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# Short-term and long-term effects of covered stent endovascular graft exclusion for the treatment of abdominal aortic aneurysm rupture

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**Abstract. – OBJECTIVE: We studied short-term and long-term effects of covered stent endovascular graft exclusion for the treatment of abdominal aortic aneurysm rupture.**

**PATIENTS AND METHODS: From January 2013 to January 2016, 88 patients with fractured abdominal aortic aneurysm were enrolled in this study. Patients were divided into the control group or the open abdomen group (n=52) and the observation group or the isolated group (n=36). Patients in the control group were treated with open abdominal aneurysm resection and artificial blood vessel transplant technique, while patients in the observation group were treated with percutaneous stent graft endovascular graft exclusion. The outcome of two methods was compared.**

**RESULTS: Surgical success rate and the mortality rate after 24 h and 30 days in the observation group were not significantly different than those in the control group ($p>0.05$). Short-term total mortality and complication rate in the observation group were lower than those in the control group and the differences were statistically significant ($p<0.05$). Operative time and intraoperative blood loss in the observation group was significantly less than those in the control group and the differences were statistically significant ($p<0.05$). The comparison of follow-up survival rate, recurrence rate, and secondary surgery rate in two groups showed no statistically significant differences ($p>0.05$).**

**CONCLUSIONS: Short-term effects of endovascular graft exclusion for the treatment of abdominal aortic aneurysm rupture was superior to laparotomy, while the long-term effect was similar.**

Key Words
Covered stent, Endovascular graft exclusion, Abdominal aortic aneurysm, Artificial blood vessel transplant technique.

## Introduction

The rate of abdominal aortic aneurysm (AAA) is about 2.2% and rupture mortality rate is as high as 90%. With the improvement of early diagnosis and intervention rates, mortality rate has been reduced to 5%[1]. People aged 50 and over with sudden abdominal pain, low back pain, decreased blood pressure, pulsatile masses felt in abdomen are considered patients with AAA rupture[2]. Abdominal color Doppler ultrasound is the preferred method for early detection of AAA. This method has several advantages such as simplicity, non-invasiveness, high sensitivity and high detection rate[3]. CTA (computed tomographic angiography) provides more detailed information about AAA anatomic structure and is a good reference for selecting the surgical strategy[4]. Currently, abdominal aortic aneurysm resection and artificial vascular transplantation are the standard surgical procedure for treating AAA rupture[5]. With the advent of new interventional techniques and coated stent, AAA endovascular graft exclusion has become an important choice of treatment[6]. Several studies have shown[7,8] that the short-term mortality and complication rates associated with endovascular graft exclusion are relatively low, but the forward secondary surgery rate is relatively high. In China, laparotomy is still considered the method of choice for treating AAA rupture[9]. We, in this study, analyzed the short and long term effects of covered stent endovascular graft exclusion used for treating aneurysm rupture.

## Patients and Methods

### Patients

Between January 2013 and January 2016, 88 patients diagnosed with ruptured AAA for the first time were enrolled in this study. Diagnosis was realized using color Doppler ultrasound and CAT. Patients with abdominal trauma, abdominal vascular malformations, combined severe under-

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lying diseases (such as heart, liver, lung, kidney and other organs dysfunction), patients with less than 1 month of expected survival time, those who could not tolerate the risk associated with the operation, and those with incomplete follow-up information were excluded. This study obtained the Ethics Committee's approval, and patients, as well as their family members, signed informed consent forms. Patients were divided into two groups according to the method of treatment they received: the control group (n=52) and the observation group (n=36). The baseline data in two groups were comparable (Table I).

### Research Methods

The control group (the open abdomen group) received open abdominal aneurysm resection plus artificial blood vessel transplant, while the observation group (the isolated group) received percutaneous stent graft endovascular graft exclusion. They were all treated by the same medical team. The open abdomen group received incision in the proximity of the xiphoid process and the pubic symphysis abdominal median to detect hemorrhagic effusion in abdominal cavity and retroperitoneal hematoma. If renal artery aneurysm neck was prone to expose, we used direct clamping and blocked the renal artery. In those instances that direct clamping was not possible the subphrenic abdominal aorta was blocked followed by rapid separation of the renal artery and abdominal aorta. Artificial blood vessels (Bard, Murray Hill, NJ, USA) were then used. Bifurcation blood vessel was in end-to-end anastomosis with the bilateral common iliac and the artery, as well as the internal iliac artery on the other side was in end-to-side anastomosis with the external iliac artery. For the isolated group we used general anesthesia and femoral artery approach. Sheath, guide wire and 5 F gold standard pigtail catheter were inserted into abdominal aorta under digital subtraction angiography (DSA) development and the location of abdominal aortic aneurysm was displayed on radiography. Femoral artery was cut off on the other side, and a carrier was put into with bracket and the bracket was placed in the proper position in tumor cavity through fluoroscopy. Abdominal aortic stent graft (bifurcation type purchased from Medtronic, Minneapolis, MN, USA) was released and sacculus was expanded. Subsequently, another single stent graft was placed through lateral femoral artery to contact the trunk.

**Table I.** Comparison of baseline data between patients in two groups.

| Group | Cases | Male/female | Age (years old) (cm) | Aneurysm neck diameter (cm) | Aneurysm neck length (°) | Aneurysm neck angulation (mmHg) | Average aterial pressure | Schumacher type [case (%)] | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | I | IIa | IIb | IIc | III |
| Control group | 52 | 30/22 | 53.6±11.4 | 6.3±1.3 | 3.6±0.7 | 34.9±5.8 | 64.9±4.7 | 8 (15.4) | 12 (23.1) | 16 (30.8) | 10 (19.2) | 6 (11.5) |
| Observation group | 36 | 19/17 | 54.2±13.3 | 6.4±1.2 | 3.5±0.6 | 35.7±5.4 | 65.2±4.2 | 4 (11.1) | 8 (22.2) | 11 (30.6) | 9 (25.0) | 4 (11.1) |
| $\chi^2$ | | 0.208 | 0.325 | 0.426 | 0.427 | 0.634 | 0.129 | 0.626 | | | | |
| $p$ | | 0.648 | 0.549 | 0.632 | 0.739 | 0.527 | 0.865 | 0.960 | | | | |

*Criteria for successful EVGE:* (i) AAA was completely isolated without internal leakage or rupture; (ii) no fracture when stent graft was imported in channel; (iii) accurate positioning of the stent without displacement; (iv) normal form of stent graft without distortion or break angle; (v) smooth blood flow in stent graft without stenosis and occlusion; and (vi) there was no need for second-phase remedies.

### Observation Indexes

Success rate of operation, mortality rate, prevalence of complications, operation time and blood loss during the operation were compared between groups. The follow-up was set for one year, and survival rate, recurrence rate and secondary operation rate were compared between groups.

### Statistical Analysis

SPSS19.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Quantitative data were expressed by the mean±standard deviation and comparisons among groups were tested by *t*-test. Qualitative data were expressed by number of cases or percentage and comparisons within groups were tested (corrected) by $\chi^2$-test. Kaplan-Mayer test was used for the statistical analysis of the survival rate. $p<0.05$ meant that the difference was statistically significant.

## Results

### Success Rate of Operation, Mortality Rate and Prevalence of Complications

Comparison of operation's success rate and mortality rate at 24 hours and 30 days in two groups showed no significant differences ($p>0.05$). Short-term total mortality rate and prevalence of complications in the observation group were significantly lower than those in the control group, and the differences were statistically significant ($p>0.05$) (Table II).

### Operation Time and Intraoperative Blood Loss

Operation time and blood loss during operation in the observation group were significantly lower than those in the control group, and the differences were statistically significant ($p<0.05$) (Table III).

**Table II.** Comparison of success rate of operation, mortality rate and prevalence of complications [case (%)].

| Group | Cases | Success rate of operation | Mortality rate at 24h | Mortality rate at 30d | Total mortality rate | Infection | Gastro intestinal bleed | Heart, lung, kidney dysfunction | Anastomotic stomastenosis | Internal leakage | Graft thrombous | Total Incidence of complications |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Control group | 52 | 43 (82.7) | 6 (11.5) | 7 (13.5) | 13 (25.0) | 2 (3.8) | 5 (9.6) | 9 (17.3) | 2 (3.8) | 0 | 0 | 18 (34.6) |
| Observation group | 36 | 29 (80.6) | 2 (5.6) | 1 (2.8) | 3 (8.3) | 0 | 2 (5.6) | 1 (2.8) | 0 | 1 (2.8) | 1 (2.8) | 5 (13.9) |
| $\chi^2$ | | 0.065 | 0.340 | 1.788 | 3.972 | | | | | | | 4.734 |
| *p* | | 0.798 | 0.560 | 0.181 | 0.046 | | | | | | | 0.030 |

**Table III.** Comparison of anesthesia effect in two groups [%].

| Group | Operation time (min) | Blood loss during operation (ml) |
|---|---|---|
| Control group | 123.4±32.6 | 345.7±45.6 |
| Observation group | 56.7±10.3 | 75.3±16.5 |
| *t* | 6.235 | 6.342 |
| *p* | 0.016 | 0.014 |

### Follow-up Survival Rate, Recurrence Rate and Second Operation Rate

Follow-up survival rate, recurrence rate and second operation rate in two groups did not reveal any significant differences ($p>0.05$) (Table IV).

## Discussion

Although laparotomy has a relatively high rate of mortality and perioperative complications, its mid to long-term curative effects are certain, especially for middle-aged patients with complex anatomical forms unsuitable for graft exclusion[10,11]. Prior studies have shown that only 20% to 46% of all patients are considered suitable for endovascular graft exclusion[12]. It was also demonstrated that bleeding control, was the key to success[13]. Currently, endovascular graft exclusion is considered a mainstream treatment. To increase the chance of success for endovascular graft exclusion, accurate measurements and evaluations must be conducted before the intervention[14]. The following parameters should be considered in those accurate measurements and evaluations: (i) the diameter of the proximal tumor neck. Valiant (Medtronic Company) and Zenith (COOK Company, Bloomington, IN, USA) suggest measuring the distance between outer membrane to outer membrane, while Excluder (GORE Company, Flagstaff, AZ, USA) suggests to measure the distance lining to the endometrium; (ii) the length and the form of the proximal tumor neck; (iii) stenosis and distortion of iliac and femoral artery diameter, and whether iliac artery is obstructed; (iv) the distance from low renal artery to abdominal aorta bifurcation and to bilateral common iliac artery bifurcation; (v) the diameter of abdominal aorta bifurcation; (vi) the appropriate support, straight type, bifurcation type and the main single iliac type. Our results suggested that surgical success rate and mortality rate at 24 h and 30 days in the observation group had no significant differences to those in the control group. Our results suggested that the key factors affecting the success rate were patients' basic conditions, intraoperative blood loss, integrity of tumors excision and the experience of the medical team. Heart, lung, and kidney dysfunction in patients, during and after operation, accounted for 5% to 10% of failures[15]. Intraoperative bleeding can prolong the operation time and this may increase the risk of accidental injuries to nerves and blood vessels[16]. An incomplete tumor resection affects the 30 days mortality rate, and increases the risk of digestive tract delayed hemorrhage, hydrops abdominis and infections[17]. Elements affecting the success rate of graft exclusion are mainly associated with the correct evaluation of preoperative image data, shape and diameters of abdominal cavity blood vessels and experience of the medical team. In treating short and proximal aneurysmal neck (< 15 mm), effective and full proximal anchor is key to a successful operation[18]. For treating retaining iliac artery, distal 24 mm diameter iliac branch is usually used. Iliac artery of tumor sample expansion is taken as anchor area coverage, while internal iliac is kept open[19,20]. Iliac artery bifurcation stents and double-tube technique are often used in these cases[21,22]. Short-term total mortality rate and complication rate in observation group were obviously lower than those in the control group and operative time and intraoperative blood loss in observation group was significantly less than those in the control group. Follow-up survival rate, recurrence rate and secondary surgery rate in the observation group were not significantly different compared to those in the control group.

**Table IV.** Comparison of follow-up survival rate, recurrence rate and re-operation rate.

| Group | Case | Survival rate | Recurrence rate | Reoperation rate |
|---|---|---|---|---|
| Control group | 39 | 32 (82.1) | 10 (25.6) | 4 (10.3) |
| Operation group | 33 | 26 (78.8) | 7 (21.2) | 3 (9.1) |
| $\chi^2$ | | 0.122 | 0.194 | 0.000 |
| *p* | | 0.727 | 0.659 | 1.000 |

## Conclusions

We observed that the short-term effects of endovascular graft exclusion were better than laparotomy while the long-term effects seemed to be similar.

### Conflict of interest

The authors declare no Conflict of Interest.

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