Long-term Results of Endovascular Abdominal Aortic Aneurysm Treatment With the First Generation of Commercially Available Stent Grafts

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Hypothesis: Little information about the long-term results of endovascular abdominal aortic aneurysm repair is available. This study was performed to evaluate the long-term data of patients treated with the first generation of commercially available stent grafts.

Design: Multicenter registry.

Setting: Sixty-two European centers that participated in the EUROSTAR (EUROpean collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair) registry.

Patients: A total of 1190 patients with a follow-up of up to 8 years, who underwent endovascular abdominal aortic aneurysm repair with a stent graft (Stentor or Vanguard).

Intervention: Elective endovascular abdominal aortic aneurysm repair.

Main Outcome Measures: The morbidity and mortality data of patients treated with the first-generation stent graft who enrolled in the EUROSTAR registry were analyzed. Incidence rates of complications were calculated to quantify annual risks. Life-table analyses and multivariate Cox proportional hazards models were used for the survival analysis.

Results: Conversion to open repair, aneurysm rupture, all-cause death, and aneurysm-related death occurred in 7.1%, 2.4%, 19.9%, and 3.0% of the patients, respectively. The cumulative percentage of the combined outcome event, conversion-free and rupture-free survival, after 8 years was 48.0%. Procedure-related complications that frequently occurred were endoleak (13.0 cases per 100 patient-years), stenosis/thrombosis (4.6 cases per 100 patient-years), and stent migration (4.3 cases per 100 patient-years).

Conclusions: Patients treated with the first generation of stent grafts will need lifelong surveillance because of a considerable risk of late complications. How these findings translate to the outcome of newer-generation stent grafts is unknown. For this reason, vigilant surveillance remains indicated in all patients who undergo endovascular abdominal aortic aneurysm repair.

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The prevalence of abdominal aortic aneurysms (AAAs) has been increasing rapidly during the past decade, and aneurysmal rupture constitutes the 13th most common cause of death in the Western world. Traditionally, non-ruptured aneurysms are treated by open surgical repair. This involves exposing the abdominal aorta, clamping the aorta and iliac artery, and replacing the aneurysmal segment by a prosthetic graft. However, during recent years, endovascular repair of AAAs (EVAR) is increasingly used in patients with suitable aortoiliac anatomical features. With this technique, an endoprosthesis is used, which is delivered through the femoral or iliac artery at the infrarenal position to exclude the aneurysmal sac from the arterial circulation. Endovascular repair has several advantages over conventional surgery. First, it is a minimally invasive technique, which is of major importance in patients with comorbid factors, who are at high risk for conventional surgery. Operative trauma, blood loss and significant disturbances of hemodynamics, and ventilatory condition associated with endovascular repair are minimal compared with the open procedure. Moreover, hospital stay and convalescence time have been reduced significantly since the introduction of EVAR, approximately from 10 to 3 days for hospital stay and from 6 months to 11 days for recovery time.

See Invited Critique at end of article
The technical feasibility and the short-term effectiveness of excluding an AAA from the circulation have been reported in several studies. \(^6\) Recently, the results from 2 randomized clinical trials\(^7,8\) demonstrated that endovascular repair with regard to initial outcome may be preferable to open repair because of a reduced aneurysm-related mortality. Although endovascular treatment of AAAs seems an acceptable alternative for conventional surgery in the short term, the long-term safety of endografts is still untested. Concern remains about the durability of the endovascular approach in preventing aneurysm rupture. For this reason, caution should be used in advising patients about which treatment option will be best.

This report documents data obtained from a large multicenter registry, organized by the EUROSTAR (EUROpean collaborators on Stent-graft Techniques for abdominal aortic Aneurysm Repair) Collaborators. The objective of the present assessment was to report the long-term outcome of EVAR obtained by the first-generation endovascular devices.

DATA COLLECTION

The EUROSTAR project was launched in July 1996 with the objective of collecting and analyzing information prospectively on the results of endovascular treatment of AAAs. Patient characteristics, aneurysm morphologic features, operative data, postoperative outcome, and clinical and imaging data at follow-up visits were collected on standardized Case Record Forms. \(^9\) The American Society of Anesthesiology risk classification and the Society for Vascular Surgery–International Society for Cardiovascular Surgery risk score were used to represent the patient’s risk profile. \(^10,11\) Follow-up examinations were performed at 1, 3, 6, 12, 18, and 24 months and yearly there-
The largest section of the aneurysm.

Deviations for Large Aneurysms

Table 4. Annual Incidence Risk Rates of the Major Complications for Large Aneurysms

<table>
<thead>
<tr>
<th>Major Complication</th>
<th>No. of Patients</th>
<th>Patient-Years of Follow-up</th>
<th>Annual Incidence Rate (95% Confidence Interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall</td>
<td>173</td>
<td>1791.58</td>
<td>0.10 (0.08-0.11)*</td>
</tr>
<tr>
<td>Procedure related</td>
<td>51</td>
<td>1791.58</td>
<td>0.03 (0.02-0.04)*</td>
</tr>
<tr>
<td>Conversion</td>
<td>61</td>
<td>1791.58</td>
<td>0.03 (0.02-0.04)*</td>
</tr>
<tr>
<td>AAA rupture</td>
<td>21</td>
<td>1791.58</td>
<td>0.01 (0.01-0.02)*</td>
</tr>
<tr>
<td>Endoleak</td>
<td>202</td>
<td>1351.50</td>
<td>0.15 (0.13-0.17)*</td>
</tr>
<tr>
<td>Type 1 or 3</td>
<td>129</td>
<td>1593.08</td>
<td>0.08 (0.07-0.10)</td>
</tr>
<tr>
<td>Type 2</td>
<td>81</td>
<td>1619.83</td>
<td>0.05 (0.04-0.06)</td>
</tr>
<tr>
<td>Kinking stent graft</td>
<td>70</td>
<td>1643.75</td>
<td>0.04 (0.03-0.05)</td>
</tr>
<tr>
<td>Stenosis/thrombosis</td>
<td>91</td>
<td>1603.50</td>
<td>0.06 (0.04-0.07)*</td>
</tr>
<tr>
<td>Graft migration</td>
<td>73</td>
<td>1640.24</td>
<td>0.05 (0.04-0.06)</td>
</tr>
<tr>
<td>Suture breakage</td>
<td>72</td>
<td>1676.92</td>
<td>0.04 (0.03-0.05)</td>
</tr>
<tr>
<td>Stent breakage</td>
<td>15</td>
<td>1777.08</td>
<td>0.01 (0.003-0.01)</td>
</tr>
<tr>
<td>Severe angulation</td>
<td>51</td>
<td>1711.08</td>
<td>0.03 (0.02-0.04)</td>
</tr>
<tr>
<td>Secondary intervention</td>
<td>194</td>
<td>1452.42</td>
<td>0.13 (0.12-0.15)*</td>
</tr>
<tr>
<td>Transfemoral</td>
<td>149</td>
<td>1495.17</td>
<td>0.10 (0.08-0.12)*</td>
</tr>
<tr>
<td>Transabdominal</td>
<td>46</td>
<td>1778.58</td>
<td>0.03 (0.02-0.04)</td>
</tr>
<tr>
<td>Extra-anatomical</td>
<td>37</td>
<td>1715.17</td>
<td>0.02 (0.01-0.03)</td>
</tr>
</tbody>
</table>

Abbreviation: See Table 1. *Significant difference (P<.05) vs small aneurysms after adjustment of differences in patient risk profile and morphologic characteristics.

After. Reminders for overdue follow-up data were regularly sent to the participating institutions. Outcome reporting adhered to the guidelines from the Society for Vascular Surgery/American Association for Vascular Surgery. Deaths were classified as aneurysm-related or as all-cause deaths. The latter included death related to comorbidity and conditions unrelated to the aneurysm. Aneurysm-related deaths included 30-day deaths, deaths that occurred as a result of aneurysm rupture or endograft infection, and those that occurred within 1 month after a secondary surgical procedure for late complications of the aneurysm.

Other outcome events observed during follow-up included endoleak, migration, device kinking, stenosis/thrombosis, and suture or stent breakage. Endoleaks were classified into types 1, 2, and 3, as described in previous reports. An endoleak is defined as a persistence of blood flow outside the lumen of the endograft but within the aneurysmal sac. An adequate seal at the proximal or distal extremity of the stent graft causes a type 1 endoleak, whereas flow in the sac from a side branch represents a type 2 endoleak. A type 3 endoleak is midgraft endoleakage originating from either fabric holes or an inadequate seal between endograft components. In many analyses, type 1 and 3 endoleaks are considered combined, because these represent device-related endoleaks associated with an increased risk of AAA rupture. In contrast, type 2 endoleaks are considered low risk for rupture and do not pose an indication for urgent treatment. Surgical grafts are sutured in place proximally and distally; however, stent grafts are held in place by a combination of radial force (from the stent), hooks or barbs, and longitudinal support (stiffness). Failure of the fixation mechanisms may result in upward or downward migration of the stent graft. Only migrations that were considered clinically significant by the physician were reported. The durability of endografts is determined by the occurrence of mechanical failure, which depends on the structural properties of the device and the forces to which it is subjected. Possible complications of mechanical failure include angulation of the stent graft (kinking) or suture line, fabric tears, and stent breakage. Finally, occlusive problems, of the stent graft limb or (rarely) the entire device, have been reported, caused by stent graft thrombosis or stenosis.

**DEVICES**

In this study, data of patients treated for AAA by the endovascular technique with the first generation of stent grafts (Stentor and Vanguard) between July 5, 1994, and December 7, 1999 in 62 European centers were analyzed. These first-generation commercially available stent grafts (Stentor; MinTec [Mimally Invasive Technologies SARL], La Ciotat, France and Vanguard; Boston Scientific, Natick, Mass) were modular devices constructed from an externally placed thin-walled polyester (Dacron) graft covering, a flexible self-expanding nitinol stent. The proximal end of the stent graft was uncovered. This bare stent segment was much shorter than in modern stent grafts, in which this part routinely provides suprarenal fixation. Fixation and sealing of the stent graft was accomplished by several mechanisms, including compression fit (ie, radial forces, exerted by the self-expanding stent, hooks, and barbs). 3,17,18

**DATA ANALYSIS**

Data were recorded on a computerized database. At the start of the study, patients with maximal aneurysmal diameters of 40 mm and larger were treated by endovascular surgery. However, the results from the UK Small Aneurysm Trial and the US Aneurysm Detection and Management Veterans Affairs Cooperative Study suggest that the risk of rupture in AAAs smaller than 55 mm does not justify surgery. Surgical repair should be withheld until the aneurysm reaches a diameter of at least 55 mm or expands rapidly or until the patient develops symptoms. For a better comparison with the outcome in series of more recently treated patients in whom large aneurysms were more frequent, we analyzed the data in 2 groups stratified according to aneurysm size. The first group had an aneurysm between 40 and 54 mm (small aneurysm); and the second group, an aneurysmal diameter of at least 55 mm (large aneurysm). The threshold of 55 mm was measured at the minor radius at the largest section of the aneurysm.

**STATISTICAL ANALYSIS**

Incidence rates with 95% confidence intervals were determined to quantify the annual risk for developing a major com-
application. Life-table analyses and log-rank tests were used to compare the outcome in the 2 study groups. Multivariate Cox proportional hazards models were used to determine whether aneurysm size was an independent risk factor for adverse outcome during follow-up, after adjustment for differences in patient-related and morphologic characteristics. Statistical significance was reached when $P < 0.05$. The analysis of data was performed with SAS statistical software, version 8.00 (SAS Institute Inc, Cary, NC).

**RESULTS**

**STUDY POPULATION AND DEVICES**

A total of 1190 patients (1077 males) underwent EVAR with the first-generation stent grafts. The Stentor device was used in 283 patients, and 907 patients were treated with a Vanguard stent graft. The mean patient age was 71 years, and more than half of the patients (57.3%) were considered unfit for open surgery (Table 1). Of the patients, 581 had an aneurysm with a diameter between 40 and 54 mm. In 609 patients, the aneurysm was 55 mm or larger. Compared with patients with a small aortic aneurysm (<55 mm), patients with a large aortic aneurysm (≥55 mm) were older (mean age, 68.8 vs 72.3 years) and more frequently had an American Society of Anesthesiology class of 3 or 4 (48.5% vs 65.7%), diabetes mellitus (6.9% vs 11.2%), cardiac disease (47.3% vs 58.5%), carotid disease (13.3% vs 17.6%), and pulmonary disease (29.4% vs 38.6%). Regarding the existing anatomical dimensions, compared with patients with small aneurysms, patients with large aneurysms had a higher incidence of significant angulation of the infrarenal neck (15.5% vs 27.4%) and the iliac artery (33.0% vs 37.7%). In addition, the infrarenal neck was wider (mean, 21.0 vs 22.3 mm) and shorter (mean, 28.8 vs 27.2 mm), and the distance between the lower renal artery and the iliac bifurcation was longer (mean, 116.0 vs 124.1 mm), in the large-aneurysm group.

**EARLY OUTCOMES AND COMPLICATIONS**

The first-month mortality in the entire cohort was 2.9% (35 patients). Significantly more patients died in the group with large aneurysms compared with those with small aneurysms (Table 2). Patients with a large aneurysm also more often underwent a conversion to open repair. Intraoperatively, device-related complications, including inability to deploy the device and device migration, occurred in 9.3% of the patients and arterial problems occurred in 3.5% of the patients. These complications occurred significantly ($P < 0.05$) more in patients with an aneurysm larger than 55 mm. In 24 patients (2.0%), there was a failure to complete the endovascular procedure (ie, conversion to open surgery, abandoning the procedure, or unplanned extra-anatomical bypass). This complication had no significant ($P = 0.13$) difference associated with aneurysm size.

From operation to hospital discharge, systemic complications (cardiac, cerebral, pulmonary, renal, hepatobiliary, bowel, and sepsis) were observed in 12.9% of the patients. Patients with large aneurysms more frequently experienced these complications (15.9% vs 9.8%). Minor complications (ie, from the access sites and lower limb arteries) occurred in 8.7% of the patients and were independent of the aneurysm size.
LATE OUTCOMES AND COMPLICATIONS DURING FOLLOW-UP

The 1190 patients had 3820 person-years of follow-up. In approximately 20% of the patients, one of the annual follow-up forms was not submitted. Late all-cause death, aneurysm-related death, conversion to open surgical repair, and aneurysm rupture occurred in 237 (19.9%), 36 (3.0%), 84 (7.1%), and 29 (2.4%) of the patients, respectively. The annual incidence rate (95% confidence interval) of all-cause death, aneurysm-related death, conversion, and AAA rupture per 100 patient-years was 7.1 (5.7-8.5), 1.9 (1.4-2.6), 1.6 (0.9-2.3), and 0.8 (0.3-1.2) case, respectively. The complications with the highest incidence rate per 100 patient-years were endoleak (13.0 cases), stenosis/thrombosis (4.6 cases), migration (4.3 cases), and suture breakage (4.0 cases). Secondary interventions were required, with an annual incidence of 11.6 cases per 100 patient-years. Complications were treated most frequently by transfemoral reinterventions (8.7 cases per 100 patient-years).

Patients with large aneurysms had a significantly higher incidence rate per 100 patient-years for all-cause death (0.097 vs 0.049 case; \(P=.003\)) and aneurysm rupture (0.012 vs 0.004 case; \(P=.007\)) (Figure 2 and Table 6). Endoleaks (14.9 vs 11.3 cases per 100 patient-years; \(P=.02\)) and stenosis/thrombosis (5.7 vs 3.7 cases per 100 patient-years; \(P=.01\)) occurred more frequently in patients with large aneurysms. This corresponded with a higher incidence of secondary interventions (13.4 vs 10.1 cases per 100 patient-years; \(P=.007\)) in this study population.

Analysis with a Cox proportional hazards model revealed that age at operation and aneurysmal diameter were risk factors independently associated with an increased mortality and rupture rate during follow-up, while conversion to open repair was related to the aneurysmal diameter. The cumulative percentage of the combined outcome event of conversion- and rupture-free survival after 8 years of follow-up was 48.0% (56.1% in patients with small aneurysms and 39.6% in patients with large aneurysms; \(P<.001\)) (Figure 1 and Table 5). The cumulative survival rate after 8 years was 63.1% (74.5% in the small-aneurysm group and 49.6% in the large-aneurysm group; \(P<.001\)). Freedom from aneurysm-related death rate was 88.3% after 96 months (94.3% in the small-aneurysm group and 78.8% in the large-aneurysm group; \(P<.001\)) (Figure 2 and Table 6).

COMMENT

A few studies have reported on the long-term follow-up of endografts for AAA. Following the era of prototypes, the first industry-produced endograft was manufactured by Endovascular Technologies, Inc, Palo Alto, Calif, and marketed as the EVT graft. This company was subsequently acquired by Guidant Corporation, Indianapolis, Ind. The EVT grafts were a unipiece configuration with fixating stents, only at the top and the bottom ends. The EUROSTAR registry did not include any prototype or self-constructed devices, and the subgroup of EVT grafts was too small for a meaningful analysis. The present report represents the long-term evaluation of results obtained from the collective experience of 62 European centers with the first generation of modular, fully stent-supported, commercially available devices. Stentor was the first of this device configuration, which formed the basis of all currently used stent grafts. The “Mialhe Stentor-B(furcated),” as formally indicated, was designed by Claude Mialhe, MD, from Draguignan, France.17 Reports of postoperative “leaks” indicated by contrast filling of the aneurysm on computed tomographic examination or angiography were reported from 1997.16,22 Defects in the thin polyester covering were increasingly identified as causes of endoleaks in the Stentor. The fabric was hand sewn and had a seam in it (Figure 3). Suture line disruption and fabric tears because of impingement of a stent apex to the polyester were recognized causes of device failure. The successor of the Stentor was
marketed by Boston Scientific as the Vanguard endograft. Although the fabric was changed into a more densely woven seamless polyester device, deterioration continued to occur and ultimately resulted in the withdrawal of this device.

Structural failure of the endovascular device constitutes an important cause of delayed failure of EVAR. The different failure modes can be discriminated into the following: (1) fabric tears and suture line disruption; (2) stent fractures caused by metal fatigue, leading to the breakdown of the mechanical components; (3) disintegration of the stent frame, because of breakdown of the polypropylene sutures connecting the different stent rows; and (4) types 1 and 3 graft-related endoleaks, which are caused by insufficient fixation at the graft extremities or at the device modules. Too short overlap zones and insufficient oversizing, sometimes because of a limited range of available diameters, may add to these complications. In Figure 4, some of these complications are illustrated (fabric tears, stent row dislocation, iliac limb dislocation, and iliac limb withdrawal). A detailed account of the failure modes of the Vanguard was provided in the literature. Many of the mechanisms of device failure have been recognized and responded to by the manufacturers. Improvement in corrosion resistance, one of the main causes of metal fatigue, was achieved by several processes, including electropolishing and chemical etching of the metal surface. Stronger fabrics are also being used, and mechanisms to eliminate or reduce friction between components constructed of different materials have been found. Therefore, there is optimism that this type of problem will be much less frequent in the current generation devices.

The risk of adverse events in patients treated with the early generation of endografts is considerably higher than with modern devices. In the long term, more than half of these patients will die, experience a rupture of their aneurysm, or have a conversion to open repair. There was a distinct difference between patients with large and small aneurysms. Unfavorable anatomical characteristics were more frequently wider, shorter, and severely angulated infrarenal necks. These findings result in unsuitability of many patients with an aneurysm of 55 mm or larger for endograft repair, compared with smaller aneurysms. With current stent grafts, sealing and fixation can be achieved in aneurysms that previously would be considered unsuitable for EVAR. The correlation of aneurysm size, the applicability of EVAR, and an increased operative risk have been documented previously. Intraoperative and early postoperative complications, including systemic events, endoleak, primary conversion, and first-month mortality rates, all occurred significantly more frequently in the large-aneurysm group. However, the 4.4% early mortality in the large-aneurysm group still compares favorably with the rate of 5% to 6% associated with open surgery reported in many previous studies in which good- and poor-risk patients were combined.

The most frequent complications reported during follow-up included endoleak, stenoses/thromboses, endograft migration, and suture breakage, all of which occurred at a higher incidence in the large-aneurysm group. This higher incidence is most likely because of a generally unfavorable anatomical condition in the large size category. The higher annual complication rate was also reflected in a higher incidence of secondary interventions. In a study of patients treated with the current generation of stent grafts, aneurysm size was also identified as an independent predictor for secondary interventions. Secondary interventions in general, despite the fact that most are by transfemoral route, have a negative effect on the quality of life of patients and the cost-effectiveness of EVAR. In a recent EUROSTAR analysis, the annual risk of secondary interventions in currently used stent grafts was 3.7% in the entire cohort and 4.0% in the patients with large aneurysms, which compared favorably with the incidences in the present analysis.

The rates of mortality, conversion, and AAA rupture in the present study were significantly higher in pa-
patients with large aneurysms and in patients with an advanced age. These findings were irrespective of the brand of the device. In the AneuRx Clinical Trial, Zarins and colleagues observed aneurysm rupture in 0.8%, aneurysm-related death in 0.7%, and late conversion in 3.2% of the patients during the 6-year follow-up. The lower mortality rate in the study by Zarins and colleagues probably is the result of AneuRx belonging to the current device generation. Nevertheless, the conversion and the rupture rates were similar in the AneuRx trial and in the presently assessed cohort with first commercially available stent graft generation.

Significant differences in major complications, including aneurysm-related death, were observed between the large- and small-aneurysm groups. After 8 years of follow-up, the cumulative rate of the combined outcome event, conversion- and rupture-free survival, was 56.1% and 39.6% in patients with small and large aneurysms, respectively. Freedom from aneurysm-related death was observed in 94.3% and 78.8% of patients with small and large aneurysms, respectively. To our knowledge, long-term aneurysm-related mortality after open repair has not been assessed in a comparable way as after EVAR. However, Hallett et al reported an overall survival rate of 72% after open surgery for AAA, of which only 2.6% of survivors of the operation died of graft-related operative complications. The cumulative survival after 8 years was 74.5% in the small-aneurysm group compared with 49.6% in patients with...
large aneurysms. A worse initial physiologic and morphologic status in this category likely caused this difference. Although the potential advantage of EVAR seems to be smaller in patients with large aneurysms and more comorbid factors, prevention from rupture in this category with an unfavorable natural history and a higher risk for open surgery may still pose an excellent indication for EVAR. \(^\text{23,40}\) Finally, newer-generation stent grafts were also associated with similar high complication rates in patients with small aneurysms.\(^\text{27}\)

Our study is also relevant for patients with a small aneurysm. The 74.5% survival rate in this group compared favorably with the long-term outcomes in the UK Small Aneurysm Trial, in which this rate was 59% in the early surgery group and 51% in the surveillance group after 8 years of follow-up. Recently, Zarins et al\(^\text{41}\) considered, based on the available literature data, that EVAR in small aneurysms reduced the risk of rupture and aneurysm-related death and improved patient survival compared with an initially conservative policy. Our long-term follow-up findings are in agreement with the conclusions of Zarins et al, and support the recent initiatives for 2 trials\(^\text{22,43}\) (the PIVOTAL [Positive Impact of EndoVascular Options for Treating Aneurysms Early] and the CAESAR [Comparison of surveillance vs Aortic Endografting for Small Aneurysm Repair] trials) that will compare EVAR with an initially conservative approach in patients with small aneurysms.

There are several disadvantages of a voluntary multicenter registry. The possibilities of collecting a large amount of patient data in a relatively short period, of addressing upcoming questions, and of evaluating long-term effectiveness are unique for a registry. Drawbacks include a larger interobserver variation, a lower accuracy, and an incomplete data set. Nevertheless, the patient population in a registry represents well the common-day clinical practice. The EUROSTAR database constitutes the largest study group available with long-term follow-up results. One third of all Stentor and one sixth of all Vanguard devices ever placed in the world were included in this report. Despite the fact that the investigated endografts are no longer available, the long-term outcomes are highly relevant. First, many patients underwent operations with these devices in the past and need accurate aftercare. Second, the high annual incidence rate of complications after EVAR seems generalizable to some extent to the present situation.

In conclusion, patients treated with the first generation of stent grafts will need lifelong surveillance, because of the risk of complications. This risk is particularly high in patients with large aneurysms at operation. The long-term effectiveness of endografts currently used has not been demonstrated. Vigilant surveillance is indicated in all patients after EVAR.

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**REFERENCES**


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