ORIGINAL ARTICLE

Efficacy of Unibody Bifurcated Endovascular Stent-Graft Repair in the Treatment of Abdominal Aortic Aneurysm

Chaohai Shi and Quan Chen

Abstract

Objective: To compare the clinical efficacy of unibody bifurcated endovascular stent-graft repair *versus* conventional open surgery for abdominal aortic aneurysm (AAA).

Study Design: Interventional study.

Place and Duration of Study: Department of Vascular Surgery, Gansu Province People's Hospital, China, from January 2015 to December 2016.

Methodology: A total of 80 patients with AAA were randomly divided into Group A and Group B, with 40 cases in each group. Group A was treated with conventional open surgical repair, and Group B was treated with unibody bifurcated endovascular stent-graft repair. The efficacy of the two groups was compared.

Results: The operation time, intraoperative blood loss, postoperative ambulation time, and postoperative hospital stay in Group B were all lower than those in Group A (all $p < 0.001$). The incidence of pulmonary complications and electrolyte imbalance in Group B were lower than those in Group A ($p=0.026$ and $p < 0.001$, respectively). The survival rate of patients in Group B at 6 months, 12 months and 24 months after operation was higher than that of Group A ($p=0.002$, 0.002 and 0.005, respectively).

Conclusion: Unibody bifurcated endovascular stent-graft repair for abdominal aortic aneurysm has advantages of short operation time, little trauma, short recovery time, high safety and efficacy compared with the conventional open surgery.

Key Words: *Unibody bifurcated stent-graft, Endovascular repair, Abdominal aortic aneurysm (AAA), Survival rate.*

INTRODUCTION

Abdominal aortic aneurysm (AAA) refers to the local disease of abdominal aorta associated with systemic fibrous connective tissue degeneration.[1,2] In recent years, the incidence of abdominal aortic aneurysms has shown an increasing trend with the development of medical imaging diagnostic techniques and the aging of the population. Most patients with abdominal aortic aneurysm are asymptomatic, diagnosed by imageological examination for pulsatile mass in the abdomen or other reasons during the physical examination, or mild abdominal discomfort; a few patients have more obvious abdominal pain, which can be stretched to the waist and the back. Severe abdominal pain suggests that the aneurysm has a tendency for rupture or has broken already. However, prognosis associated with AAA rupture is grim, as mortality is high, which has seriously affected the patient's life safety. The traditional method for abdominal aortic aneurysm repair is through open surgery, but the success rate of surgery is low, and it causes great damage to the patient.[3] With the development of surgical techniques, there are more and more surgical methods for treating abdominal aortic aneurysms.

Unibody bifurcated endovascular stent-graft repair is a new method applied in treating abdominal aortic aneurysms in recent years.[4] Research suggested that endovascular treatment of Trans-Atlantic Inter-Society Consensus II (TASC) D aortoiliac occlusive disease using unibody bifurcated endografts was feasible.[5] A study concluded that, compared with patients treated with a well established endograft of the same material and pure infrarenal fixation as the Gore Excluder, the short-term result of the AFX stent-graft system used with infrarenal aortic component was better.[6] Unibody bifurcated stent-graft has its own features in endovascular repair of abdominal aortic diseases. However, relatively few reports have revealed the efficacy of the unibody bifurcated endovascular stent-graft repair compared with conventional open surgery.

The objective of this study was to compare the clinical efficacy of unibody bifurcated endovascular stent-graft repair *versus* conventional open surgery for AAA.

METHODOLOGY

This study was conducted at Department of Vascular Surgery, Gansu Province People's Hospital, China, from January 2015 to December 2016, after approval from the Hospital Ethics and Research Committee. A total of 80 patients with AAA were selected as subjects. Inclusion criteria included patients diagnosed with AAA;

Department of Vascular Surgery, Gansu Province People's Hospital, Lanzhou, 730000, China

Correspondence: Dr. Quan Chen, Department of Vascular Surgery, Gansu Province People's Hospital, Lanzhou, 730000, China

E-mail: mvmj63@163.com

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patients who underwent surgery within 2 hours of admission; and patients with no surgical contra-indications. Exclusion criteria included patients with ruptured AAA; those who did not want to participate in the study; severe complications in the cardiovascular or urinary system; and unconscious patients.

The patients were randomly divided into Group A and Group B, with 40 cases in each group, according to the random number table method. Group A were treated with conventional open surgery, namely, after general anesthesia, the median abdominal incision was taken, the aneurysm neck was exposed by opening the posterior peritoneum, and bilateral internal iliac and external iliac arteries were controlled to protect the ureter. Aneurysms were dissected, plaques and thrombus were removed, lumbar artery, inferior mesenteric artery and middle sacral artery were sutured and ligated, abdominal aortic aneurysm was resected. Prosthetic vessel replacement was performed, and suitable vascular prosthesis was obtained. The straight type of vascular prosthesis was used for those tumors which did not involve the common iliac artery; and the bifurcated type of vascular prosthesis was used for those who involved the double iliac artery. Vascular prosthesis was inserted to reconstruct the abdominal aortic lesions, and the two ends were sutured with the proximal abdominal aorta and the distal abdominal aorta, respectively. The abdominal aorta was opened gradually to avoid the occurrence of clamp hypotension. After restoring the blood flow, the anastomotic outlet was determined to be free of leakage, and then the implanted vascular prosthesis was wrapped by the aneurysmal cyst wall. The operation was completed after suture layer by layer.

Group B were treated with unibody bifurcated endovascular stent-graft repair, namely, based on the stereoscopic imaging results of the preoperative spiral CT for main and brachial artery, one side of the femoral artery was selected as the guide device. Under general anesthesia, the other side of the femoral artery was punctured by Seldinger technique, and the multi-functional catheter was delivered to the contralateral femoral artery under the guidance of the guide wire, which was withdrawn later. Superhard guide wires were introduced into the descending aorta through the femoral incision. The contralateral guide wire on the guide device of unibody bifurcated stent-graft was accessed from the end of the multi-functional catheter, through the contralateral femoral artery, and finally exited from the end of the multi-functional catheter, which was withdrawn later. The guide device was sent to the abdominal aorta bifurcation by means of a superhard guide wire through the femoral artery incision. The contralateral assistant adjusted the contralateral guide wire with the guide device. The guiding device was completely withdrawn to introduce the pigtail catheter. The aneurysm was observed by radiography. If there was endoleak, it could be remedied by balloon expansion or by placing a short stent-type artificial blood vessel (Cuff). The artery and skin incision were sutured layer by layer. The contralateral puncture sheath could be pulled out after 4 hours and bandaged with pressure. Three-dimensional CT imaging after operation showed no endoleak, stent covered slippage, graft occlusion, stent degeneration, stent fracture etc., indicating the success of the operation (Figure 1).

Figure 1: Three dimensional CT imaging after operation.

The operation of the two groups of patients was observed. Complications such as electrolyte disturbance during perioperative period were compared between the two groups. One year after hospital discharge, the patient was paid a return visit every 3 months and reviewed once every other year. The survival rate of patients at 6 months, 12 months and 24 months after operation was compared.

SPSS version 25.0 software was adopted for data statistical analysis. Mean ±SD was calculated for numerical variables like operation time, intraoperative blood loss, postoperative ambulation time and post-operative hospital stay, examined by independent sample t-test. Frequencies and percentages were calculated for categorical variables like gender, peri-operative complications, and follow-up survival rates. Chi-square test was applied to compare the categorical variables in two groups. The p-values less than 0.05 were regarded as significant.

RESULTS

Among the 80 subjects, 49 (61.25%) were males and 31 (38.75%) were females, aged 52-79 years, mean age being 65.72 ±6.14 years. Two cases (5.00%) had coexistent iliac aneurysms in Group A, and three cases (7.50%) had iliac aneurysms in Group B.

The operation time, intraoperative blood loss, post-operative ambulation time, and postoperative hospital stay in Group B were all lower than those in Group A (all $p < 0.001$, Table I).

Table I: Comparison of surgical conditions.

Groups	n	Operation time (min)		Intraoperative blood loss (mL)		Postoperative ambulation time(d)		Postoperative hospital stay (d)	
		Mean ±SD	p-value	Mean ±SD	p-value	Mean ±SD	p-value	Mean ±SD	p-value
Group A	40	216.48 ±42.05	<0.001	395.21 ±64.45	<0.001	8.63 ±3.40	<0.001	19.15 ±6.79	<0.001
Group B	40	183.25 ±47.60		90.43 ±7.51		5.15 ±2.04		13.22 ±3.01	

Table II: Comparison of perioperative complications.

Groups	n	Pulmonary complications		Electrolyte imbalance		Cardiac complications		Incision complications	
		n (%)	p-value	n (%)	p-value	n (%)	p-value	n (%)	p-value
Group A	40	16 (40.00)	0.026	25 (62.50)	<0.001	9 (22.50)	0.785	4 (10.00)	0.692
Group B	40	7 (17.50)		9 (22.50)		8 (20.00)		3 (7.50)	

Table III: Comparison of follow-up survival rates.

Groups	n	At 6 months after operation		At 12 months after operation		At 24 months after operation	
		n (%)	p-value	n (%)	p-value	n (%)	p-value
Group A	40	29 (72.50)	0.002	27 (67.50)	0.002	24 (60.00)	0.005
Group B	40	39 (97.50)		38 (95.00)		35 (87.50)	

During the perioperative period, the incidence of pulmonary complications and electrolyte imbalance in Group B were lower than those in Group A (p=0.026 and p <0.001, respectively). There were no significant difference in the incidence of cardiac complications and incision complications between the two groups (p=0.785 and 0.692, respectively, Table II).

The survival rate of patients in Group B at 6 months, 12 months and 24 months after operation was higher than that of Group A (p=0.002, 0.002 and 0.005, respectively, Table III).

DISCUSSION

Unibody bifurcated stent-graft repair is an important endovascular repair for abdominal aortic aneurysm. Since the unibody bifurcated stent-graft does not require to be assembled in the body, the type III internal leakage of the stent junction site is avoided. The bifurcation part of the unibody bifurcated stent-graft is located at the bifurcation of the abdominal aorta, forming a "two-point" fixation with the proximal end of the stent and tumor neck anchor, which enjoys long-term stability after implantation.[7,8] Placement of the guide wire on the opposite side of the unibody bifurcated stent-graft in advance can shorten the operation time and simplify the surgical procedure.[9,10] In view of the above-described advantages of the unibody bifurcated stent-graft, this endovascular repair has received increasing attention.

The amount of intraoperative blood loss can directly reflect the degree of the trauma of the operation and the disturbance of the physiological state of the human body. This study found that the unibody bifurcated endovascular stent-graft repair has obvious advantages in this respect. Its interference to the patient's intraoperative circulatory system is small, and the intraoperative blood loss is significantly reduced compared with the traditional open surgery. No blood transfusion is required. It reduces the economic burden of patients, as well as the risk of complications of blood transfusion. In addition, the time of postoperative ambulation time and postoperative hospital stay in Group B were shorter than those in Group A. It indicated that the vital signs of patients treated with unibody bifurcated endovascular stent-graft repair were more stable, and their physiological state recovered more quickly; which in turn, shortened the postoperative ambulation time and postoperative hospital stay. The results of this study are basically consistent with the findings of Huang *et al*.[11] This also demonstrates the unique advantages of unibody bifurcated endovascular stent-graft repair. Abdullah *et al*. revealed that although not without complications, endovascular stent-grafts might be life-saving to patients who were not candidates for conventional surgical repair.[12] Albertini *et al*. found endovascular repair using the bifurcated powerlink stent-graft as safe and effective, and unibody design seemed to confer advantages in terms of durability.[13]

Further analysis showed that the incidence of pulmonary complications and electrolyte imbalance in Group B patients was lower than that in Group A during the perioperative period. The reason may be that the trauma of the unibody bifurcated endovascular stent-graft repair is relatively small, the blood loss of the patient is little, and the incidence of electrolyte disorder is low; the incision in this endovascular repair is smaller, and small area of the patient's lungs in contact with the external environment contributes to a lower incidence of pulmonary complications in patients.[14] At the same time, the unibody bifurcated endovascular stent-graft repair uses the rapid balloon blocking technique, which can quickly and effectively reduce the amount of bleeding during surgery, prevents patients from hemorrhagic shock, and ensures the blood perfusion of the internal organs during surgery; therefore, reducing the risk of perioperative complications.[15] Postoperative follow-up showed that the survival rate of Group B was higher than that of Group A at 6 months, 12 months and 24

months after operation. The long-term effect of unibody bifurcated endovascular stent-graft repair is better. The conclusions of this study are basically consistent with the findings of O'Neill *et al*.[16]

The unibody bifurcated stent-graft is suitable for most abdominal aortic aneurysms.[17] However, attention needs to be paid to the following problems in clinical use: First, the unibody bifurcated stent-graft requires a more precise length of the main stent. If the length of the main stent is too long, it can easily block the renal artery-opening; if too short, the tumor cannot be completely isolated and the proximal extension stent needs to be added. Therefore, an accurate imaging evaluation is required before surgery; and a customised stent is required, if necessary. Secondly, the operation should ensure that the main body and branch stents accurately enter the abdominal aorta and the bilateral iliac arteries, and that the branch stent is not wrapped with guide wire.[18] Third, during the process of withdrawing the delivery system after the stent is placed, the operator should not pull the stent when passing through the stenosis of the blood vessel to avoid displacement and breakage of the stent.[19] Fourth, after the unibody bifurcated stent-graft is implanted, type I endoleak may occur at the proximal end of the stent. If the proximal anchoring zone of the stent is of sufficient length (>15 mm), the endoleak may be caused by the fact that the stent is not fully attached after implantation.[20] However, as the stent expands, the endoleak gradually disappears without balloon expansion or implantation of a Cuff catheter. If the anchoring zone is short, it is recommended to further implant the proximal extension stent. No endoleaks occurred in patients in the Group B of this study.

CONCLUSION

Unibody bifurcated endovascular stent-graft repair for abdominal aortic aneurysm has advantages of short operation time, little trauma, short recovery time, high safety and efficacy compared with the conventional open surgery. These results need to be confirmed by longer follow-up and larger series.

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