Endoleak after stent-graft treatment of abdominal aortic aneurysm: a meta-analysis of clinical studies

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Authors' objectives
To evaluate whether or not the number of endoleaks has decreased during and after the learning period and after the replacement of several "first generation" endovascular devices.

Searching
A MEDLINE (after 1995) search of English, German, French and Dutch language articles was conducted using the following keywords: aorta, aortic, aneurysm, stent, endograft and endoprosthesis. Full details of the search strategy were given.

Study selection
Study designs of evaluations included in the review
Articles were included if they reported on the endovascular stent-graft treatment of at least ten AAAs and were published in 1995 or later. Case reports were excluded and attempts were made to identify duplicated data.

Specific interventions included in the review
Stent-grafts of the following configurations were included: tube; bifurcated; and aortounilateral. Device types studied included the following: AneuRx; Chuter; Corvita; EVT; Ivancev-Malmö; Parodi; Perth; Stentor-Vanguard; Talent; and White-Yu GAD.

Participants included in the review
Patients who had an abdominal aortic aneurysm (AAA) treated with an endovascular stent-graft were included. Patients in whom treatment of AAA could not be differentiated from treatment of aneurysms at other locations were excluded.

Outcomes assessed in the review
The number of endoleaks was assessed.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The authors do not state that they assessed validity.

Data extraction
The following data were extracted: number of patients treated; number and type of transfemorally placed endovascular grafts; length of follow-up; primary conversion rate; site of origin; time of appearance of endoleak; and fate of endoleak; relationship between the diameter change of aneurysmal sac and presence or absence of endoleak. The authors do not state how data were extracted for the review, or how many of the reviewers performed the data extraction.

Methods of synthesis
How were the studies combined?
The overall rates of endoleaks was calculated.
How were differences between studies investigated?
Studies were grouped according to year of publication, device configuration and device type and outcomes compared to the overall rate of endoleaks.

Results of the review
Twenty-three studies were included (1189 patients, of whom 1118 patients available for follow-up analysis).

71 (6%) of procedures were converted to laparotomy at the initial implantation.

270 (24%) of patients had an endoleak, either immediately after treatment or during follow-up.

Year of publication and endoleak rate: 1996 leak rate = 16% (25/155 grafts); 1997 and 1998 leak rate = 25% (245/985 grafts).

Site of endoleak: The majority of endoleaks arose from the distal stent attachment site (36%). Rates for other sites were: proximal stent attachment site 24%; side branch 18%; and graft related 15%. Timing of endoleak: most occurred immediately (66%). Delayed leak accounted for 27% and recurrent leak for 2%.

Fate of endoleak with time: most were persistent (37%). Other fates: spontaneous thrombosis 21%; radiological intervention 30%; conversion 10%.

Device configuration: tube grafts had the highest rate of endoleak (35%), significantly higher than the bifurcated graft leak rate (18%; P < 0.0001) and the mixed graft leak rate (20%; P = 0.002). Device type: leak rates in the Corvita group (52%) and the first generation EVT (44%) were higher than that of other devices (leak rates ranged from 6% to 26%). In the Stentor -Vanguard group 24% of leaks were graft related.

Self-expanding stent-grafts were significantly more frequently associated with endoleaks than balloon-expandable stent grafts (25% vs 17%; P = 0.037). The balloon-expandable graft had a higher proportion of endoleaks than the self-expanding grafts (66% vs 34%; P = 0.001). Delayed endoleaks were more common in the balloon-expandable graft compared to the self-expanding grafts (52% vs 25%).

Authors’ conclusions
Endovascular treatment of abdominal aortic aneurysm is an evolving field. Even after the initial learning curve and attention to device-related problems, it is still accompanied by a significant number of endoleaks. Uniform presentation of results of treatment is necessary for analysing the effect of differences between patients, aneurysm morphology and device type.

CRD commentary
The aims and inclusion criteria were stated. Articles in four languages were considered for inclusion and full details of the search strategy were given. However, only one database was searched. Some investigation was undertaken of factors that may influence results. As the authors mention in the discussion, the inability to analyse results taking account of patient selection, graft sizing, aortic morphology and technical difficulty during implementation, limits the conclusions that can be drawn from the data.

Limiting included studies to those located in one database may have resulted in the omission of some relevant studies. No attempt was made to locate unpublished studies thus raising the possibility of publication bias. Methods used to select primary studies and extract data were not described. Neither validity nor heterogeneity was assessed. No investigation was reported of potential confounding factors such as surgical centre and experience of operator. It is not clear what proportion of such operations were included in the review and hence how representative the results reported were of all such operations.

In view of the above, caution is advised when considering these results. The authors state that results from major endovascular registries are being presented at conferences and will be published in the near future.
Implications of the review for practice and research
Practice: The authors do not report any implications for practice.

Research: The authors state that future reports on endovascular treatment of AAA should include the following: number of endoleaks; site of origin of leak; presence of an outflow tract; time of occurrence; imaging technique used for visualising the endoleak; and diameter of the change for the total stent-graft group, the sub-group with endoleakage, related to follow-up period. Information should be supplied separately for each endovascular device and configuration.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.