NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of totally endoscopic robotically assisted coronary artery bypass surgery

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in November 2004

Procedure name

Totally endoscopic coronary artery bypass surgery

Specialty societies

- British Cardiovascular Interventional Society
- Society of Cardiothoracic Surgeons of Great Britain and Ireland

Description

Indications

Patients with coronary artery disease (CAD) with either single or multiple vessel disease.

CAD is the build up of plaque deposits on the inner walls and lining of the coronary arteries, leading to hardening and narrowing of the artery, and decreasing the oxygen supply to the heart muscle. Potential clinical effects include angina and myocardial infarction when oxygen supply to the heart is reduced or cut off, and long term heart muscle weakening leading to heart failure or arrhythmia. One treatment option for patients with CAD is coronary artery bypass graft (CABG) which aims to increase blood flow to the heart muscle by the construction of bypass grafts beyond narrowed or occluded coronary arteries. This is achieved by surgically creating alternative blood flow routes around diseased arteries by harvesting a section of artery from a non-diseased area and attaching it across the diseased site.

Current treatments and alternatives

CABG is usually performed with open surgery through a sternotomy. Lesser invasive approaches avoiding sternotomy, cardiopulmonary bypass and general anaesthesia

have been developed using either left anterior small thoracotomy (LAST), regional anaesthesia or catheter based intervention.

What the procedure involves

The development of endoscopic surgical techniques with robotic assistance has enabled this technology to be used for coronary artery bypass grafting. Systems may vary slightly depending on equipment used but generally consist of a surgeon's viewing and control console with display system (sometimes in three dimensions) at a console with remote-control surgical equipment handles. These handles control robotic arms that position and precisely manoeuvre endoscopic instruments and an endoscope within the patient using software to magnify the distance required to move the remote control handles to deliver small movements of the endoscopic tools, thus reducing the effect of operator muscle fatigue. Some equipment uses voice-controlled robotic arms.

Following deflation of the lung, small-port incisions are made at three intercostal spaces through which one robotic arm carrying the endoscope and two arms with surgical implement attachments are introduced. Grafts are harvested from suitable donor sites, and anastomosis is achieved across the diseased coronary artery in one or more vessels.

TECAB treatment of the beating heart is carried out using a stabilisation device, consisting of two branches like those used in the MIDCAB procedure, that hold the site for anastomosis steady while the heart continues to beat and removes the need for cardiopulmonary bypass. The stabilisation device requires an additional chest incision to be made when it is used.

Efficacy:

Operative time recorded in the case series available varies according to type of procedure undertaken and the number of vessels being bypassed. In 45 consecutive patients undergoing TECAB mean operating time was 4.2 hours for single vessel surgery and 6.3 hours for two vessel surgery(1) . In 35 cases including eight on the beating heart mean operating time was 5.8 hours, and ranged from 3.5 to 8 hours(2). In a small case series of four closed chest procedures (on single or multiple vessels) the median operating time was 4 hours and the maximum time 7.5 hours(3). Finally, in 37 cases (29 on the beating heart) mean operating time for the early cases was 4.7 hours but this was reduced to 3.1 hours following introduction of endoscopic stabilisation(4).

Mean length of stay in an intensive care unit varied between 14 and 74 hours, and mean total length of stay ranged from 5 to 15.4 days.

Fully patent grafts were achieved in 95% (21/22) of cases where this was assessed by post operative angiogram(2).

Intraoperative conversion rates to open procedures, either mini-thoracotomy or full sternotomy, ranged from 51% (19/37)(4) to 18.5 % (5/27)(2) of procedures initiated as TECAB.

Safety:

Where reported separately in the literature for patients undergoing TECAB procedures there were no cases of operative mortality.

Among 45 cases of the TECAB procedure from a case series operative complications included myocardial infarction 2% (1/45) , hypoxic brain dammage2% (1/45), internal thoracic artery injury 2% (1/45), prolonged cross clamp time 9% (4/45), and port access failure 7% (3/45)(1).

In a series of 37 patients followed up to 3 months post TECAB 8% (3/37) needed secondary investigation due to increased drainage, but none displayed delayed wound healing or cosmetic impairment(4).

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to TECAB. Searches were conducted via the following databases, covering the period from their from commencement to 23/09/2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with CAD undergoing a CABG procedure
Intervention/test	Totally endoscopic coronary artery bypass using robotic endoscopic equipment
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on 4 case series, where result for totally endoscopic procedures are reported separately from semi closed chest procedures.

Existing reviews on this procedure

No existing systematic reviews or evidence based guidelines on this procedure were located during electronic searching

Table 1 Summary of key efficacy and safety findings on selective internal radiation therapy

Abbreviations used: MI – myocardial infarction, LVEF – left ventricular ejection fraction, NYHA – New York heart association, ITA – internal thoracic artery, MIDCAB – Minimally invasive direct coronary artery bypass, LAD -

Study Details	Key efficacy findings	Key safety findings	Comments
Dogan S (2002) (1) Case series (consecutive patients) Germany n=45 Single artery bypass = 37 Double vessel bypass = 8 Age =63yrs, Male =71%, LVEF =56%, NYHA class =2.1 Da Vinci telemanipluation system	**Operative parameters** For the single vessel procedure Operating time was 4.2 hours (±0.9) and for two vessel 6.3 hours (±1.0) Postoperative bleeding for the single and double vessel procedures was measured to be 743ml (±671) and 968ml (±821) respectively. For the single vessel procedure the ICU length of stay was 24hours (±21) and total hospital stay 8.6days (±2.7). The corresponding times for the double vessel procedure were 74hours (±64) and 15.4 days (±6.4). **Graft patency** Of 22 patients who had a post operative angiogram only 1 (5%) displayed an ITA graft with non-significant stenosis in the middle segment.	**Operative conversion rates** Complication % n= Conversion to minithoracotomy 15.6 (7/45) Conversion to full sternotomy 6.7 (3/45) The majority of complications were seen in the first 20 patients of the series **Operative complications** Complication % n= Prolonged crossclamp time 8.9 (4/45) Port-access failure 6.7 (3/45) MI 2.2 (1/45) Hypoxic brain damage 2.2 (1/45) ITA injury 2.2 (1/45) Hypovolemic shock 2.2 (1/45) **Post-operative complications** Two patients required postoperative re-exploration due to bleeding from the anastomotic site. There was no wound infection at the port site throughout the series.	Consecutive case series, using a conservative protocol. Authors state that the complications cited exceed those reported for single coronary artey bypass. Significant learning curve in operative skill. No long term outcomes reported post discharge.

Abbreviations used: MI – myocardial infarction, LVEF – left ventricular ejection fraction, NYHA – New York heart association, ITA – internal thoracic artery, MIDCAB – Minimally invasive direct coronary artery bypass, LAD -

Study Details	Key efficacy findings	Key safety findings	Comments
Mohr FW (2001) (2) Case series Germany n=27 TECAB n=8 TECAB on beating heart using stabilisation technique Single artery bypass=35 Age =62yrs, Male =74%, LVEF =64% (demographic and clinical status data for the 27 TECAB patients only) Da Vinci telemanipluation system	**Operative parameters** Operating room time for the 27 TECAB procedures on the arrested heart 347minutes with a range from 3.5 to 8 hours. Length of stay in ICU was 15.5 hours (± 6.4), and overall hospitalisation was a mean 9.4 days (± 2.9). **Graft patency** A fully patent graft as determined by angiography and a good functional result at 3 months was achieved in 95% (21/22) of patients who completed TECAB surgery without conversion to other operative method. **Mortality** No operative mortality was reported in patients undergoing TECAB or those in whom conversion was necessary	**Operative conversion rates** In patients undergoing TECAB with arrested heart the rate of conversion to a minithoracotomy or a sternotomy was 18.5 % (5/27). 4 of these conversions were made interopatively and oen postoperatively. For the 8 patients undergoing TECAB on the beating heart 75% (6/8) of the procedures were converted to a minithoracotomy, these were all elective conversions. **Operative complications** No absolute figures for complications were reported, however, conversion of procedure was required for the following complications, bleeding from the anastomosis, unintended grafting of a large diagonal branch, and torsion of the pedicle. TECAB on beating heart. One patient developed ventricular fibrillation during the procedure which required emergency conversion and required cardiopulmonary bypass.	A heterogeneous patient cohort may make generalisation of findings difficult A large learning curve in operator confidence, and thus later interventions were completed more quickly. If cardiopulmonary bypass and cardiac arrest are still required for TECAB then comparison to the MIDCAB procedure needs to be made.

Abbreviations used: MI – myocardial infarction, LVEF – left ventricular ejection fraction, NYHA – New York heart association, ITA – internal thoracic artery, MIDCAB – Minimally invasive direct coronary artery bypass, LAD -

Study Details	Key efficacy findings	Key safety findings	Comments
Boehm DH (2000) (3) Case series Germany n= 25 open robotic procedures of which n=4 closed chest on beating heart Both single vessel and multiple vessel diseased patients included in the overall cohort, but not clear which patients underwent TECAB Age =63yrs, Male =76%, LVEF =65% (demographic and clinical status data for the 27 TECAB patients only) ZEUS computer assisted surgical system	**Operative parameters** Median overall operating time for the 4 closed chest was 5.5 hours with a range from 4.0 to 7.5 hours. ICU stay was 14 hours (range 12 to 36 hours) and length of hospitalisation was 5 days (range 4 to 11 days) **Mortality** There were no instances of operative mortality in all the procedures throughout the study, including the closed heart interventions.	**Operative conversion rates** 25% (1/4) of the closed chest procedures were converted to a MIDCAB incision, this was owing to a small sized and calcified left anterior descending coronary artery. **Adverse events** No details of adverse events are presented, although no reinterventions were required.	A small port incision of a minimum 2.5cm was required to position the coronary artery stabilisers. Two dimension visualisation gives good resolution on monitors, but three dimensional displays allow for depth perception for operators. Currently operative times for coronary artery anastomoses are longer compared to regular coronary artery surgery Not stated how patients for closed chest surgery were selected from the whole cohort
Kappert U (2001) (4) Case series Germany n=37 TECAB of which n=29 on beating heart Both single and multiple vessel CAD patients Age=62yrs, Male=86%, NYHA class I =8%, class II =42%, class III =48%, class IV =1% (for whole study not just TECAB patients) Da Vinci telemanipluation system 3 months follow up	**Operative parameters** Mean overall operating time for the TECAB procedure was 280 minutes (±80 minutes) prior to introduction of endoscopic stabilisation, and 186 minutes (± 59 minutes) thereafter. ICU stay was 24.9 hours (± 6.4 hours) and length of hospitalisation was 6 days (± 1 day) **Mortality** Operative survival rates were not analysed separately for TECAB treated patients	**Operative conversion rates** Conversion to a MIDCAB procedure in patients undergoing TECAB was necessary in 19 cases, due to poor LAD identification in 5 cases, LAD sclerosis in (5) poor stabilisation (3) plural adhesions (2) intramural LAD course (2) and insufficient occlusion of the LAD (2) **Operative complications** 8% (3/37) of patients undergoing TECAB required a second exploratory investigation owing to increased drainage, bleeding muscle tissue adjacent to the endoscope ports was coagulated thoroughly **Post-operative complications** None of the TECAB treated patients showed any signs of delayed wound healing or suffered cosmetic impairment.	No separate analysis of single and multiple vessel treated patients To ensure good anastomosis and maintain patient safety , conversion to MIDCAB has to be made at the time of LAD opening

Validity and generalisability of the studies

- All the series are drawn from patients at German centres

- Studies include a range of techniques, including TECAB on beating heart

- Carefully selected cohort in case series

Specialist advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

- The TECAB procedure aims to provide angina relief, and could reduce hospital length of stay compared to alternatives

- The procedure can be difficult in terms of vessel identification due to bleeding

- Coronary patency is yet to be established, and there is potential for stenosis or occlusion at site of anastomosis

- Adverse events reported include bleeding and ischemia. And theoretical complications of myocardial infarction, pneumothorax, cardiac tamponade, and lethal haemorrhage have been identified

- The equipment is extremely expensive, and training is required in robot, endoscopic, and off-pump techniques, probably limiting the take-up of the procedure to a minority of sites.

Issues for consideration by IPAC

- There may be significant learning curves for operative time and conversion rates with this procedure, but no formal analysis made in the studies included in this overview.

References

(1) Dogan S, Aybek T, Andressen E, Byhahn C, Mierdl S, Westphal K et al. Totally endoscopic coronary artery bypass grafting on cardiopulmonary bypass with robotically enhanced telemanipulation: report of forty-five cases.[see comment]. Journal of Thoracic & Cardiovascular Surgery 2002; 123(6):1125-1131.

(2) Mohr FW, Falk V, Diegeler A, Walther T, Gummert JF, Bucerius J et al. Computer-enhanced "robotic" cardiac surgery: experience in 148 patients. Journal of Thoracic & Cardiovascular Surgery 2001; 121(5):842-853.

(3) Boehm DH, Reichenspurner H, Detter C, Arnold M, Gulbins H, Meiser B et al. Clinical use of a computer-enhanced surgical robotic system for endoscopic coronary artery bypass grafting on the beating heart. Thoracic & Cardiovascular Surgeon 2000; 48(4):198-202.

(4) Kappert U, Schneider J, Cichon R, Gulielmos V, Tugtekin S-M, Nicolai J et al. Development of robotic enhanced endoscopic surgery for the treatment of coronary artery disease. Circulation Vol. 104(12 SUPPL.):18.

Appendix A: Additional papers on totally endoscopic robotically assisted coronary artery bypass surgery not included in the summary tables

Article title	Number of patients/follow-up	Comments	Direction of conclusions
Falk V, Diegeler A, Walther T, Banusch J, Brucerius J, Raumans J et al. Total endoscopic computer enhanced coronary artery bypass grafting. European Journal of Cardio-Thoracic Surgery 2000; 17(1):38-45.	n=22 TECAB 3 months FU	Same sample as Moliv (2001)	220 to 507 minutes operating time. Conversion rate 18%.
Kappert U, Schneider J, Cichon R, Gulielmos V, Schade I, Nicolai J et al. Closed chest totally endoscopic coronary artery bypass surgery: fantasy or reality? Current Cardiology Reports 2000; 2(6):558-563.	n=13 TECAB 3 months FU	Same sample as Kappert et al (2001)	235 minute surgery 100% survival
Kappert U, Schneider J, Cichon R, Gulielmos V, Matschke K, Tugtekin SM et al. Wrist-enhanced instrumentation: moving toward totally endoscopic coronary artery bypass grafting. Annals of Thoracic Surgery 2000; 70(3):1105-1108.	n=61 n=7 TECAB Follow up to end of procedure	Same sample as Kappert et al (2001)	280 minute surgery. No conversion of technique required
Kappert U, Cichon R, Schneider J, Gulielmos V, Ahmadzade T, Nicolai J et al. Technique of closed chest coronary artery surgery on the beating heart. European Journal of Cardio-Thoracic Surgery 2001; 20(4):765-769.	n=37 n=22 TECAB 3 months FU	Same sample as Kappert et al (2001)	Conversion rate to sternotomy =3.4%. 100% survival

Appendix B: Literature search for totally endoscopic coronary artery bypass surgery

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PredMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1	endoscopy/	9950	Display
2	endoscopy.tw.	10901	Display
3	endoscopes/	1719	Display
4	endoscopes.tw.	574	Display
5	tecab.tw.	12	Display
6	da vinci sytem.tw.	0	-
7	zeus system.tw.	9	Display
8	cabg.tw.	3851	Display
9	grafting.tw.	13909	Display
10	bypass surgery.tw.	4490	Display
11	anastomosis, surgical/	7286	Display
12	anastomosis.tw.	9350	Display
13	coronary artery bypass/	12170	Display
14	e-cabg.tw.	3	Display
15	or/1-14	55372	Display
16	arterial disease.tw.	1732	Display
17	arterial stenosis.tw.	365	Display
18	blocked arter$.tw.	12	Display
19	atherosclerosis.tw.	19004	Display
20	coronary disease/	27057	Display
21	coronary arteriosclerosis/	7204	Display
22	coronary arteriosclerosis.tw.	102	Display
23	arterial occlusive disease/	4775	Display
24	arterial occlusive disease.tw.	780	Display
25	arteriosclerosis/	14710	Display

26	myocardial ischemia/	12347	Display
27	or/16-26	71780	Display
28	15 and 27	6520	Display
29	robot.tw.	790	Display
30	robotics/	2001	Display
31	29 or 30	2203	Display
32	28 and 31	38	Display