THE CARBO-SEAL COMPOSITE VALVE CONDUIT FOR AORTIC ROOT REPLACEMENT: EARLY EXPERIENCE

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SUMMARY

This study assesses retrospectively early results with the Carbo-seal composite conduit for aortic root replacement in 25 patients operated on for ascending aortic aneurysm and/or dissection with the open technique from August 1993 to January 1999. Fourteen patients were Marfan and 11 non-Marfan. There were 2 operative deaths (8%) for low output state. Two patients were re-explored for bleeding which was not due to transgraft haemorrhage. Post operative complications were 1 stroke, 1 compartment syndrome, 1 haemothorax, 1 pneumothorax, 2 pericardial effusions. During the follow-up one patient died of rupture of a descending aortic aneurysm, and one patient in atrial fibrillation had a transient ischaemic attack. All the remaining patients are well and free of complications. Carbo-seal may be considered a reliable device for use in the aortic root replacement. A long follow-up and a larger population are necessary to confirm these positive early results. *PJCTS 1999;1: 4-7*

INTRODUCTION

Composite graft replacement of the aortic root is a complex operation. One of the main complications encountered during this procedure was the diffuse haemorrhage through the interstices of the Dacron graft (1-6). Numerous authors tried to solve this problem by applying methods for albumin coating and baking of the grafts at the time of the operation (4,5). This diminished haemorrhage to a degree, but it also eliminated the malleable nature of Dacron and increased the operative time. Recently Carbo Medics released the Carbo-seal® tube graft. It was the intention of the manufacturers that the union of these two prosthetic devices should eliminate the risk of haemorrage and the difficulties associated with manipulating and sewing a non compliant graft, while grafting low valve related complication rates. Furthermore, gelatin sealant promotes natural healing and leads to the formation of smooth pseudointima (7,8). Therefore, we decided to assess the results of the Carbo-seal composite valve conduit in our patients operated upon for aortic root replacement with this prosthetic device.

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MATERIAL AND METHODS

From August 1993 to January 1999 60 patients had replacement of the ascending aorta. Twenty five of them underwent aortic root replacement with a Carbo-seal valve conduit. Of these 25 patients, 20 were male and 5 female with an age range of 17 to 76 years (mean 52±7.4). There were 14 Marfan patients. 11 patients had an aortic aneurysm and 3 patients a dissected aortic aneurysm, 3 patients had aortic dissection, 1 patient had annuloaortic ectasia and the remaining patient presented with a new aortic dissection distal to the previous site of repair. All 7 patients with aortic dissection were operated on as emergencies whereas 3 patients received urgent treatment and the remaining 13 patients had an elective procedure. At the time of hospital admission 5 patients were in NYHA functional class I, 11 in II, 4 patients in III and 5 patients in IV. Four patients had a history of chest pain and one had undergone surgical repair of aortic coarctation. Three patients had concomitant ischaemic heart disease.

OPERATIVE TECHNIQUE

In all cases the approach was by median sternotomy. In 16 patients hypothermic (28°C) cardiopulmonary bypass was instituted by means of aortic and right atrial cannulation. In 7 patients the common femoral artery and right atrium were cannulated because of aortic dissection or aneurysm involving the arch which

required profound hypothermic (18°C) circulatory arrest for an open distal aortic anastamosis. Myocardial protection consisted of intermittent cold blood cardioplegia in the coronary ostia and topical 4°C saline solution. Aprotinin was administrated as follows 2,000,000 IU were added to the pump prime, and 500,000 IU/hour were infused continuously until the end of the operation. After the aorta had been opened, large coronary buttons were fashioned in a circular or rectangular shape according to the preference of the operating surgeon. The aorta was then resected completely and the aortic valve was excised. The prosthetic valve was implanted with a continuous 4/0 prolene suture or mattress suture with 2/0 Tevdek according to the surgeon's preference. Once the valve had been implanted, two rectangular or circular buttons of graft were excised with a handheld cautery, and the coronary buttons were then sewn to the graft by means of a continuous 6/0 prolene suture. Finally, the distal end of the graft was anastomosed to the ascending aorta with a 3/0 prolene suture. If aortic dissection was present the separated layers of the aorta were reinforced with strips of Teflon felt and gluteraldehyde-resorcin-formol glue. At the end of the procedure, after careful haemostasis, the pericardium was left open.

PATIENT MANAGEMENT

Postoperatively patients were anticoagulated with sodium warfarin to keep an INR level between 2.5 and 3.5. Before discharge patients underwent a transthoracic echocardiogram for the assessment of the prosthetic valve function and the presence of pericardial effusion. Furthermore during the follow-up patients underwent serial echocardiographic controls by referring cardiologists to monitor development of pseudoaneurysms, increase of aortic diameter involving other segments of the aorta the presence of new intimal tears.

FOLLOW-UP

Late follow-up was carried out at the outpatient clinic or by phone interview for those patients not seen at the clinic. The follow-up ranged from 1 to 62 months with a mean of 23.4±17 months and was 100% complete. Valve associated complications were defined according to the relevant guidelines for reporting valve related morbidity and mortality (9).

RESULTS

Two patients received a 23 mm valve conduit, 8 patients a 25 mm, 8 patients a 27 mm and 7 patients a 29 mm conduit. Four patients had associated coronary artery bypass grafting because of coronary artery disease in 3 patients and of aortic dissection involving the right coronary artery in the fourth patient. Mean cardiopulmonary bypass time and aortic cross clamp time were 186.7±68 and 125.3±34 respectively. 5 patients undergone deep hypothermia mean circulatory arrest time was 25.3±8 minutes.

OPERATIVE MORBIDITY AND MORTALITY

There were 2 operative deaths (8%) they were both due to low output syndrome and both occurred in patients operated on as an emergency for aortic dissection. With regard to bleeding, in one patient with a 27 mm valve conduit, despite a prolonged period of haemostasis excessive bleeding from the proximal anastomosis was observed. After careful evaluation the bleeding was thought to be due to a mismatch between the size of the prosthetic valve and the diameter of the aortic annulus. Therefore a larger Carbo-seal device was implanted. Once the valve conduit had been replaced with a 29 mm, the bleeding was easily controlled and the rest of the procedure was uneventful. Three patients were re-explored. In one patient the source of bleeding was found to be at the suture line of the right coronary button. In the other 2 patients multiple bleeding sites were detected at the back of the sternum. In all 3 cases the bleeding was easily controlled. He is reported free of infection Recurrences at the end of the follow-up 22 months later. Another patient in chronic atrial fibrillation and with a 29 mm conduit had a transient ischaemic attack despite the INR being within the desired range. He underwent transoesophageal echocardiogram which revealed a patent foramen ovale and no prosthetic or intracardiac thrombosis. No further thromboembolic episodes were observed. Of the 18 patients alive at the end of the follow-up, 13 are in NYHA functional class I and 5 patients in class II, and all are free of complications at the time of writing.

DISCUSSION

The operative mortality in our series was simi-

lar to that reported for larger series of patients undergoing similar procedures (5). Both deaths were not related to failure of the device but to the very poor preoperative conditions and the anatomical extent of the lesions. In several reports transgraft haemorrhage was considered to be a major complication of aortic root replacement, being a cause for the large transfusion requirement and high mortality (2-6). The Bentall inclusion technique is a method for controlling this haemorrhage with an additional wrap to a right atrial shunt needed occasionally when bleeding persists (5,6). Moreover the accumulation of blood around the graft can lead to complications such as pseudoaneurysm formation or coronary artery dehiscence at the site of coronary anastomoses (5). In one major series of aortic root replacement the formation of false aneurysm was also observed as a consequence of graft failure (5). In one patient a left haemothorax was observed at chest X-ray the morning after the operation 800 ml of blood was drained. One patient developed a left pneumothorax which required the insertion of a chest drain. One Marfan patient with acute aortic dissection woke up with a stroke and also developed a compartment syndrome which required fasciotomy. The average blood and fresh frozen plasma transfusions were 540±280 ml the 320±120 ml respectively. In one patient the echocardiogram before discharge showed pericardial effusion, on aspiration the fluid was of a straw yellow colour. One patient was readmitted 10 days after discharge for shortness of breath. The echocardiogram demonstrated a pericardial effusion. 800 ml of blood stained fluid were aspirated. The remaining 14 patients had an uneventful post-operative recovery.

FOLLOW-UP

Normal prosthetic valve function was observed in all patients at all echocardiographic controls. In no patients has routine echocardiography revealed the presence of pseudoaneurysms, new dilatations or dissections involving other segments of the aorta. One patient died 2 years after root replacement for aortic dissection because of sudden rupture of a descending aortic aneurysm. At repeated previous transesophageal echocardiographic controls the diameter of the descending aortic aneurysm was 6 cm. One patient developed mediastinitis two months after surgery the CT scan revealed the presence of an anterior mediastinal haematoma. He then underwent successful surgical removal of the infected haematoma. In our series 5 patients experienced bleeding complications, three to an extent requiring re-exploration. In the first two cases this may have been due to the learning curve of one of the operating surgeons an undersized valve prosthesis in the first case and loose suture line around the right coronary button in the second case. In the third patient bleeding was totally unrelated to the Carbo-seal conduit. Finally, one of the first patients in our series was found to have a left haemothorax at a routine chest X-ray the morning after operation 800 ml of blood were drained. Unfortunately at that time it was difficult to assess whether this was caused by graft porosity or surgical bleeding. No cases of transgraft haemorrhage were identified in our series despite that the Bental inclusion technique was not adopted. This finding may confidently be due to the gelatin impregnated Dacron material which minimizes graft porosity (7,8). Furthermore echocardiography carried out on our patients during the follow-up did not show any pseudoaneurysm formation. It is difficult to assess the effects of gelatin impregnated grafts on blood product usage. In a small series confounding variables such as reoperation, circulatory arrest or aprotinin can mask any significant impact on transfusion. In our series blood and fresh frozen plasma transfusions were comparable to those required for non-aortic surgery cases. It could be advocated that the presence of a prefabricated, haemostatic graft may reduce the number of blood product used and shorten the operative time (7,8). During follow-up one patient developed mediastinitis two months after surgery. He underwent successful removal of the haematoma during the operation surgical inspection did not detect any false aneurysm related to the graft. One non-Marfan patient died of sudden rupture of an aneurysm in the descending aorta. As the diameter of the aneurysm did not increase at serial echocardiographic controls, it was decided not to treat it surgically because of the very high mortality and morbidity related to such a procedure (10). Although our case seems not to confirm the policy of periodic echocardiographic assessments, we still share the view that stresses the need for periodic evaluation of the aorta for the lifetime of the patients, especially

those with Marfan syndrome (2,5,6). A high incidence of subsequent operation was observed by Kouchoukos and associates among the patients with Marfan syndrome (5). A similarly high incidence of operation on the residual aorta in patients with Marfan syndrome before or after operations on the ascending aorta or aortic valve was reported by Crawford (11). In our series so far none of the patients have required surgery for an aneurysm involving other segments of the aorta, despite 56% of them being Marfan. As in the other major series the CarboMedics valve has shown satisfactory results in terms of valve related morbidity and mortality (12). Two patients had thromboembolic events. In one patient it occurred during the operation, probably due to deep hypothermia and poor dearing. The other thromboembolic event was observed during the follow-up and it occurred in a patient with atrial fibrillation and a patent foramen ovale, therefore it was quite difficult to establish whether the thrombus developed on the atrial wall or prosthetic surfaces. In conclusion, the Carboseal composite valve conduit may be considered a reliable device for use in aortic root replacement. The combination of satisfactory valve haemodynamics and excellent graft haemostasis and pliability make it one of the composite grafts of choice for this complex procedure. Nevertheless a longer follow-up in a larger population is necessary to confirm these positive early results.

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