NICE National Institute for Health and Care Excellence

Surveillance report 2017 – Head injury: assessment and early management (2014) NICE guideline CG176

Surveillance report

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Contents

Surveillance decision

We will not update the guideline on head injury at this time.

During surveillance editorial or factual corrections were identified. Details are included in appendix A: summary of evidence from surveillance.

Reason for the decision

Assessing the evidence

We found 100 studies through surveillance of this guideline.

This included evidence that is consistent with current recommendations relating to:

- pre-hospital assessment, advice and referral to hospital
- immediate management at the scene and transport to hospital
- assessment in the emergency department
- investigating clinically important brain injuries
- transfer from hospital to a neuroscience unit
- admission and observation
- discharge and follow-up.

We did not find any evidence on:

- investigating injuries to the cervical spine
- information and support for families and carers.

We did not find any evidence in areas not covered by the original guideline.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the evidence and views of topic experts and stakeholders, we decided that no update is necessary for this guideline.

See how we made the decision for further information.

Commentary on selected evidence

With advice from topic experts we selected 3 studies for further commentary.

Immediate management at the scene and transport to hospital – immediate management

We selected the randomised trial by Garner et al. (2015) for a full commentary because it highlights the difficulties in identifying traumatic brain injury at the scene of injury.

What the guideline recommends

The guideline does not make recommendations on the type of clinician who should provide immediate management. Instead, it recommends care based on the principles set out in several training courses for medical staff.

Methods

The HIRT trial (Head Injury Retrieval Trial) assessed helicopter physician response in addition to standard paramedic ground response compared with standard paramedic ground response alone in people with severe blunt head injury in Sydney, Australia. Physicians had training and experience in anaesthesia, emergency medicine, or intensive care medicine. If the helicopter physician had not arrived by the time the paramedic was ready to leave the scene, the paramedic proceeded with transport to hospital, unless the patient had high-grade airway obstruction. The patient was transported to hospital in the helicopter only if it was faster than by ambulance. The paramedics could cancel the helicopter physician if they judged that the patient did not need a higher level of intervention.

People aged older than 15 years with reported altered consciousness or high-energy mechanism of injury were identified by monitoring the ambulance dispatch system. Incidents with 5 or more casualties were excluded because of additional procedures in such cases.

The trial originally included people with Glasgow Coma Scale (GCS) score of less than 9;

however, after the first interim analysis this criterion was changed to CGS 3–12 and abbreviated injury score (AIS) of 3 or more. This was because many people meeting the original criterion did not have severe brain injury, and conversely, many people not meeting the criterion did have severe brain injury.

Randomisation was done using computer-generated permuted blocks of 10, stratified by mechanism of injury. Blinding of treating physicians was not possible, however, the outcome assessment at 6 months was made blind to treatment allocation. The sample size calculation indicated that 510 participants would be necessary, with a predicted rate of non-compliance of 5%.

The primary outcome was Glasgow Outcome Score at 6 months, categorised as either: death, persistent vegetative state, severe disability, moderate disability or good recovery. Secondary outcomes included 30-day mortality.

Results

Overall, 3,124 incidents were randomised, and of these 182 people allocated to physician care and 156 patients allocated to paramedic care were eligible for inclusion according to the modified inclusion criteria. Compliance was also lower than anticipated, with 25 of the 182 patients (14%) allocated to physician care not treated by a physician, and 32 of the 156 patients (21%) allocated to paramedic care treated by a physician. The study stopped early because of the low recruitment and high rate of non-compliance. The authors noted that non-compliance was driven by changes in policy that increased the use of physician care, and this was expected to further reduce compliance.

People allocated to the physician care were at the scene of injury for 6 minutes longer than those allocated to paramedic care (p=0.02 for patients meeting modified criteria). There was no significant difference in Glasgow Outcome Score at 6 months (odds ratio [OR] 1.14, 95% confidence interval [CI] 0.73 to 1.75, p=0.56 for patients meeting the modified criteria). There was also no significant difference in 30-day mortality (OR 1.05, 95% CI 0.66 to 1.66, p=0.84 for patients meeting modified criteria).

Strengths and limitations

Strengths

This study attempted to address an important question using robust methods. However, it

had several limitations that were outside of the investigators' control and appear to be common problems when conducting trials in emergency medicine. The authors reported the changes in protocol and non-compliance clearly, which is a strength of the report.

Limitations

The main limitations of this study were the change in inclusion criteria after the trial started, the low recruitment rate and the high rate of non-compliance. Although no significant effect was seen in this study, this may have been influenced by the lower number of participants than the power calculation indicated. Therefore, an effect cannot be ruled out.

Impact on guideline

This study found no evidence of an effect of physician care on patients' outcomes, and thus cannot affect current recommendations, which do not specify the type of clinician to respond to cases of potential brain injury. However, the study highlights the issues with identifying head injury at the scene of injury, in that GCS alone was inadequate for predicting severe traumatic brain injury.

Immediate management at the scene and transport to hospital – transport destination

We selected Lecky et al. (2016) for a full commentary because it was a UK-based study that aimed to address a research recommendation from the 2007 version of the guideline.

What the guideline recommends

The guideline recommends transporting patients who have sustained a head injury directly to a hospital that has the resources to further resuscitate them and to investigate and initially manage multiple injuries. All acute hospitals receiving patients with head injury directly from an incident should have these resources, which should be appropriate for a patient's age. In the NHS in England, these hospitals would be trauma units or major trauma centres. In the NHS in Wales, this should be a hospital with equivalent capabilities.

Methods

The HITS-NS study (Lecky et al. 2016) was a cluster randomised controlled trial that assessed the feasibility of a future trial to assess the effectiveness of early neurosurgery. Overall 74 ambulance stations were randomised using a stratified matched pair design to take people with suspected brain injury to either a neurosciences centre (for potential early neurosurgery) or to the nearest emergency department (standard care).

The primary outcomes for feasibility of the study were:

- recruitment rate that would enable meeting the number of participants indicated by the power calculation in a reasonable time-frame (350 patients in a year with monthly recruitment increasing each month; the full trial would have needed to recruit 4,200 patients within 3 years)
- rates of diagnosis of traumatic brain injury in patients recruited to the trial not exceeding 80%
- rates of non-compliance with trial randomisation of no more than 10%
- absence of selection bias associated with non-compliance (the characteristics of patients in the compliant and non-compliant groups should not differ significantly)
- number of eligible patients listed on the Trauma Audit and Research Network database who were not recruited into the study
- acceptability of both treatment pathways to patients and carers (measured by questionnaire and a nested qualitative study).

Patients eligible for the study were aged 16 years or older with signs of significant traumatic brain injury such as reduced consciousness and external signs of head injury. Eligible patients also needed to have no obvious signs of airways, breathing or circulatory compromise. Additionally, patients must have been injured in a location no more than 1 hour's travel to a neuroscience centre. Time to neurosurgery was measured from the point that the ambulance left the scene of injury. Neurosurgery was defined as craniotomy for intracranial haematoma, debridement of open fractures, or insertion of an intracranial pressure monitor.

Blinding was maintained where possible; however, clinical staff in participating sites were not blind to the patient's trial status. Patients were considered to have been initially blind

to their destination because of their reduced level of consciousness. The researcher who recorded 30-day mortality was blinded throughout the study. Participants who survived to discharge from hospital were identified and approached to consent to use of their data in the study.

A second part of the study was a health economic analysis of management pathways for adult patients with stable suspected significant head injury.

Results

Overall, data were available for 30-day mortality in 273 people and 6-month outcomes in 57 people. The outcome of achieving recruitment levels that would demonstrate feasibility of a full-scale trial was thus not met. In analysis of the robustness of the methods of identifying eligible patients, only 5 patients eligible for inclusion were not identified. However, of the 184 people identified as not eligible for inclusion, 64 people with GCS at the scene that met exclusion criteria had traumatic brain injury had, and 23 of those needed neurosurgery.

There were no significant differences in patients' characteristics between the patients in the intervention group (taken to a neurosciences centre) and those in the control group (taken to the nearest emergency department). The proportion of participants who had traumatic brain injury was lower than the 80% needed to demonstrate feasibility of the study, at 21.6% in the intervention group and 30.7% in the control group (25% overall; between-group difference −9.1%, 95% CI −19.7% to 1.5%).

Neurosurgical intervention was performed in 20 people overall; 11.4% of people in the intervention group and 31.4% of those in the control group (between-group difference −20.0%, 95% CI −38.6% to 1.4%). It was not possible to assess the effects of early neurosurgery in this small sample. A significantly lower proportion of people in the intervention group were transferred to another hospital after their initial admission (4.9%) compared with control (15.8%; between-group difference −10.9%, 95% CI −18.3% to −3.4%).

The overall compliance with transfer according to allocated group (62%) was substantially lower than the 90% needed to demonstrate feasibility of a larger study. The compliance was reported to be significantly lower in the intervention group (49%, 95% CI 41% to 57%) than in the control group (81%, 95% CI 72% to 91%). In analysis of selection bias arising from non-compliance, the only factor that differed significantly was the estimated time

from a neurosciences centre.

Patients in the intervention group were less likely to be taken to a neurosciences centre (that is, not to comply with intervention) when the estimated time to the neurosciences centre was an average of 3.5 minutes longer (95% CI 6.3 to 0.6 minutes), than when there was compliance with trial-assigned destination. Patients in the control group were more likely to be taken to a neurosciences centre (that is, not to comply with control) when the estimated time to a neurosciences centre was 2.6 minutes shorter (95% CI 1.5 to 12.0 minutes) than when there was compliance with control trial-assigned destination.

Patients' satisfaction was measured with a questionnaire in 28 patients or their carers, of whom 40% of patients had traumatic brain injury diagnosed on admission. Although statistical analysis of responses was not reported, generally people appeared to be satisfied with little difference between the intervention and control groups. The qualitative study indicated that participants viewed research as important, which influenced their decision to participate. However, participants did not always fully understand the purpose of the trial, but remained happy about their participation after this was explained.

In the health economic deterministic base-case analysis, compared with selective transfer, routine transfer of patients with traumatic brain injury to a neuroscience centre was the most cost-effective option with an incremental cost-effectiveness ratio of £2,217. Routine bypass to neuroscience centres may not be cost effective compared with selective transfer, with an incremental cost-effectiveness ratio of £27,100. The probabilistic base-case analysis produced similar results, at £2,260 and £27,157, respectively. Sensitivity analyses demonstrated that results were critically dependent on the costs and effects for routine transfer and bypass strategies. Additionally, alternative assumptions about life expectancy after injury, utility associated with Glasgow Outcome Score, neurosurgery costs, and discounting rates changed the results in favour of bypass.

Strengths and limitations

Strengths

The RCT part of the study was well planned and conducted and clearly reported. Although there were several limitations, these were generally unforeseeable and out of the authors' control. Importantly, these were clearly acknowledged and explained, which was a strength of the report.

Limitations

The authors noted that around the time their study began recruitment, a new model of trauma care was being established in NHS England, in which patients with major trauma would usually be taken directly to a major trauma unit, and these units generally have neuroscience facilities. The trial protocols were subsequently amended in several areas: for example, specific eligibility criteria on GCS or respiratory rate were changed in response to the service-wide changes in trauma bypass, but these criteria differed across the 2 participating ambulance services.

Additionally, the authors recognised that several economic model inputs were based on unadjusted data or expert opinion, so the base-case analysis should be regarded with caution.

Impact on guideline

The changes in the trauma services mean that, increasingly, people with head injury and a low GCS will be admitted to a hospital that has on-site neuroscience facilities. This means that a future randomised controlled trial to answer this question would be even more difficult to implement. Furthermore, the question about whether early neurosurgery is beneficial remains to be answered.

This study indicates that many people with reduced consciousness at the scene of injury do not have traumatic brain injury or a need for neurosurgery. Conversely, people with high levels of consciousness often do have traumatic brain injury and may need neurosurgery. This adds to similar findings in the study by Garner et al. (2015), which needed to modify its inclusion criteria because of poor detection of head injury in the pre-hospital setting. Systems for secondary transfer of patients with traumatic brain injury who need neurosurgery on to major trauma centres therefore must be provided until more reliable methods for paramedics to assess traumatic brain injury become available.

The evidence has little impact on the current recommendation to transport people with suspected head injury to to a hospital that has the resources to further resuscitate them and to investigate and initially manage multiple injuries, which would generally be trauma units or major trauma centres. The foundations of this recommendation still apply, although patients may be more likely to be taken to a major trauma centre under current trauma policies.

Investigating clinically important brain injuries – people taking warfarin at the time of head injury

We selected the cohort study by Mason et al. (2017) for a full commentary because it was a UK-based study investigating a question that is highly relevant to the guideline.

What the guideline recommends

Current guidance recommends that all patients having warfarin treatment who have sustained a head injury, with no other indications for CT, should have CT within 8 hours of the injury.

Methods

The AHEAD study included 3,566 people who presented to an emergency department with head injury between September 2011 and March 2013, who were taking warfarin at the time of injury. Overall, 33 hospitals across England and Scotland participated in the study. Head injury was defined as any non-penetrating injury above the neck.

Research staff at participating hospital used routine medical records to identify consecutive patients from all attendances at the emergency department and obtain basic information on demographics and the injury. Investigations of the injury were undertaken according to clinical need and no additional investigations were needed as part of the study.

To minimise missing eligible patients, people taking warfarin, those undergoing head CT, and people having their international normalised ratio (INR) checked were assessed for inclusion. After identification, patients were sent a package of information and an opt-out method was used for consent.

Research staff followed-up with the patient 10 weeks after their attendance at the emergency department. CT reports were retrospectively reviewed by an independent group of clinical experts and classified as: intracranial abnormality likely to be due to injury; other abnormality likely to be due to injury; abnormality not likely to be due to injury; and normal CT. This classification was agreed before any CT reports were reviewed and a selection of 381 scans reviewed by 5 reviewers suggested good reliability (Krippendorff's alpha 0.82, 95% CI 0.77 to 0.86).

The primary outcome of interest was an adverse outcome, defined as death or neurosurgery resulting from the initial injury, CT findings of brain injury or re-attendance with significant head-injury-related complication within 10 weeks of the initial injury. Detecting risk factors for adverse events was a secondary aim. The sample size calculation suggested that 3,000 people would be needed to detect a doubling in risk for up to 10 potential risk factors. Missing data were dealt with using multiple imputation.

Results

About two-thirds of the 3,534 people included in the study had no symptoms of head injury (n=2,428, 68.7%). Most people had GCS of 15 at admission (n=2,871, 81.2%), and a minority had GCS of 12 or lower (n=60, 1.7%). Most people had their INR measured (n=2,934, 83%) but less than a third of people had INR outside the normal range, defined as 2–4 (n=993, 27.1%). Less than two-thirds of patients had CT (n=2,114, 59.8%);

Overall, adverse outcomes were seen in 5.9% of patients (n=208). This included 192 intracranial abnormalities likely to be due to injury (5.4%); 18 neurosurgeries (0.5%); 37 re-attendances (1.0%) and 41 head-injury related deaths (1.2%). People with more than one category of adverse event were counted only once in the overall data.

Univariate analysis assessed GCS, INR, vomiting, amnesia, loss of consciousness and headache. Age and sex were considered to be potential confounders. Compared with GCS of 15, all lower GCS scores were associated with significantly greater risk of adverse outcome (all $p<0.001$). The risk increased as GCS fell: at GCS 14, the relative risk (RR) of adverse outcome was 3.11 (95% CI 2.20 to 4.41); at GCS 13, the RR was 8.79 (95% CI 5.37 to 14.37); and at GCS 12 and below, the RR was 10.53 (95% CI 7.90 to 15.36).

For INR, univariate Poisson regression suggested a significant association between increased INR and adverse outcomes ($p=0.029$), but after excluding people with GCS less than 15 (as a confounding factor), there was no longer a significant association (RR 1.11, 95% CI 0.95 to 1.18, $p=0.298$).

For the neurological symptoms – vomiting, amnesia and loss of consciousness – all were significantly associated with adverse outcomes, and all remained significant after excluding people with GCS less than 15 (all analyses $p<0.001$). The RRs for people with GCS 15 were:

- 9.84 (95% CI 5.65 to 16.56) for vomiting

- 14.07 (95% CI 10.36 to 18.83) for amnesia
- 10.48 (95% CI 7.61 to 14.26) for loss of consciousness.

Headache was significantly associated with adverse outcome ($p<0.001$) overall, but not in people with GCS 15 ($p<0.062$). The lowest risk of adverse outcome was in people with GCS 15 and no symptoms (RR 2.7, 95% CI 2.1 to 3.6).

Strengths and limitations

Strengths

This study identified patients at a large number of emergency departments in the UK, and performed expert analysis of CT reports, which should have increased the reliability of the classification system.

Limitations

This cohort study was observational in nature, and as such, is at risk of confounding. The authors noted the possibility of missing some adverse outcomes and that they had no gold standard reference test for the adverse outcomes. Additionally, because the study did not require specific information to be recorded at the time of treatment, some data values were missing.

Impact on guideline

This study provides some support for the current recommendation to perform CT in people with head injury who are taking warfarin even if they have no other symptoms. This study suggests that a small proportion (2.8%) of people on warfarin and no symptoms may have clinically important brain injury. Although the authors noted that the risk in this population was low (RR 2.7), it was higher than the threshold of RR 2 that they designated as clinically important. The study was conducted before the current recommendation was issued, so the third of patients who did not receive CT would now be eligible.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on a surveillance review of NICE's guideline on head injury: assessment and early management (NICE guideline CG176) in 2014.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence

We found 98 studies in a search for observational studies, randomised controlled trials, and systematic reviews published between 31 May 2013 and 27 October 2016. We also included 1 relevant study from a total of 18 identified by members of the guideline committee who originally worked on this guideline. One additional study was identified in comments received during consultation on the surveillance decision

From all sources, we considered 100 studies to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: summary of evidence from surveillance for details of all evidence considered, and references.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline and other correspondence we have received since the publication of the guideline.

Views of stakeholders

Stakeholders were invited to comment on the decision not to update the guideline. Overall, 11 stakeholders responded. See appendix B for stakeholders' comments and our

responses.

Ten stakeholders commented on the proposal to not update the guideline: 7 agreed with the decision and 3 disagreed with the decision.

One commentator suggested that the guideline should cover hypopituitarism as a consequence of head injury. However, because this disorder generally occurs some time after the head injury, it is outside of the remit of the guideline.

One commentator suggested that further recommendations on referral for rehabilitation should be made. However, in this surveillance review, we did not find any new evidence that could impact on recommendations around referral for rehabilitation, and no references were provided by the commentator to support an update in this area. Additionally, a guideline on rehabilitation for chronic neurological disorders, including traumatic brain injury, is planned.

One commentator highlighted a study on the cost effectiveness of CT in people on warfarin. This study was added to the summary of evidence from surveillance, but did not impact on current recommendations.

One commentator suggested that the guideline should include recommendations on sports-related concussion. The guideline did not consider sports-related concussion as a discrete type of injury. Sports-related concussion is thus covered by any recommendation in the guideline that applies to concussion (or mild traumatic brain injury). The strategy for selecting studies focused on methods for identifying people at risk of severe head injury. In response to the consultation comment, the search results were re-checked for studies relevant to concussion or mild traumatic brain injury. A further 2 studies were added to the summary of evidence from surveillance, but did not impact on current recommendations.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

NICE Surveillance programme project team

Kay Nolan
Associate Director

Philip Alderson

Consultant Clinical Adviser

Emma McFarlane
Technical Adviser

Lynne Kincaid
Technical Analyst

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