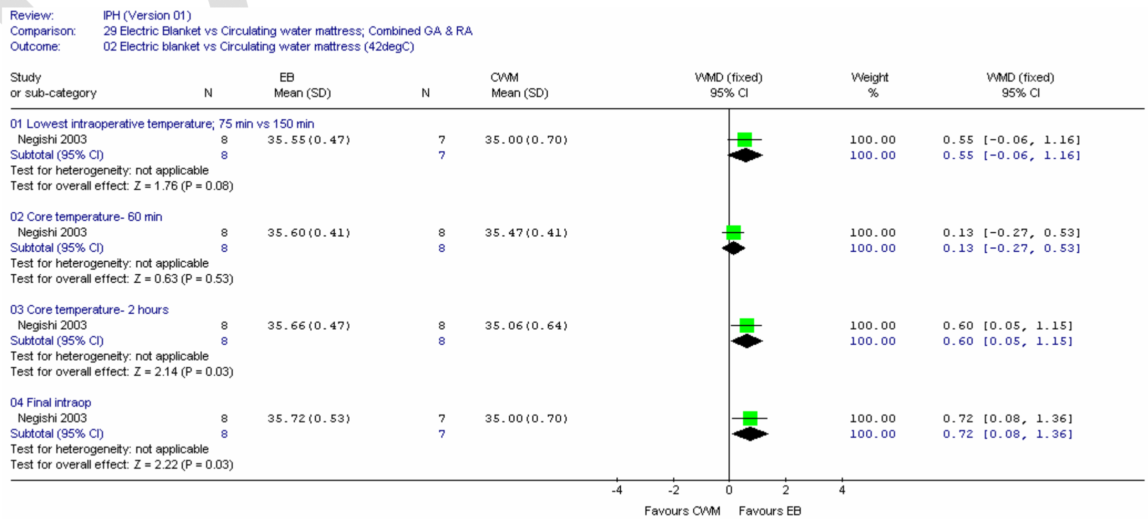
Figure 87: Change in core temperature: intraoperative period; combined anaesthesia



The core temperatures were also extracted from the graph.

The mean difference was not significant at the lowest intraoperative temperature (75 minutes and 150 minutes for the electric blanket and circulating water mattress groups respectively) and 60 minutes. At 2 hours, the mean difference is significant; the confidence interval is wide (0.60°C [95%CI 0.05, 1.15] for a control group core temperature of 35.0°C SD 0.64). At the final intraoperative period (150 minutes) the mean difference is significant; the confidence interval is wide (0.72°C [95%CI 0.08, 1.36] for a control group core temperature of 35.0°C SD 0.70) (Figure 88).

Figure 88: Change in core temperature: intraoperative period; active warming 1 versus active warming 2; combined anaesthesia



We note that there are large differences in effect size at 2 hours when comparing change in core temperature reported in text (1.10) to the mean difference from core temperatures extracted from the graph (0.60).

2. Lowest intraoperative temperature

Lowest intraoperative temperature was reported at 75 minutes and 150 minutes for the electric blanket and circulating water mattress groups respectively. The mean core temperature was significantly higher for the electric blanket group: MD 0.61°C (95% CI -0.03, 1.25) for a core temperature of 35.0°C in the circulating water mattress group. The confidence interval is wide (Figure 89).

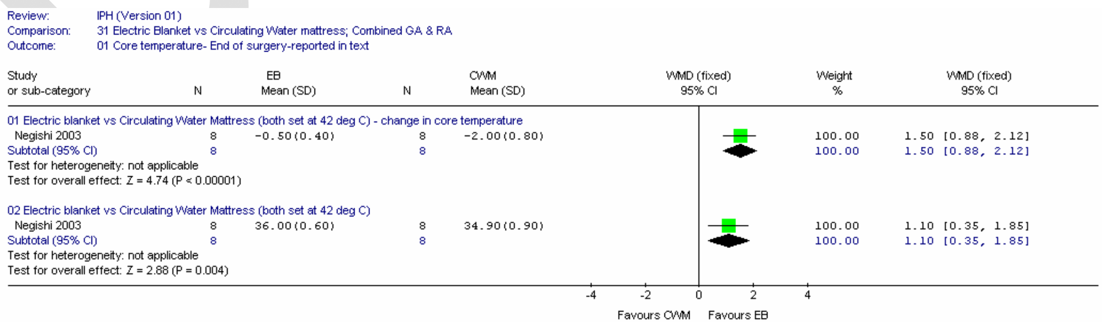
3. Change in core temperature: end of surgery

One study (Negishi 2003) with 16 patients reported core temperature at end of surgery (both change and absolute values are presented) (Figure 90). Mean duration of surgery was 253 minutes (SD 69) and 208 minutes (SD 51) for the forced air warming and circulating-water mattress groups respectively.

At end of surgery, the mean core temperature was significantly higher in the electric blanket group: MD1.50°C (95% CI 0.88, 2.12) for a change in core temperature -2.00°C (SD 0.8) for the circulating water mattress group. The confidence interval is fairly wide.

The authors also reported absolute values. The mean core temperature was significantly higher in the electric blanket group: MD 1.10°C (95% CI 0.35, 1.85) for core temperature 34.90°C for the circulating water mattress group.

Figure 89: Change in core temperature: intraoperative period; active warming 1 versus active warming 2; combined anaesthesia



NB: Scale -4 to 4

IVg. Forced air warming (upper body) versus electric heating pad and pre-warmed heating gel pad + actively warmed IV fluids in both groups

Two studies (Ng 2006; Leung 2007) compared the effectiveness of forced air warming (43°C) with an electric heating pad (39°C) (with a prewarmed heated pad placed on top of it). The electric heating pad (104cm x 45cm) warmed the entire back. All patients received warmed (37°C) IV fluids. It should be noted that in the heating pad group, warming was started 10 minutes before patients were transferred to the operating table.

In one study (Ng 2006) initial tympanic temperature was recorded only after transfer to theatre (that is after induction of anaesthesia) so it is unclear if there were any baseline differences in core temperature. After induction, there was no significant difference in core temperature.

In one study (Ng 2006) rectal temperature was used to record intraoperative temperature. The authors reported initial rectal temperature (recorded after initial equilibration) was reported and there was no significant difference. Intraoperative temperature was measured with a nasopharyngeal probe in the other study (Leung 2007).

Results for the two studies are presented separately due to differences in type of anaesthesia: general (Leung 2007); combined spinal-epidural (Ng 2006).

We note that data on intraoperative core temperatures were extracted from graphs for both studies.

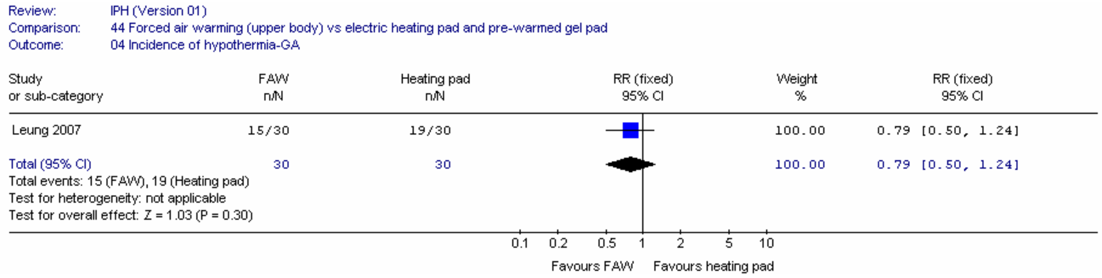
A. General anaesthesia

One study (Leung 2007) with 60 patients undergoing laparotomy under general anaesthesia compared effectiveness of forced air warming (43°C) with an electric heating pad (39°C) (with a prewarmed heated pad placed on top of it).

1. Incidence of hypothermia

One study (Leung 2007) with 60 patients reported the number of patients with final temperature less than 36°C. There was no significant difference (Figure 90). These patients were given forced air warming in the postoperative period.

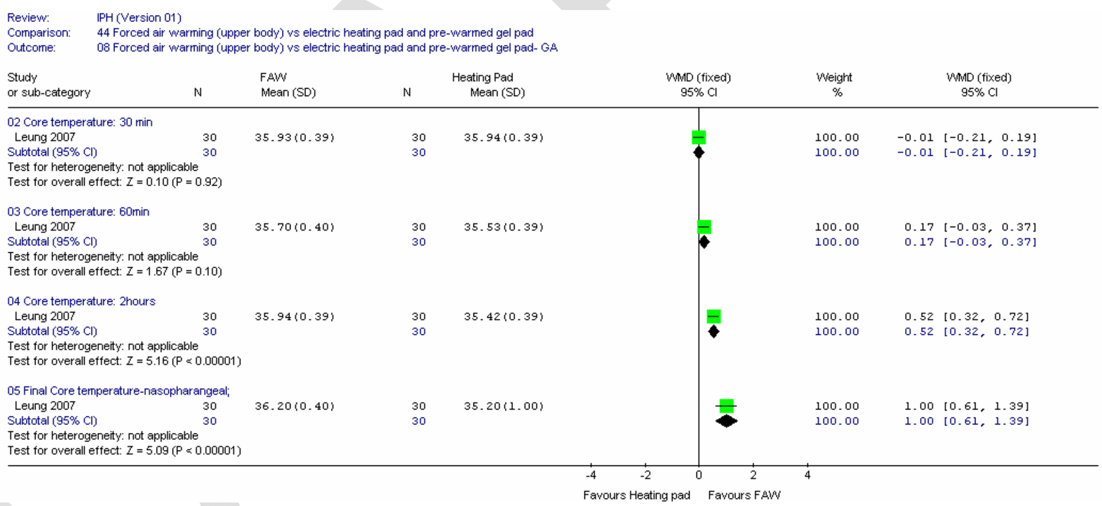
Figure 90: Incidence of hypothermia; active warming 1 versus active warming 2; general anaesthesia



2. Intraoperative core temperature

One study (Leung 2007) with 60 patients reported intraoperative core temperatures at 30 minutes, 60 minutes, 120 minutes and final core temperature. The mean difference was not significant at 30 minutes and 60 minutes. At 2 hours, the mean core temperature was significantly higher for the forced air warmed group 0.52°C (95% CI 0.32, 0.72) for a core temperature of 35.4°C in the electric heating pad group (Figure 91).

Figure 91: Core temperature; forced air warming versus electric heating pad; general anaesthesia



3. Incidence of shivering

One study (Leung 2007) with 60 patients reported that two patients in each group experienced shivering in the recovery room. Details on how shivering was assessed were not provided.

B. Regional anaesthesia

One study (Ng 2006) with 60 patients undergoing total knee replacement under combined spinal-epidural anaesthesia compared the effectiveness of forced air warming (43°C) with an electric heating pad (39°C) (with a prewarmed heated pad placed on top of it).

1. Incidence of hypothermia

One study (Ng 2006) reported no patients in either the forced air warmed group or the electric heating pad group had final rectal temperatures less than 36.0°C.

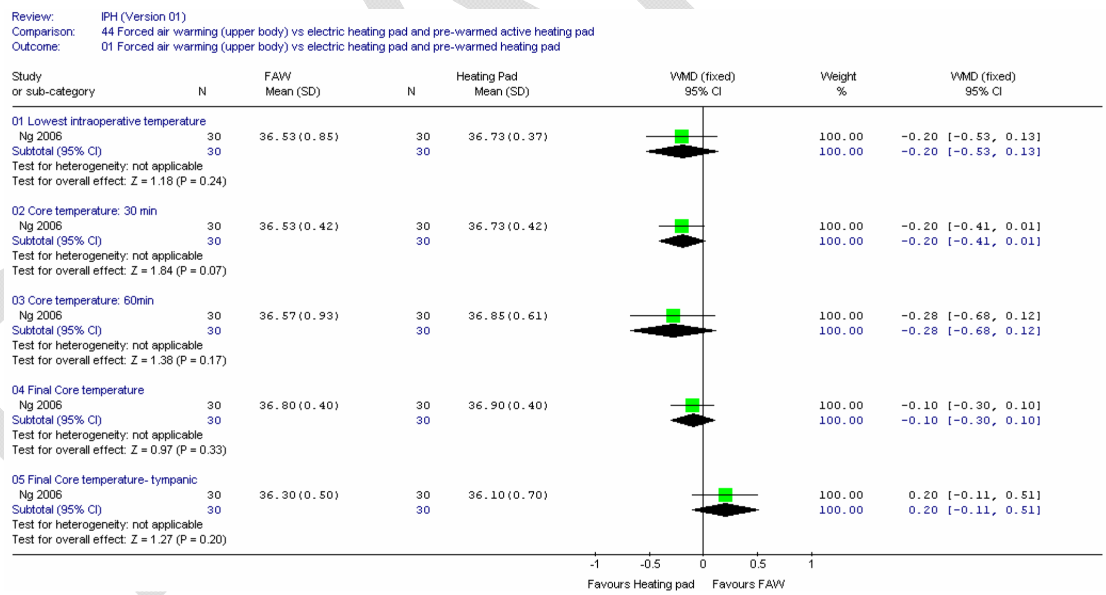
2. Core temperature – intraoperative period

One study (Ng 2006) with 60 patients reported core temperatures during the intraoperative period. Mean values and confidence intervals were reported. The mean core temperature was extracted at 30 minutes and 60 minutes. The final core temperature was reported in the text of the paper. We note that rectal temperature measurement was used during the intraoperative period and both rectal and tympanic core temperatures were reported for the final measurement.

The lowest intraoperative core temperature was recorded at 30 minutes and 15 minutes for the forced air warming and electric heating pad groups respectively.

The mean difference was not significant at any times (Figure 92).

Figure 92: Core temperature: intraoperative period; forced air warming versus electric heating pad; regional anaesthesia



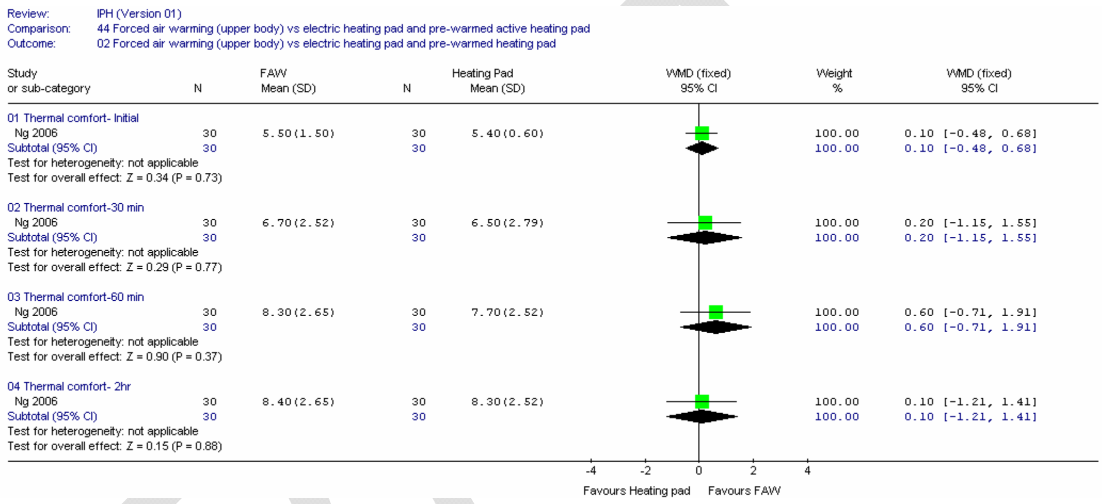
3. Thermal discomfort (end of intraoperative period)

One study (Ng 2006) reported thermal discomfort at half-hourly intervals intraoperatively, then upon arrival in PACU and after 30 minutes in the recovery room. Thermal discomfort was assessed on a VAS scale (0 = extremely cold; 5 = thermally neutral; 10 = extremely hot). The authors reported some patients received warming in the postoperative period if their core temperature was less than 36°C or if they suffered from shivering; the thermal comfort outcomes for the postoperative period were included in this review (Figure 93).

The initial mean VAS score was 5.3 for each group, which was thermally neutral.

There were no statistically significant differences in thermal comfort throughout the intraoperative period. We note that by 2 hours, thermal comfort scores for both groups had risen to 8, where 10 denotes extremely hot on the VAS scale.

Figure 93: Thermal comfort: intraoperative period; forced air warming versus electric heating pad; regional anaesthesia

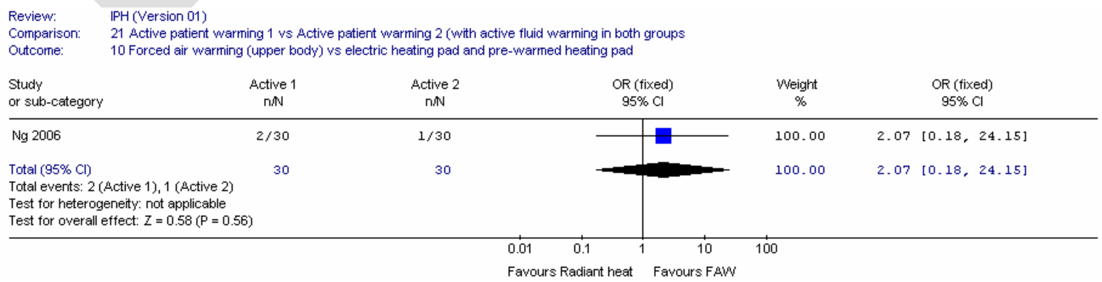


NB: Scale -4 to 4

4. Incidence of shivering

One study (Ng 2006) reported the incidence of shivering in the recovery room. Details on how shivering was assessed were not provided. The confidence interval is too wide to draw any conclusions (Figure 94).

Figure 94: Incidence of shivering; forced air warming versus electric heating pad; combined spinal-epidural anaesthesia



V. Comparisons of different types of forced air warming

Three studies (Russell 1995; Yamakage 1995; Motamed 2000) compared different types/sites of forced air warming. More specifically, the comparisons were as follows:

- Forced air warming (over blanket) versus forced air warming (under mattress) (Russell 1995) + actively warmed fluids (37°C) in both groups;
  - The GDG subgroup advised that forced air warming (under mattress) is not common practice, therefore this comparison was not considered further;
- Forced air warming (upper body) versus forced air warming (lower body) + fluid warming in both groups;
  - Forced air warming (upper body) versus forced air warming (lower body) (Motamed 2000) + warmed infusion of crystalloid (37°C) in both groups;
  - Forced air warming (upper body) versus forced air warming (lower body) (Yamakage 1995) + warmed lactated Ringer's solution (37°C) in both groups.

This left two studies eligible for analysis (Yamakage 1995; Motamed 2000). In one study (Motamed 2000) 26 patients underwent prolonged abdominal surgery under general anaesthesia. In the other study (Yamakage 1995) 14 patients underwent spinal anaesthesia for surgery on the lower abdomen or a lower extremity.

In one study (Motamed 2000) we note that the baseline core temperature was 0.19°C higher for the lower body forced air warm group. This difference was significant.

Results for the studies are presented separately.

We note that results for core temperature have been extracted from graphs in both studies.

A. General Anaesthesia

1. Core temperature – intraoperative

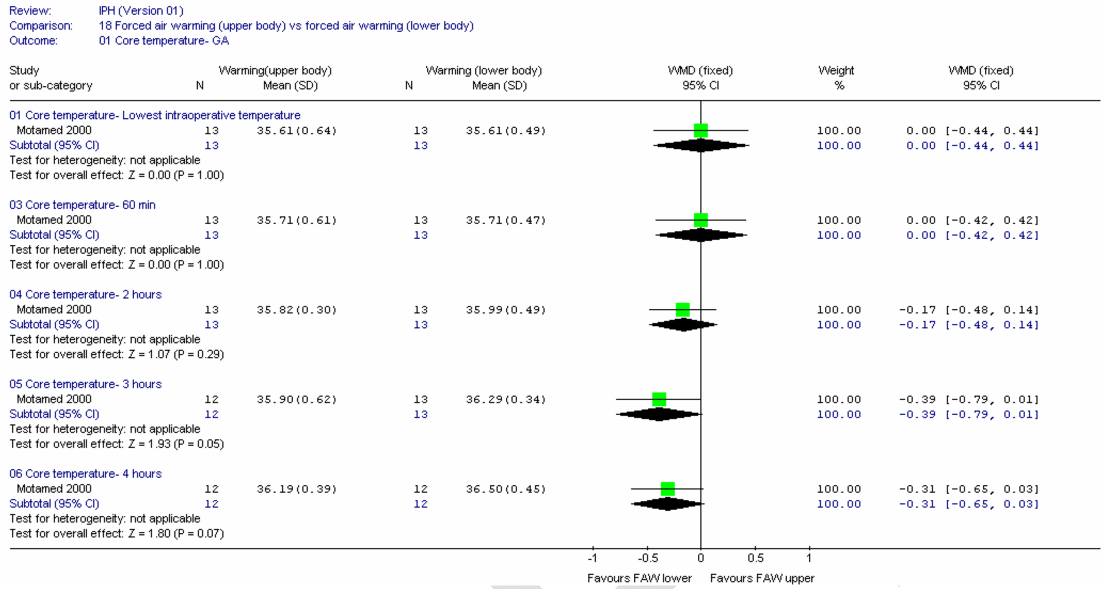
One study (Motamed 2006) with 26 patients compared the effectiveness of upper body forced air warming with lower body forced air warming. The forced air warmer was set to high (43°C), however, if the mean core temperature exceeded 37.5°C the blower was turned off. Core temperatures were reported at 60 minutes, 2 hours, 3 hours and 4 hours (Figure 95).

The mean difference was not significant at 60 minutes, 2 hours and 4 hours.

2. Lowest intraoperative temperature

The lowest intraoperative temperature was at 80 minutes and 20 minutes for the upper body and lower body groups respectively. The mean difference was not significant.

Figure 95: Core temperature during intraoperative periods; forced air warming (upper body) versus forced air warming (lower body); general anaesthesia



B. Regional anaesthesia

1. Core temperature during intraoperative period

One study (Yamakage 1995) with 14 patients compared the effectiveness of upper body with lower body forced air warming. The change in core temperature was reported at 30 minutes, 60 minutes and 90 minutes (final intraoperative).

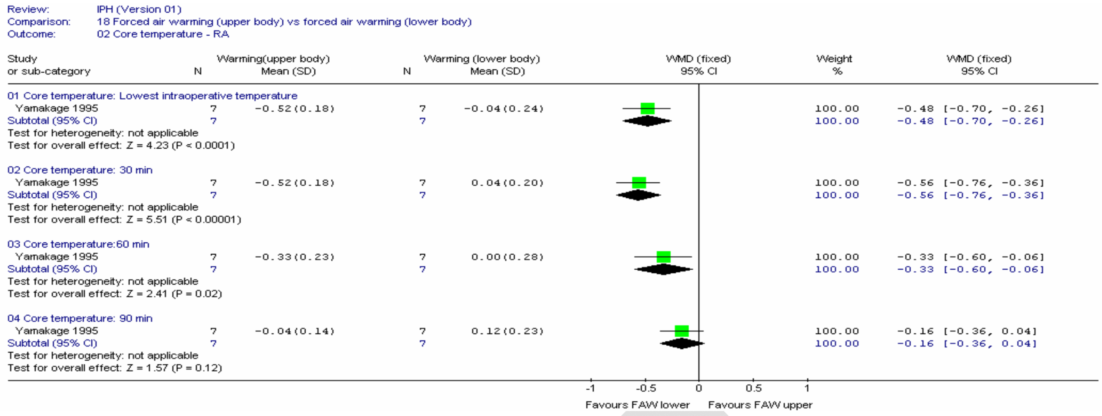
At 30 minutes the mean core temperature was significantly higher in the lower body group: MD -0.56°C (95% CI -0.76, -0.36) for a change in core temperature -0.5°C in the upper body warmed group.

At 60 minutes the mean core temperature was significantly higher in the lower body group: MD -0.33°C (95% CI -0.60, -0.06) for a change in core temperature -0.3°C in the upper body warmed group. The confidence interval is fairly wide. The mean difference was not significant at the final intraoperative time period (1 hour 30 minutes).

The lowest intraoperative temperature was reached at 40 minutes for both groups. The mean difference was significant in favour of the lower body group (0.48°C [95% CI -0.70, -0.26]) for a change in core temperature of -0.04°C in the lower body group.

We note however that this is a small study (14 patients) so recommendations should not be made on the basis of this evidence (Figure 96).

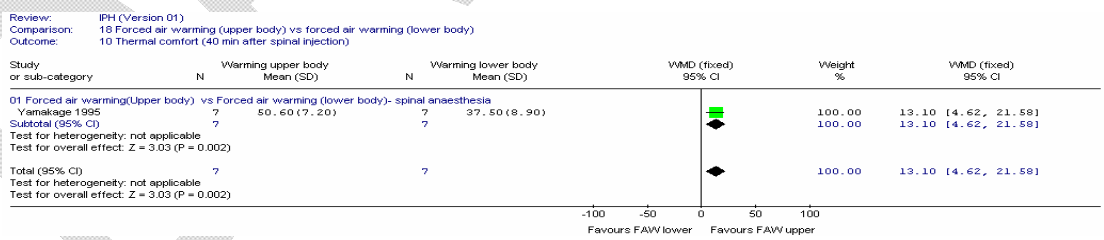
Figure 96: Core temperature during intraoperative period; forced air warming (upper body) versus forced air warming (lower body); regional anaesthesia



2. Thermal comfort (intraoperative period)

One study (Yamakage 1995) reported thermal comfort 40 minutes after spinal injection. Thermal comfort was assessed on a 100mm visual analog scale (VAS), with 0mm defined as worst imaginable cold, 50mm as thermally neutral, and 100mm as insufferably hot. The difference (13.10mm [95% CI 4.62, 21.58]) was significant with the upper body group reporting thermal comfort and the lower body group being colder (37.50mm on a scale of 100mm) (Figure 97). We note that at 40 minutes, although change in core temperature was smaller in the lower body group compared with upper body group (-0.04°C [SD 0.24] versus -0.53°C [SD 0.26] respectively) patients in the lower body group reported chilly sensations.

Figure 97: Thermal comfort; forced air warming (upper body) versus forced air warming (lower body) regional anaesthesia



NB: Scale -100 to 100

VI. Comparisons of different settings for forced air warming (dose comparison)

Four studies (Camus 1993b; Kurz 1996; Lenhardt 1997; Winkler 2000) compared different settings for forced air warming. More specifically the comparisons were:

- o Forced air warming (40°C) + actively warmed IV fluids versus forced air warming (ambient temperature) + IV fluids (Kurz 1996);

- o Insulated forced air warming (lower body) versus forced air warming (upper body) (Camus 1993b) + ambient IV fluids and actively warmed irrigation fluids (37°C) in both groups;
- o Extra warming versus usual care (Lenhardt 1997);
- o Aggressive forced air warming versus conventional forced air warming (Winkler 2000) + warmed IV fluids (37°C) in both groups (regional anaesthesia).

Lenhardt (1997) stated that 100 of the 150 patients enrolled in the study were also enrolled in the Kurz (1996) study which included 200 patients. It was agreed not to consider the Lenhardt (1997) study.

There were no significant differences in baseline core temperature in either study.

Information on core temperatures were extracted from graphs for two studies (Camus 1993b; Kurz 1996).

The results are presented separately due to differences in interventions and anaesthesia.

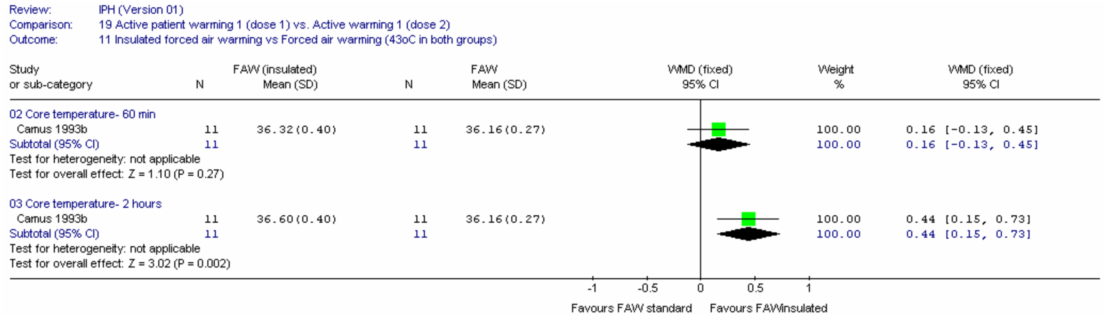
A. General anaesthesia
Results for the two studies (Camus 1993b; Kurz 1996) were not combined as the interventions were different.

1. Core temperature: intraoperative period
a) Insulated forced air warming versus standard forced air warming
One study (Camus 1993b) with 22 patients undergoing elective abdominal surgery with warmed irrigation fluids (37°C) received either insulated lower body forced air warming (2 cotton sheets on top of the forced air blanket; the authors did not stated whether the cotton sheets were tucked in) or lower body forced air warming. The forced air warmer was set to 'high' (approximately 43°C).

The mean difference was not significant at 60 minutes intraoperatively.

At 2 hours the mean core temperature was significantly higher in the insulated forced air warming group: MD 0.44°C (95% CI 0.15, 0.73) for the standard forced air warming group core temperature 36.16°C. The confidence is fairly wide (Figure 98).

Figure 98: Core temperature; forced air warming (insulated) versus forced air warming (standard); general anaesthesia



b) Forced air warming (40°C) versus forced air warming (ambient)

One study (Kurz 1996) with 200 patients undergoing elective colorectal resection received either forced air warming (40°C) and warmed (37°C) IV fluids or forced air warming set to deliver air at ambient temperature. For the patients in the forced air warming (ambient temperature setting) group, core temperature was reached to 34.5°C.

Intraoperative core temperatures were reported at 60 minutes; 2 hours; 3 hours and end of surgery. The mean core temperature in PACU was reported for entry into PACU and hourly until six hours in recovery. In addition, thermal comfort, incidence of shivering, incidence of wound infection, admission to ICU, duration of hospitalisation and deaths were reported.

At 60 minutes the mean core temperature was significantly higher for the group receiving forced air warming (set to 40°C) MD 0.39°C (95% CI 0.22, 0.56) for a mean core temperature of 35.42°C in the group receiving forced air warming at ambient temperature. This was clinically significant.

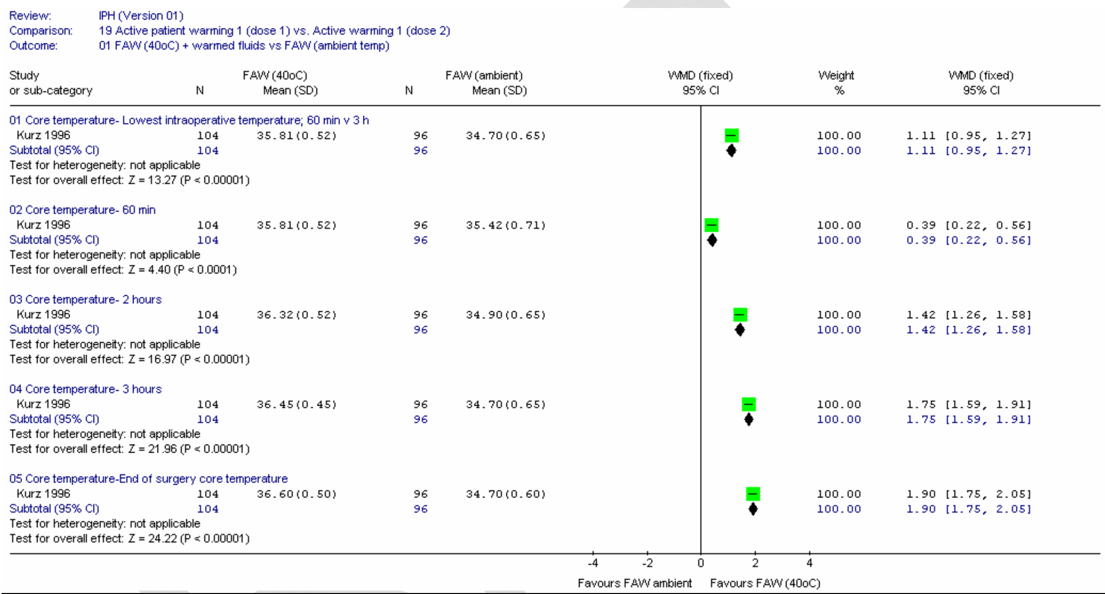
At 2 hours the mean core temperature was significantly higher for the group receiving forced air warming (set to 40°C) MD 1.42°C (95% CI 1.26, 1.58) for a mean core temperature of 34.9°C in the group receiving forced air warming at ambient temperature; the difference was clinically significant.

At 3 hours, the mean core temperature was significantly higher for the group receiving forced air warming (set to 40°C) MD 1.75°C (95% CI 1.59, 1.91) for a mean core temperature of 34.7°C in the group receiving forced air warming (at ambient temperature) temperature; the difference was clinically significant.

The lowest intraoperative temperature was reported at 60 minutes and 3 hours for the active forced air warming (40°C) and forced air warming (ambient) groups respectively. The mean core temperature was significantly higher in the group receiving forced air warming (40°C) 1.11°C (95% CI 0.95, 1.27) for a mean core temperature of 34.7°C in the group receiving forced air warming (at ambient temperature); the difference was clinically significant.

Core temperature was reported at end of surgery. Mean duration of surgery was 3.1 hours for both groups. The mean core temperature was significantly higher in the group receiving forced air warming (40°C) MD 1.90°C (95% CI 1.75, 2.05) for a mean core temperature of 34.7°C in the group receiving forced air warming (at ambient temperature); the difference was clinically significant.

Figure 99: Core temperature during the intraoperative period; forced air warming (40°C) versus forced air warming (ambient); general anaesthesia



NB: Scale -4 to 4

2. Core temperature: PACU

One study (Kurz 1996) with 200 patients reported core temperature for the duration of stay of up to 6 hours in PACU (Figure 100).

Core temperature was reported at entry into PACU. The mean core temperature was significantly higher for the forced air warmed (40°C) group: MD 1.55°C (95% CI 1.37, 1.73) for a mean core temperature of 34.9°C in the group receiving forced air warming (at ambient temperature). The difference was clinically significant.

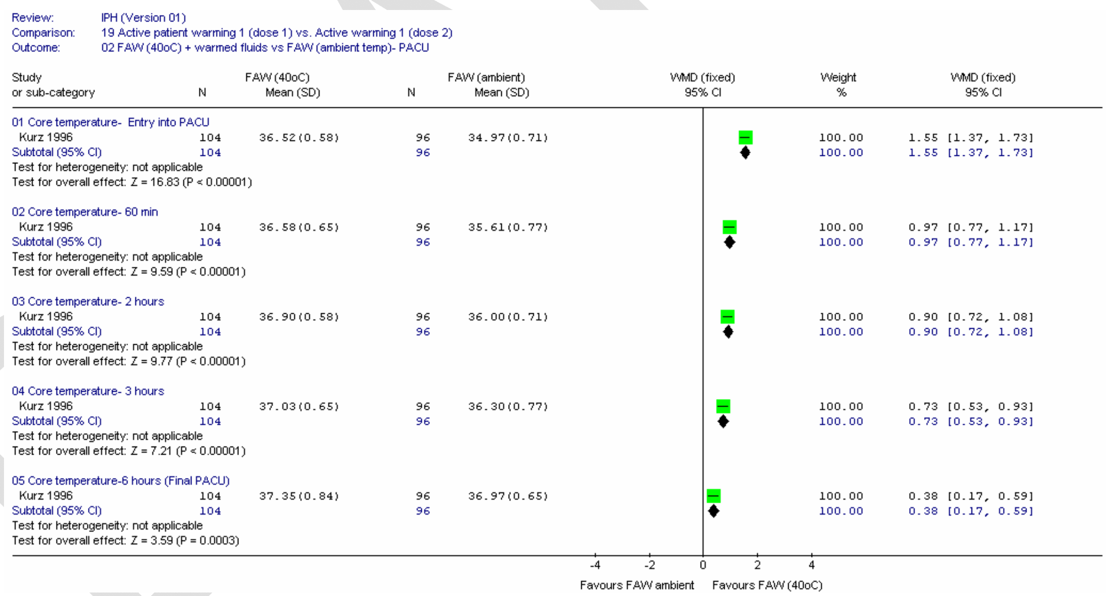
After 60 minutes in recovery room, the mean core temperature was significantly higher for the forced air warmed (40°C) group: MD 0.97°C (95% CI 0.77, 1.17) for a mean core temperature of 35.6°C in the group receiving forced air warming (at ambient temperature). The difference was clinically significant.

After 2 hours in the recovery room, the mean core temperature was significantly higher for the forced air warmed (40°C) group: MD 0.90°C (95% CI 0.72, 1.08) for a mean core temperature of 36.0°C in the group receiving forced air warming (at ambient temperature). The difference was clinically significant.

After 3 hours in the recovery room, the mean core temperature was significantly higher for the forced air warmed (40°C) group: MD 0.73°C (95% CI .53, 0.93) for a mean core temperature of 36.3°C in the group receiving forced air warming (at ambient temperature). The difference was clinically significant.

The final core temperature in the PACU was recorded at 6 hours. The mean core temperature was significantly higher for the forced air warmed (40°C) group: MD 0.38°C (95% CI 0.17, 0.59) for a mean core temperature of 36.9°C in the group receiving forced air warming (at ambient temperature). The difference was clinically significant.

Figure 100: Core temperature in PACU; forced air warming (40°C) versus forced air warming (ambient); general anaesthesia

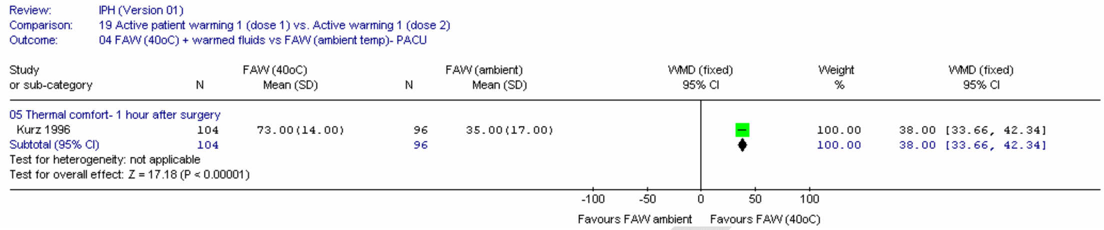


NB: Scale -4 to 4

3. Thermal comfort

One study (Kurz 1996) reported thermal comfort one hour after surgery. Thermal comfort was evaluated at 20 minute intervals for 6 hours in the postoperative period with a 100mm visual analogue scale (VAS), on which 0mm denoted intense cold, 50mm denoted thermal comfort, and 100mm denoted intense warmth. Thermal comfort was significantly higher in the forced air warming group (40°C) (38mm [95% CI 33.66, 42, 34]), although neither group was thermally neutral. The authors stated that the difference in thermal comfort remained statistically significant for three hours (Figure 101).

Figure 101: Thermal comfort; forced air warming (40°C) versus forced air warming (ambient); general anaesthesia

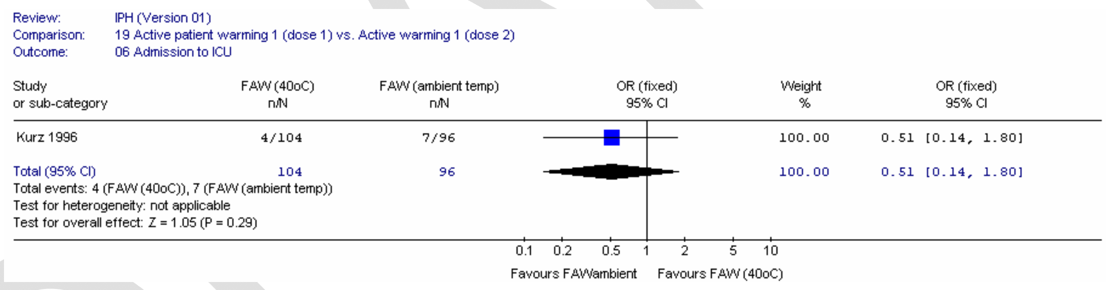


NB: Scale -100 to 100

4. Admission to ICU

One study (Kurz 1996) reported on number of patients admitted to ICU due to wound dehiscence, colon perforation and peritonitis. The confidence interval is fairly wide (Figure 102).

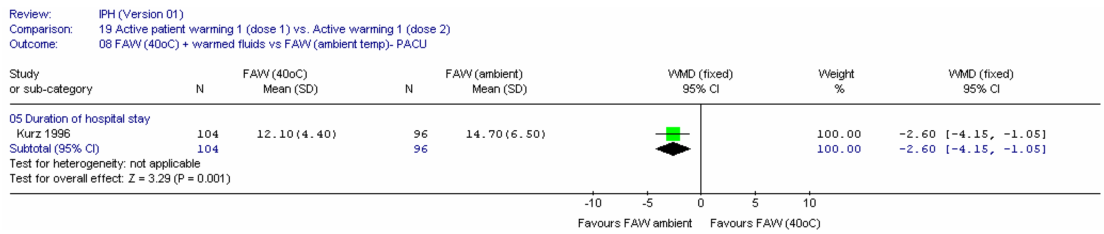
Figure 102: Admission to ICU; active 1 (dose 1) versus active 2 (dose 2); general anaesthesia



5. Duration of hospitalisation

One study (Kurz 1996) with 200 patients undergoing colorectal surgery with mean duration of surgery of 3 hours reported on the duration of stay in hospital. The length of stay was significantly shorter by 2.6 days in 14.7 days in the group warmed with forced air warming at 40°C (Figure 103).

Figure 103: Duration of stay in hospital; active 1 (dose 1) versus active 1 (dose 2); general anaesthesia

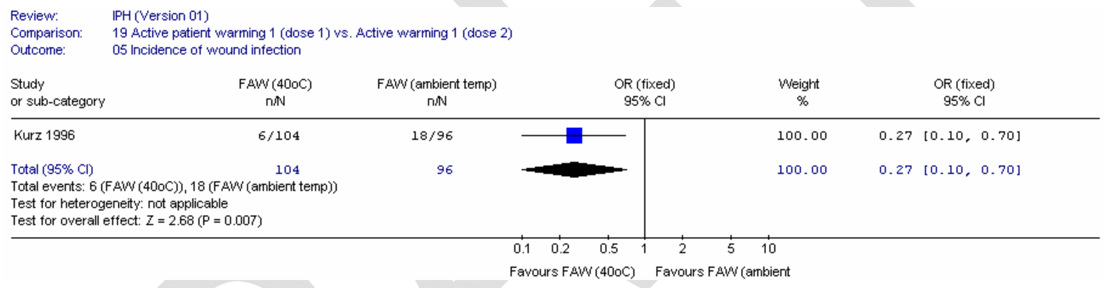


6. Incidence of wound infection

One study (Kurz 1996) reported on the incidence of wound infection assessed by a physician blinded to group assignment. Wounds were classified as infections if 'pus could be expressed from the surgical incision or aspirated from a loculated mass inside the wound' and tested positive for pathogenic bacteria. Wound infection was also evaluated by ASEPSIS system, with scores exceeding 20 on this scale classified as an infected wound. Wound infections diagnosed within 15 days of surgery were included in the data analysis.

The incidence of wound infection was significantly lower in the group warmed with forced air warming at 40°C setting (OR 0.27 [95% CI 0.10, 0.70]). This corresponds to an NNT of 8 (95% CI 5, 25) for a control group rate of 18/96 (19%) (Figure 104).

Figure 104: Incidence of wound infection; active 1 (dose 1) versus active 1 (dose 2); general anaesthesia



7. Death

One study (Kurz 1996) reported that 2 patients in each group died during the month following surgery.

8. Incidence of shivering

One study (Kurz 1996) with 200 patients recorded the incidence of shivering. The study reported that in 59% of patients in the forced air warming (ambient setting) group shivering was observed and the authors stated shivering was observed 'only [in] a few patients' assigned to receive forced air warming at 40°C. Due to insufficient data conclusions on dose effect on incidence of shivering were not drawn.

9. Pain

Kurz (1996) reported that pain scores and the amount of opioid administered were 'virtually identical' in the two groups at each postoperative measurement.

B. Regional Anaesthesia

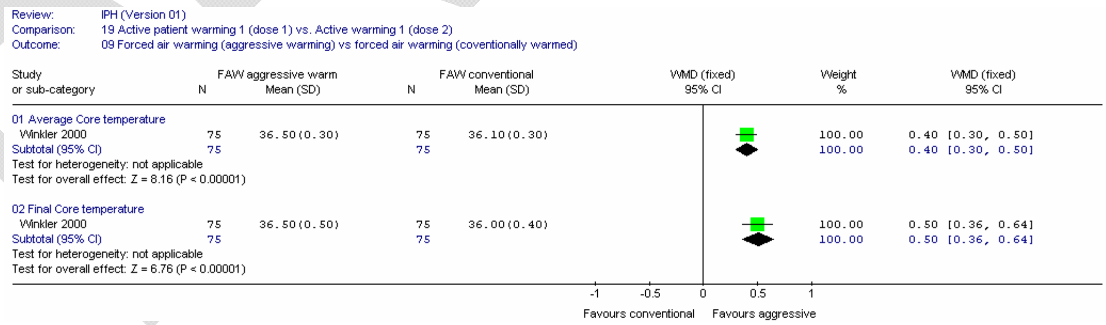
One study (Winkler 2000) of 150 patients undergoing total hip arthroplasty with combined epidural-spinal anaesthesia compared the effectiveness of upper and lower forced air warming set to either maintain core temperature near 36.5°C (aggressive warming) or maintain core temperature near 36.0°C (conventional warming). The temperature of the warmers was adjusted to maintain the target core temperature. All patients received warmed (37°C) IV fluids. The study did not report at what times into the intraoperative period the settings needed to be adjusted.

The mean core temperature was recorded for the final intraoperative time period and at 3 hours in recovery. In addition, blood loss in the intraoperative and postoperative periods was also reported.

1. Core temperature

One study (Winkler 2000) with 150 patients reported the average core temperature and final intraoperative core temperature. Mean duration of surgery was 102 minutes (SD 36) and 97 minutes (SD 36) for the aggressively warmed and conventionally warmed groups respectively. The mean difference for the average core temperature was statistically significant in favour of the aggressive forced air warming group (0.50°C [95% CI 0.36, 0.64] for a temperature of 36.10°C [SD 0.30] for the conventionally warmed group). The mean difference for the final core temperature was clinically and statistically significant in favour of the aggressive forced air warming group (0.50°C [95% CI 0.36, 0.64] for a control group rate of 36°C [SD 0.40]) (Figure 105).

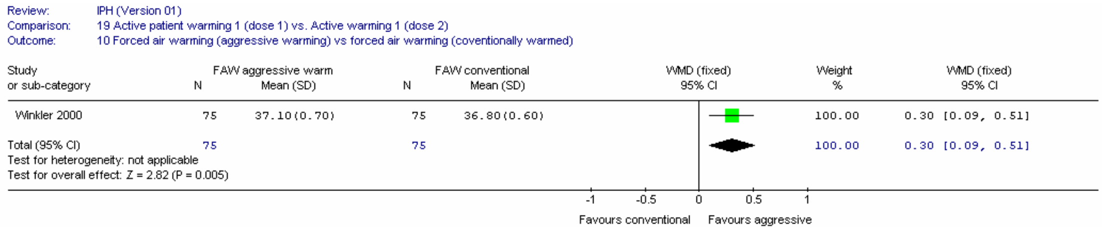
Figure 105: Intraoperative core temperature; forced air warming (aggressive warming) versus forced air warming (conventional warming); regional anaesthesia



2. Outcome: core temperature – PACU (3 hours)

One study (Winkler 2000) with 150 patients reported the mean core temperature at 3 hours in PACU. The mean core temperature was significantly higher for the aggressive forced air warming group: MD 0.30°C (95%CI 0.09, 0.51) for a mean core temperature of 36.8°C for the conventionally warmed group (Figure 106).

Figure 106: Final intraoperative core temperature; forced air warming (aggressive warming) versus forced air warming (conventional warming); regional anaesthesia



3. Blood loss

Blood loss was estimated during the intraoperative period; 6 hours in recovery, and; the first and second postoperative mornings. Intraoperative blood loss was estimated by combining changes in sponge weights with scavenged blood volume. Observers who calculated blood recovered by a red-blood cell scavenging system and weighed the gauze-sponges were blinded to group assignment. Median and interquartile ranges for the aggressively warmed and conventionally warmed groups were reported and the authors stated that the difference in intraoperative blood loss and total blood loss was statistically significant in favour of the aggressively warmed group.

Volume of median blood loss for the aggressively warmed and conventionally warmed groups respectively were as follows:

- Intraoperative blood loss: 488ml (IQR 368 to 721) and 618ml (IQR 480 to 864); the difference was significant (p=0.002);
- At 0 to 6 hours at 600ml (IQR 400 to 820) and 600ml (IQR 368 to 835);
- At 6 hours after surgery until the first postoperative morning: 200ml (IQR 120 to 280) and 220ml (IQR 110 to 400);

The total blood for the aggressively warmed and conventionally warmed groups respectively were as follows: 1531ml (IQR 1055 to 1746) versus 1678ml (IQR 1366 to 1965); the difference was significant (p=0.031).

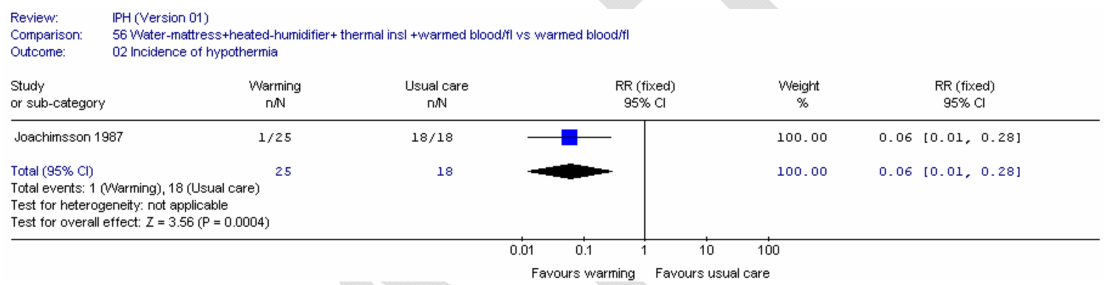
VII. Active 1 + active 2 + thermal insulation versus usual care

One study (Joachimsson 1987a) with 43 patients undergoing major abdominal surgery reported intraoperative core temperature under general anaesthesia. Patients in the intervention group received active warming (water mattress and heated humidifiers) and thermal insulation (reflective blankets) and the control group received usual care. Patients in both arms received warmed fluids and blood products. The authors reported that 33% of the patients (n=14/43) received epidural analgesia.

1. Incidence of hypothermia

One study (Joachimsson 1987) with 45 patients reported incidence of hypothermia at end of surgery. Only the results presented at the following temperature ranges were considered: 35.9°C to 35.0°C; 34.9°C to 34.0°C; less than 34°C. It was decided to combine the events for the three temperature ranges. The study reported that one patient in the warmed group and all the patients in the control group had core temperatures less than 36.0°C. There was a significantly lower incidence of hypothermia in the warmed group (RR 0.06 [95% CI 0.01, 0.28]). This corresponds to an NNT 2 (95% CI 1, 2) for a control group rate of 100% (18/18) (Figure 107).

Figure 107: Incidence of hypothermia; active 1 + active 2 + thermal insulation versus usual care



2. Intraoperative core temperature

One study (Joachimsson 1987a) with 43 patients reported mean core temperature in the intraoperative period. The mean core temperature for the warmed group was significantly higher throughout the intraoperative period. Mean duration of surgery was over 5 hours for both groups (Figure 108).

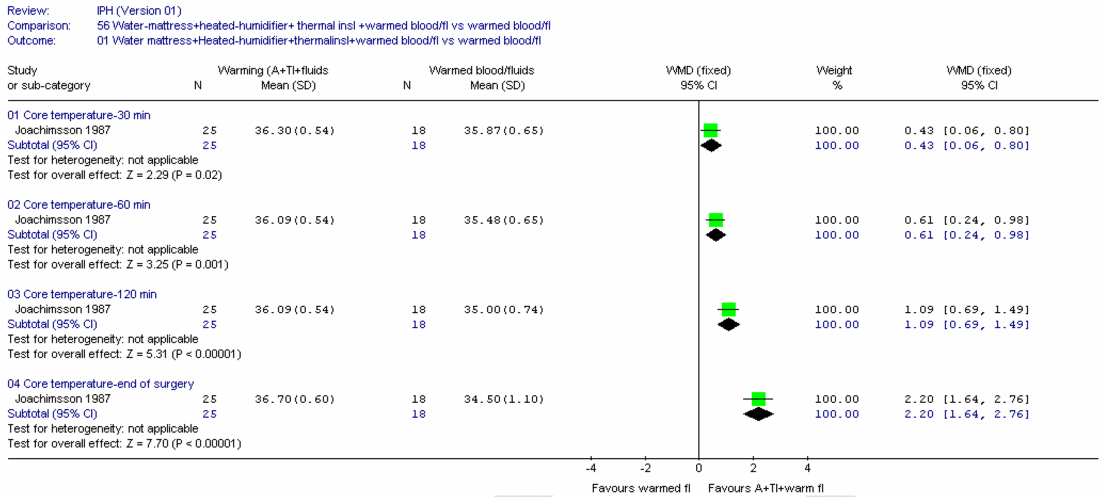
At 30 minutes the mean core temperature for the warmed group was significantly higher: MD 0.43°C (95% CI 0.06, 0.80) for a control group temperature of 35.8°C. This was clinically significant although the confidence interval is fairly wide.

At 60 minutes the mean core temperature for the warmed group was significantly higher: MD 0.61°C (95% CI 0.24, 0.98) for a control group temperature of 35.4°C. This was clinically significant although the confidence interval is fairly wide.

At 2 hours the mean core temperature for the warmed group was significantly higher: MD1.09°C (95% CI 0.69, 1.69) for a control group temperature of 35.0°C. This was clinically significant although the confidence interval is wide.

At end of surgery the mean core temperature for the warmed group was significantly higher: MD 2.20°C (95% CI 1.64, 2.76) for a control group temperature of 34.5°C. This was clinically significant although the confidence interval is wide.

Figure 108: Core temperature; active 1 + active 2 + thermal insulation versus usual care



NB: Scale -4 to 4

VIII. Thermal insulation (site 1 + 2) versus thermal (site 1)

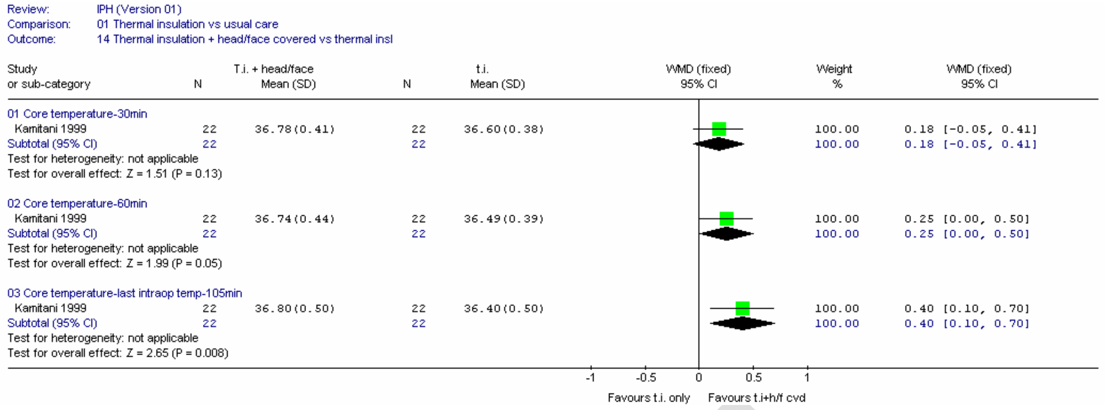
A. Combined general and regional anaesthesia

One study (Kamitini 1999) with 44 patients undergoing abdominal surgery under general and regional anaesthesia compared the effectiveness of thermal insulation at the head and face in addition to thermal insulation on extremities and trunk. Patients in the control group received thermal insulation on the extremities and trunk only.

At 30 minutes there was no significant difference. At 60 minutes the mean core temperature was borderline for significance favouring the intervention group: MD 0.25°C (95% CI 0.00, 0.50) for a control group temperature of 36.4°C. This is not clinically significant.

Final intraoperative temperature was recorded at 105 minutes. The mean core temperature was significantly higher in the intervention group: MD 0.40°C (95% CI 0.10, 0.70) for a control group temperature 36.4°C. The confidence interval is fairly wide.

Figure 109: Core temperature; thermal insulation (site 1 + 2) versus thermal insulation (site 1); combined regional and general anaesthesia


Review: IPH (Version 01)
Comparison: 01 Thermal insulation vs usual care
Outcome: 14 Thermal insulation + head/face covered vs thermal insl
Study or sub-category
T.i. + head/face N Mean (SD)
t.i. N Mean (SD)
WMD (fixed) 95% CI
Weight %
WMD (fixed) 95% CI
01 Core temperature-30min
Kamitani 1999 22 36.78(0.41) 22 36.60(0.38) 100.00 0.18 [-0.05, 0.41]
Subtotal (95% CI) 22 22 100.00 0.18 [-0.05, 0.41]
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.51 (P = 0.13)
02 Core temperature-60min
Kamitani 1999 22 36.74(0.44) 22 36.49(0.39) 100.00 0.25 [0.00, 0.50]
Subtotal (95% CI) 22 22 100.00 0.25 [0.00, 0.50]
Test for heterogeneity: not applicable
Test for overall effect: Z = 1.99 (P = 0.05)
03 Core temperature-last intraop temp-105min
Kamitani 1999 22 36.80(0.50) 22 36.40(0.50) 100.00 0.40 [0.10, 0.70]
Subtotal (95% CI) 22 22 100.00 0.40 [0.10, 0.70]
Test for heterogeneity: not applicable
Test for overall effect: Z = 2.65 (P = 0.008)
-1 -0.5 0 0.5 1
Favours t.i. only Favours t.i+h/f cvd