Original Article **Brunei Int Med J.** *2010; 6 (2): 76-82*

Use of Heartstring aortic seal device with selective epiaortic scanning in OPCAB

Chee Fui CHONG [1], Mohd Isham JAAFAR [1, 2], Dhakshina Moorthi PERIASAMY [2]
[1] Department of Surgery (Cardiothoracic Division), RIPAS Hospital and
[2] JPMC Cardiac Centre, Jerudong Park, Brunei Darussalam

ABSTRACT

Introduction: Excessive manipulation of the aorta in conventional on-pump coronary artery bypass (ONCAB) is associated with postoperative neurological complications. We assessed the results of a protocol of 'minimal-aortic manipulation' in off-pump-CABG (OPCAB) using Guidant Heartstring aortic-seal with selective epiaortic scanning. **Materials and Methods:** A protocol of 'minimal-aortic manipulation OPCAB' using Heartstring aortic-seals was introduced in patients undergoing OPCAB from January 2005. Data were prospectively collected for one year. Intra-operative epiaortic scanning was selectively used. Mean graft flow and pulsatility index (PI) were routinely measured. **Results:** Sixty-nine Heartstring aortic-seals were used in 31 patients (23 Male; 8 Female). Mean age and left ventricular ejection fraction (LVEF) were 62.5 ± 10.8 years and 57.8 ± 14.2% respectively. Five patients had intra-operative epiaortic scanning performed. Left internal thoracic artery (LITA) to left anterior descending (LAD) artery was achieved in 100% with mean LITA graft flow and PI of 32.09 ± 19.48 ml/min and 3.26 ± 1.74 respectively. Mean flow and PI in radial artery graft (RAG) and saphenous venous graft (SVG) were 20.47 ± 5.37 ml/min; 1.97 ± 0.31 and 22.84 ± 16.88 ml/min; 3.93 ± 2.83 respectively. There were no postoperative neurological complications or death. **Conclusions:** Routine use of Heartstring aortic-seals with selective epiaortic scanning in a protocol driven 'minimal-aortic manipulation OPCAB' is safe. The avoidance of partial aorta cross-clamping may translate to a reduction in postoperative neurological complications.

Keywords: Coronary artery bypass grafting, off-pump coronary artery bypass, stroke, ultrasonography

INTRODUCTION

Off-pump coronary artery bypass surgery or OPCAB was first reported in 1984 as an alternative minimally invasive method of performing coronary artery bypass grafting (CABG).[1] By avoiding cardiopulmonary bypass and aortic cross-clamping, it was hope to address the problem of postoperative stroke secondary to particulate embolisations as complication of conventional on-pump CABG (ONCAB).[2] However, current evidence from large retrospective studies, meta-analysis and prospective randomised controlled trials (RCTs) comparing OPCAB and ONCAB has been conflicting in their reports of stroke risk reduction benefit.[3-]

Correspondence author: CF Chong
Department of Surgery (Cardiothoracic Division), RIPAS Hospital, Bandar Seri Begawan BA 1710, Brunei Darussalam.
Tel: +673 2242424 Ext 272, Fax: +673 2242690
E mail: chong_chee_fui@hotmail.com

[12] This was partly due to the heterogeneity of the different studies and RCTs and in most of these studies, partial aortic cross-clamping was still utilised in performing proximal aorto-saphenous anastomoses.[2]

The introduction of numerous proximal aortic-seal or occluder devices by industries such as the Guidant Heartstring proximal aortic-seal or the Novare Enclosed II devices has allowed the proximal anastomoses to be performed without clamping of the aorta.[13, 14] We investigated the feasibility of a protocol driven 'minimal-aortic manipulation OPCAB', using Guidant Heartstring proximal aortic-seal combined with selective epiaortic ultrasound scanning (USS) in reducing risk of post-operative stroke in patients undergoing surgical revascularisation.

MATERIALS AND METHODS

Patients: We introduced our protocol of 'minimal-aortic manipulation OPCAB' from January 2005 with the routine use of Guidant Heartstring proximal aortic-seal and selective epiaortic ultrasound scanning in patients suspected of significant ascending aortic disease at time of surgery. Data from patients undergoing isolated OPCAB using this protocol were prospectively collected for a period of one year (January to December 2005).

Surgical techniques

All distal anastomoses were performed on OPCAB using Guidant sternal retractor and suction stabiliser to isolate the segment of coronary artery to be grafted. After performing the arteriotomy which was usually approximately 6mm in length, a 1.5 to 2.5mm shunt was inserted into the coronary artery to perfuse the distal coronary vessels while the anastomoses were being performed. In coronary artery less than 1.25mm in diameter, a coronary occluder was used instead. Left internal thoracic artery (LITA) to left anterior descending (LAD) artery was usually performed first in order to perfuse the septum and large bulk of the lateral wall. This was then followed by either the right posterior descending artery (RPDA) or obtuse marginal (OM), using a Guidant Expose apical suction device to elevate and position the apex of the heart.

Proximal anastomoses were performed after completion of each distal anastomosis. The ascending aorta was assessed by the lead surgeon using manual palpation. For ascending aorta that was deemed diseased due to thickening and calcification, epiaortic USS was performed to select a suitable site for insertion of the Guidant Heartstring proximal aortic-seal. The Guidant Heartstring proximal aortic-seal was assembled by the lead surgeon according to the instruction. A four mm aortic puncture was then used to create a hole in the ascending aorta at an area that was soft or selected by epiaortic USS. The puncture hole was then occluded using finger pressure before the Heartstring aortic-seal was introduced into the ascending aorta and deployed. Once deployed, the anastomosis was performed using a 6/0 Prolene suture with the assistant sucking any blood from the operative field.

Once the anastomosis was completed, the suture holding the device in tension was cut and the diaphragm of the aortic-seal was removed by applying control traction on the device. The suture for the anastomosis was then tightened and tied. On occasions when the suture was caught in the diaphragm, the diaphragm is gently pulled out of the anastomosis and cut to release the suture.

Clinical end-points: Clinical end-points were prospectively collected in patients undergoing OPCAB with this protocol and these include postoperative neurological complications and 30-days hospital mortality.

Intraoperative transit flow measurements: Graft flow measurements and pulsatility index (PI) were carried out in all grafts upon completion of each graft and again on reversal of heparin with protamine. The latter reading was taken as the final graft flow and used as indicator of graft patency. All grafts suspected of distal anastomotic problems (high PI>5.0 and poor mean flow) were revised.

Statistical Analysis

All continuous data was presented as mean ± standard deviation and analysed using unpaired student t-test while categorical data were analysed using chi-square test (SPSS version 10, Chicago, Il, USA). A $p<0.05$ was accepted as significant.

RESULTS

A total of 31 patients (23 male; 8 female) underwent OPCAB using this protocol and patients' demographics are presented in table 1. The mean age and LVEF were 62.5 ± 10.8 years and 57.8 ± 14.2% respectively. The mean number of grafts per patient was 3 ± 0.7. Preoperative risk factors consisted of hypertension, diabetes mellitus, hyperlipidemia and smoking. Eleven patients (35%) have a history of previous myocardial infarction while three patients (9.7%) had undergone previous percutaneous coronary intervention (PCI) prior to surgery. Preoperative carotid doppler was performed in 27 patients (87%), all of whom showed minor atherosclerotic disease. One patient had severely calcified ascending aorta typically of eggshell aorta on coronary angiogram and underwent CT angiogram to delineate the severity. Her carotid doppler only showed minor disease.

Perioperatively five patients had intraoperative epiaortic USS performed due to thickening in the ascending aorta on direct digital palpation and this included the patient with the eggshell aortic calcification. Intraoperative epiaortic USS was used to determine suitable sites for inserting the proximal anastomoses.

A total of 93 grafts were performed with LITA to LAD performed in all 31 patients (Table 2). Only three radial artery grafts (RAG) were used and the remaining 59 grafts were saphenous vein grafts (SVG). A total of 69 Guidant Heartstring aortic-seal were used (Table 2). There was an initial learning curve where six devices failed to deploy appropriately with the diaphragm still logged in the introducer despite activating the plunger. Suturing of the diaphragm occurred in three cases but this did not disrupt the anastomoses when removing the diaphragm of the Heartstring aortic-seal.

The mean LITA-LAD graft flow and PI were 32.09 ± 19.48 ml/min and 3.26 ± 1.74 respectively. The mean flow and PI in RAG were 20.47 ± 5.37 ml/min and 1.97 ± 0.31 respectively. The mean SVG graft flow and PI were 22.84 ± 16.88 ml/min and 3.93 ± 2.83 respectively. These are shown in (Figures 1a

Table 1: Demography of OPCAB patients (n = 31).

Mean age (yrs)	62.5 ± 10.8
Gender	
Male: female	23 (71.2%): 8 (28.6%)
Co-morbid conditions	
Diabetes mellitus	16 (52%)
Hypertension	30 (97%)
Hyperlipidemia	29 (93%)
Previous cerebrovascular accident	3 (9.7%)
Smoking	18 (58%)
Carotid doppler (normal/minor disease)	27 (87%)
Previous percutaneous coronary intervention (PCI)	3 (9.7%)
Previous myocardial infarction	11 (35%)
Left ventricular ejection fraction (LVEF)	57.8 ± 14.2%
Mean grafts per patient	3 ± 0.7

and 1b).

There were no perioperative ischaemic events and no postoperative neurological complications in all 31 OPCAB patients. There was no death in all 31 patients undergoing OPCAB using this protocol.

DISCUSSION

The incidence of stroke in patients undergoing conventional ONCAB (2% to 9%) with the severity of the atherosclerosis of the ascending aorta as the single most important risk factor for postoperative stroke occurrence.[15] The majority of these strokes are due to particulate emboli dislodged during manipulation of an atherosclerotic ascending aorta. Aortic cannulation, aortic cross-clamping or partial cross-clamping accounted for 56% of all emboli load with 24% arising during cardiopulmonary bypass (CPB).[15,16] Such adverse neurological events are associated with a five to 10-fold increase in observed mortality and a doubling of hospital length of stay.[17] Furthermore, the 13 years actuarial survival for patients with postoperative CVA is significantly reduced compared to those without CVA.[17]

Table 2: OPCAB Patient's operative demographics (n = 31).

Patients' operative demographics	**OPCAB**
Total Coronary grafts performed	29 (93)
Left internal thoracic artery (LITA) graft	31 (100)
Saphenous vein grafts (SVG)	17 (59)
Radial artery grafts (RAG)	1 (3)
Epiaortic ultrasound scanning	5 (16)
Total Guidant Heartstring aortic-seal used	21 (69)
No. of Guidant Heartstring aortic-seal failed to deploy	6 (19.4)

Figure presented in parenthesis is percentage

By avoiding CPB and aortic cross-clamping, OPCAB has been hotly debated in the cardiac surgery community to be more superior to conventional ONCAB in terms of stroke risk reduction. Numerous clinical trials have been conducted in the past decade comparing the two operative strategies, which included several large retrospective analyses, meta-analyses, and RCTs that address different aspects of ONCAB and OPCAB.[3-12] But despite all these available clinic trials, definitive conclusions regarding whether one technique is better than the other have been difficult to reach. However, several generalisations may be possible. Both operative techniques are excellent with good clinical outcomes and individuals' outcomes were more likely to be depended more on factors other than whether they underwent ONCAB or OPCAB.[18] What is more definitive from all these studies is that they all have shown a common theme which is OPCAB is associated less blood loss and need for transfusion, less myocardial enzyme release after OPCAB up to 24 hours, less early neurocognitive dysfunction, and less renal insufficiency.[18]

The severity of atheromatous ascending aortic disease (AAAD) has been repeatedly shown to be the most important indicator for perioperative neurological events and avoidance of aortic clamping or creating proximal anastomoses in the ascending aorta by using arterial grafts is associated with a significant reduction in postoperative stroke rate.[19] The failure of the various RCTs and non-RCTs to show a significant stroke risk reduction with OPCAB compared to ONCAB has been thought to be due to the heterogeneity of the different trials and in most of these studies, partial aortic cross-clamping was still utilized in performing proximal aorto-saphneous anastomoses.[2] Thus a protocol aimed at avoiding any aortic manipulation particularly those patients proven to have AAAD with epiaortic USS during OPCAB should in theory reduce the risk of peri or postoperative stroke events.

The introduction of proximal aortic-seal devices such as the Guidant Heartstring proximal aortic-seal or the Norvacor II devices can alleviate the need to partially clamp the aorta in order to perform proximal aorto-saphenous anastomoses.[13, 14] There is still a need to manipulate the ascending aorta but

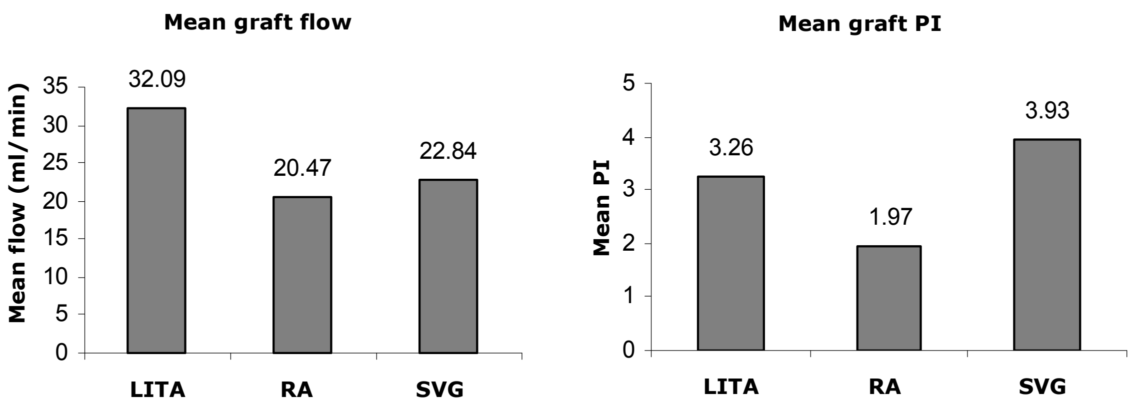

Fig 1: a) Intra-operative transit mean graft flow measurements and 1b) Mean graft pulsatility index (PI) measurements for LITA, RA and SV grafts.

these maneuvers are reduced to a minimum required to insert the devices. A reduction of solid particulate emboli has also been shown to be associated with insertion of such devices compared to performing aortic partial cross-clamping.[20]

Although the incidence of postoperative permanent stroke in our unit is already low at 1.2%, we have introduced this protocol of 'minimal-aortic manipulation OPCAB' by using Guidant Heartstring proximal aortic-seal with selective epiaortic USS as a quality assurance to further improve our unit's performance and perhaps prevent the disastrous complication of a permanent stroke in our patients undergoing OPCAB. Our initial result in 31 patients using this protocol shows that such a protocol, using industrial directed devices is safe and easily implemented. There were no postoperative neurological complications in all 31 patients, even in the patient with severe egg-shell calcification of the ascending aorta. In this patient, the use of epiaortic USS permitted us to find a suitable clean area on the ascending aorta to implant the proximal anastomoses. The use of the Guidant Heartstring proximal aortic-seal avoided the application of an aortic side clamp on such a fragile and diseased ascending aorta.

The use of such devices also did not complicate graft flow as measured using an intra-operative transit doppler flow meter. Graft flows were satisfactory and comparable to previously published data. The use of intraoperative transit doppler flow measurements has the advantage of detecting early graft problems prior to closure of the sternum and this can allow for revision of the graft in the same settings. The number of patients presented in this study is small but the data shown is promising and currently all our patients undergoing OPCAB use this protocol.

In conclusions, a protocol of minimal-aortic manipulation OPCAB using Guidant Heartstring proximal aortic-seal and combined with selective epiaortic USS in high risk patients is safe and easily implemented. The avoidance of partial aortic cross-clamping when performing proximal anastomoses may in the long-term translate into a reduction in postoperative neurological complications. The use of intraoperative transit doppler flow measurements will also detect early graft problems and permit revision of the grafts in order to resolve the problem.

REFERENCES

1: Archer R, Ott DA, Parravicini R et al. Coronary artery revascularization without cardiopulmonary bypass. Tex Heart Inst J 1984; 11:52-7.

2: Mack MJ, Duhaylongsod FG. Through the open door! Where has the ride taken us? J Thorac Cardiovasc Surg 2002; 124:655-9.

3: Hannan EL, Wu C, Smith CR et al. Off-pump versus on-pump coronary artery bypass graft surgery: differences in short-term outcomes and in long-term mortality and need for subsequent revascularization. Circulation 2007; 116:1145-52.

4: Sisillo E, Marino MR, Juliano G, Beverini C, Salvi L, Alamanni F. Comparison of on pump and off pump coronary surgery: risk factors for neurological outcome. Eur J Cardiothorac Surg 2007; 31:1076-80.

5: Racz MJ, Hannan EL, Isom OW et al. A comparison of short- and long-term outcomes after off-pump and on-pump coronary artery bypass graft surgery with sternotomy. J Am Coll Cardiol 2004; 43:557-64.

6: Mack MJ, Pfister A, Bachand D et al. Comparison of coronary bypass surgery with and without cardiopulmonary bypass in patients with multi-vessel disease. J Thorac Cardiovasc Surg 2004; 127:167-73.

7: Reston JT, Tregear SJ, Turkelson CM. Meta-analysis of short-term and mid-term outcomes following off-pump coronary artery bypass grafting. Ann Thorac Surg 2003; 76:1510-5.

8: Parolari A, Alamanni F, Cannata A et al. Offpump versus on-pump coronary artery bypass: meta-analysis of currently available randomized trials. Ann Thorac Surg 2003; 76:37-40.

9: Gerola LR, Buffolo E, Jasbik W et al. Off-pump versus on-pump myocardial revascularization in low-risk patients with one or two vessel disease: perioperative results in a multicenter randomized controlled trial. Ann Thorac Surg 2004; 77:569-73.

10: Straka Z, Widimsky P, Jirasek K et al. Off-pump versus on-pump coronary surgery: final results from a prospective randomized study PRAGUE-4. Ann Thorac Surg 2004; 77:789-93.

11: Puskas JD, Williams WH, Duke PG et al. Off-pump coronary artery bypass grafting provides complete revascularization with reduced myocardial injury, transfusion requirements, and length of stay: a prospective randomized comparison of two hundred unselected patients undergoing off-pump versus conventional coronary artery bypass grafting. J Thorac Cardiovasc Surg 2003; 125:797-808.

12: Nathoe HM, Van DD, Jansen EW et al. A comparison of on-pump and off-pump coronary bypass surgery in low-risk patients. N Engl J Med 2003; 348:394-402.

13: Akpinar B, Guden M, Sagbas E, Sanisoglu I, Ergenoglu MU, Turkoglu C. Clinical experience with the Novare Enclose II manual proximal anastomotic device during off-pump coronary artery surgery. Eur J Cardiothorac Surg 2005; 27:1070-3.

14: Weber A, Reuthebuch O, Turina M. Guidant Heartstring: initial experience in OPCAB surgery. Heart Surg Forum 2005; 8:E4-E8.

15: van der LJ, Hadjinikolaou L, Bergman P, Lindblom D. Postoperative stroke in cardiac surgery is related to the location and extent of atherosclerotic disease in the ascending aorta. J Am Coll Cardiol 2001; 38:131-5.

16: bu-Omar Y, Balacumaraswami L, Pigott DW, Matthews PM, Taggart DP. Solid and gaseous cerebral microembolization during off-pump, on-pump, and open cardiac surgery procedures. J Thorac Cardiovasc Surg 2004;127:1759-65.

17: Calafiore AM, Di MM, Teodori G et al. Impact of aortic manipulation on incidence of cerebrovascular accidents after surgical myocardial revascularization. Ann Thorac Surg 2002; 73:1387-93.

18: Hannan EL, Wu C, Smith CR et al. Off-pump versus on-pump coronary artery bypass graft surgery: differences in short-term outcomes and in long-term mortality and need for subsequent revascularization. Circulation 2007; 116:1145-52.

19: Sellke FW, DiMaio JM, Caplan LR et al. Comparing on-pump and off-pump coronary artery bypass grafting: numerous studies but few conclusions: a scientific statement from the American Heart Association council on cardiovascular surgery and anesthesia in collaboration with the interdisciplinary working group on quality of care and outcomes research. Circulation 2005;31;111:2858-64.

20: Mishra M, Malhotra R, Karlekar A, Mishra Y, Trehan N. Propensity case-matched analysis of off-pump versus on-pump coronary artery bypass grafting in patients with atheromatous aorta. Ann Thorac Surg 2006; 82:608-14.

21: Guerrieri WL, bu-Omar Y, Choudhary BP, Pigott D, Taggart DP. Gaseous and solid cerebral microembolization during proximal aortic anastomoses in off-pump coronary surgery: the effect of an aortic side-biting clamp and two clampless devices. J Thorac Cardiovasc Surg 2007; 133:485-93.