Surgical Treatment for Thoracic Aneurysms: Comparison of Stent Grafting and Open Surgery

Koichi Yuri, MD, Atsushi Yamaguchi, MD, PhD, Daijiro Hori, MD, Manabu Shiraishi, MD, Hiroshi Nagano, MD, Atsushi Tamura, MD, Kenichiro Noguchi, MD, Kazuhiro Naito, MD, Kazunari Nemoto, MD, and Hideo Adachi, MD, PhD

Objectives: Early and mid-term results of stent graft (SG) treatment for thoracic aortic aneurysms (thoracic endovascular aneurysm repair: TEVAR) were retrospectively compared with open surgical treatment.

Methods: The records of 213 patients in whom single thoracic aortic aneurysm repairs had been performed in our department from January 2006 through August 31, 2009 were reviewed. Acute aortic dissection was excluded. Each case was reviewed for indications for TEVAR from an anatomical standpoint. Among 62 cases in which TEVAR was indicated, 30 (SG group) were treated by TEVAR and 32, by open surgery (OP group). Early and mid-term results were analyzed retrospectively in both groups.

Results: There were no operative deaths in either group. The SG group demonstrated significantly less operative bleeding, a shorter operative time, and shorter postoperative hospital stay compared with the OP group. There were 3 deaths in the SG group and 4 in the OP group, which occurred within an average of 656.4 days during the follow up period. The 3 year actuarial survival rate was 88.7% in the SG group and 87.1% in the OP group, and there were no significant differences between the groups.

Conclusion: Although early and mid-term results of TEVAR and open surgery were similar, TEVAR is generally less invasive and may be preferable for high-risk patients, compared with open surgical repair.


Keywords: thoracic aortic aneurysm, vascular surgery, endovascular surgery

INTRODUCTION

With advances in medical techniques in recent years, surgical treatment for thoracic aneurysms has markedly improved. The indications for surgery have expanded to patients with complications and elderly patients, and surgery has been actively performed. In 2008, commercially available SG devices for thoracic aneurysms began to be covered by insurance in Japan, and treatment choices have increased. Therefore, the indications for stent grafting (SG) for thoracic aneurysms are expected to expand further.

Open surgery for thoracic aneurysms is an almost established method. However, in many cases, its invasiveness requiring thoracotomy and extracorporeal circulation is a problem. On the other hand, since SG (thoracic endovascular aneurysm repair: TEVAR) is a new treatment method, its long-term results are still unclear. At present when there are many treatment choices, the indications for both should be adequately considered, and the most appropriate treatment strategy for each patient should be selected. Although some studies have shown the superiority of TEVAR, it is unclear whether open surgery was selected for lesions strictly indicated for TEVAR.1, 2)
We retrospectively evaluated early and mid-term treatment results in patients in whom both TEVAR and open surgery could be anatomically selected, and compared the two surgical methods.

**Subjects and Methods**

We performed a retrospective study in 213 cases with a single thoracic aneurysm excluding acute aortic dissection, who were surgically treated in our hospital between January, 2006 and August 31, 2009. All cases were classified according to the location of the lesion, and sizing of the SG device was performed. SG was indicated in whom the landing zone could be ≥15 mm from the left common carotid artery on the proximal side and ≥15 mm from the celiac artery on the distal side, the arterial diameter at the landing zone was 20–38 mm, and excessive calcification was absent. Of the 213 patients, 62 (29.1%) had indications for SG in our center. When these patients were classified according to the actually selected treatment, 30 patients were classified as the TEVAR group (SG group) and the other 32 as the open surgery group (OP group). The both groups were retrospectively evaluated.

For TEVAR, the Tokyo Medical University (T.M.U.) type SG device (Najuta, Kawasumi Laboratories, Tokyo) was introduced in 2006, and a commercially available SG device (TAG® W.L. Gore, USA) was introduced in January 2008. Before the introduction of the commercially available SG device, open surgery was the first choice. After the introduction of the SG device, SG was recommended as the first choice to high-risk patients such as those with many comorbidities, but the surgical method was finally selected by patients and their families with adequate, informed consent. Preoperative respiratory disorders were defined as those that require controlled ventilation ≥72 hours after surgery. All values are expressed as the mean plus standard deviation, and statistical differences were analyzed using Student’s t-test and the χ² test. The survival rate was analyzed using the Kaplan-Meier and Log-rank methods. *P* <0.05 was regarded as significant.

**Results**

1. Patient background

The reasons for the selection of SG in the 30 cases in the SG group are shown in **Table 1**. SG was selected due to high risk in 21 cases (70%). The most frequent reason was the patients’ wish, which was observed in 9 cases (30%). These results did not always reflect our selection criteria.

A T.M.U. type Najuta was used in 23 of the 30 cases and a TAG® in 7. The proximal landing was further than Zone 4 in 21 patients; the other 9 cases needed a proximal landing zone from Zone 0 to Zone 3. In the OP group, replacement of the descending aorta via left thoracotomy was performed in 25 of 32 cases, and total arch replacement using the median sternotomy, in 7. In all cases in this group, extracorporeal circulation was used. Four cases of descending aorta replacement performed at a normal temperature and the other 17 cases were performed under hypothermic circulatory arrest. In the 7 cases who underwent total arch replacement, the minimum core temperature was 25°C, and distal circulatory arrest/antegrade selective cerebral perfusion was used as the standard procedure.

As shown in **Table 2**, there were no significant differences in the mean age, male/female ratio, presence/absence of atherosclerosis risk factors, preoperative respiratory dysfunction, emergency operation, or the history of open heart surgery, between the SG and OP groups.

2. Early results

There were no operative deaths in either group, and all cases in both groups were discharged on foot or transferred to another hospital. Postoperative cerebral infarction was observed in 3 cases in the OP group, paresis in 2, in the SG group, and paraplegia in 1, in the OP group. However, these conditions improved after rehabilitation, and their incidence did not significantly differ between the two groups. The operation time, period (days), until the initiation of postoperative oral intake, and

<table>
<thead>
<tr>
<th>Major specific indication</th>
<th>Number</th>
<th>%</th>
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<tbody>
<tr>
<td>Patient request</td>
<td>9</td>
<td>30.0</td>
</tr>
<tr>
<td>Advanced age</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>Cardiopulmonary disorder</td>
<td>4</td>
<td>13.3</td>
</tr>
<tr>
<td>Advanced age • post-thoracotomy</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Central nerve disorder</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>Post-thoracotomy</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Multiple aneurysms</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>Dialysis</td>
<td>1</td>
<td>3.3</td>
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<tr>
<td>Cancer</td>
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the postoperative hospital stay (days) were significantly shorter in the SG group, and the bleeding volume was significantly smaller in the SG group. The percentage of blood transfusion and the incidence of postoperative respiratory dysfunction were significantly lower in the SG group. Thus, the SG group was superior to the OP group, in terms of early results (Table 3).

3. Mid-term results

During the follow-up period, for a mean of 656.4 w 547.8 days, 3 cases in the SG group and 4 in the OP group died or dropped out, but no significant differences were observed between the two groups ($P = 0.89$). The 3 year survival rate was 88.7% in the SG group and 87.1% in the OP group (Fig. 1). The cause of death was pneumonia/respiratory dysfunction in 2 cases, malignant tumors in 2, multi-organ failure in 2, and hematemesis, resulting in sudden death, in 1.

Events considered being associated with aneurysms were observed in 1 case in the SG group. In the above patient who died of hematemesis, even though the aneurysm at the original treatment site had decreased in size, a new aneurysm formed central to the SG area and appeared to have ruptured into the esophagus. The exact cause of death was unclear, but infection of the SG device was strongly suspected. In 2 patients in the SG group, Type II endoleak persisted from immediately after the operation, and their courses have been strictly observed on an outpatient basis despite no changes in the aneurysmal diameter. There have been no cases undergoing open surgery after TEVAR or additional TEVAR.
DISCUSSION

In Japan, as SG devices for thoracic aneurysms, TAG® (W.L. Gore, USA) and TALENT (Medtronic, USA) began to be covered by insurance in 2008 and have been used to the present. In addition, clinical trials on T.M.U. type Najuta are in progress in 11 institutions in Japan, and this device is also expected to be covered by insurance in the future. After the introduction of these devices, treatment choices for thoracic aneurysms have increased. According to the survey of the number of surgically treated cases conducted by the Japanese Society for Vascular Surgery, surgery for aneurysms in the descending aorta was performed in 683 cases in fiscal year 2006, 922 cases in 2007, and 1214 cases in 2008, showing a marked increase. Of 1214 cases, 682 (56.2%) were treated by TEVAR. These values indicate the involvement of an increase in the number of cases treated by TEVAR, and a rise in the total number of surgically treated cases. However, the number of cases treated by TEVAR has been increasing without a general consensus regarding the relative merits between open surgery and TEVAR and criteria for the selection of treatment.

Although this was a retrospective study, the open surgery and SG groups were very similar when the lesion localization and patient background were compared. No operative death was observed in either group, and early treatment results were favorable in both groups. However, postoperative cerebral infarction was observed in the open surgery group, but not in the SG group. In addition, the SG group showed a significantly smaller bleeding volume, significantly higher blood transfusion rate, and significantly shorter postoperative hospital stay. These results suggest that TEVAR is less invasive than open surgery.

In this study, in the SG group, aneurysm-associated death was observed mid-term after surgery, and Type II leak persisted after TEVAR, in 2 cases, who have been followed up to the present at the outpatient clinic, and in 9 of 30 cases, the SG device was placed proximal to Zone 3. In such cases, the proximal landing zone was often short, due to the presence of branches in the cervical area compared with TEVAR distal to Zone 4 (Fig. 2). Therefore, concerning the long-term results of TEVAR, aneurysm-associated events should be carefully analyzed by close follow-up.

The evaluation of 147 patients who underwent open surgery for aneurysms in the aortic arch, in our institution, between 2000 and April 2008, showed no operative death rate was 2.5% (1 of 40 patients), but the mid-term incidence of aneurysm-associated events that occurred during 3 years was 17.9%, which was a high rate, compared with conventional open surgery. Thus, long-term follow-up is important even at present when there are commercially available devices.

In Japan, a study, which compared the two methods using a home-made device for lesions located in the same area, showed good early-mid-term results after both open surgery and TEVAR, but a significantly higher mid-long-term incidence of aneurysm-related events after TEVAR. In this study, in the TEVAR group, the early operative death rate was 2.5% (1 of 40 patients), but the mid-term incidence of aneurysm-associated events that occurred during 3 years was 17.9%, which was a high rate, compared with conventional open surgery. Thus, long-term follow-up is important even at present when there are commercially available devices.
death nor postoperative cerebral infarction in 97 patients aged ≤75 years. However, in patients aged ≥75 years, the operative death rate was 10%, and the incidence of cerebral infarction was 8.3%. Based on these results, we recommend TEVAR using commercially available SG devices for high-risk patients, such as elderly patients, as the first choice and open surgery to relatively young low-risk patients, considering that the long-term results of TEVAR are still unclear. Comparison of the patients’ preoperative background between the two groups in this study showed no significant difference in each item such as age. Although our policies were not always reflected, the reason for the selection of TEVAR widely varied. We recommended open surgery to 9 patients in the TEVAR group, but the patients themselves finally selected TEVAR. This suggests marked demand for minimal invasiveness at present. In addition, to reflect these results in future strategies, we intend to perform closer, long-term follow up in these patients and analyze aneurysm-associated events.

A questionnaire survey conducted in 2006 by the Japanese Association for Thoracic Surgery showed that arch replacement was performed by open surgery in 1544 (35.2%) of 4382 surgically treated patients with non-ruptured thoracic aneurysms. The number of patients who underwent this operation has been increasing. The number of patients who underwent surgery of the descending aorta was 535, also showing an annual increase. The operative death rate was 4.5% each for aneurysms in the aortic arch and those in the descending aorta, and the early results of open surgery have annually improved.5) While the surgical results have continuously improved, medical companies and workers have made great efforts to improve TEVAR devices, and their indications have gradually been expanding. To expand the indications of TEVAR to arch aneurysms, the T.M.U. type Najuta was developed in Japan, which took the lead in developing new devices, and favorable mid-long-term results have gradually been reported.6) In the future, indications for TEVAR are expected to expand further, due to an improvement in development of devices for high-risk patients in whom surgery was not conventionally indicated, and the number of surgically treated patients with thoracic aneurysms may also increase.

On the other hand, long-term results have not been adequately clarified. Makaroun et al.1) evaluated the 5 year results of TEVAR using Gore TAG and reported that the incidence of major adverse events related to open surgery was 70% immediately after surgery, 77% after 1 year, and 78.7% after 2 years, but the incidence did not increase, thereafter, until 5 years after surgery; however, that related to TEVAR using TAG was 28% immediately after the operation, 42% after 1 year, and 57.9% after 5 years, showing a slight increase. Therefore, in young patients who require long-term follow-up, the risks and benefits of TEVAR should be adequately evaluated for treatment.

**Conclusions**

The early-mid-term results of both TEVAR and open surgery were favorable, but TEVAR was less invasive. While the results of open surgery have improved, devices for TEVAR have been developed. In high-risk patients, the selection of less invasive TEVAR may be appropriate. However, not all problems regarding the long-term results have been overcome. According to age and the...
general condition of the patient, open surgery may be the first choice. Surgical results may further improve, and indications may further expand by selecting treatment methods with consideration given to the advantages of both TEVAR and open surgery.

REFERENCES


