Suprarenal endograft fixation and medium-term renal function: systematic review and meta-analysis


CRD summary
The authors concluded that there was insufficient evidence to determine precisely how the use of suprarenal fixation in endovascular abdominal aortic aneurysm repair affects medium-term renal function. They stated that more research was needed. Despite some limitations in reporting of review methods, these conclusions were appropriately cautious and appeared reliable.

Authors' objectives
To compare the effects on medium-term renal function of suprarenal versus infrarenal endograft fixation in patients undergoing endovascular abdominal aortic aneurysm repair (EVAR).

Searching
MEDLINE and EMBASE were searched from 1991 to December 2006. Search terms were reported. The reference lists of articles retrieved were handsearched, as were the conference proceedings of six professional bodies from 1998 to 2006.

Study selection
Studies of renal function after EVAR were eligible for inclusion provided they compared suprarenal versus infrarenal fixation and reported both pre- and post-operative measures of renal function. The outcome of interest in the review was post-EVAR renal impairment. Only studies for which complete individual patient data were available were included in meta-analysis. Pre-operative renal impairment was defined as serum creatinine over 1.5 milligrams per decilitre (>1.5 mg/dL) or creatinine clearance of under 60 millilitres per minute (<60 mL/min). Postoperative renal impairment was defined as an increase or decrease of more than 20 per cent in serum creatinine from baseline, serum creatinine >1.5 mg/dL or a decrease in creatinine clearance to <60 mL/min.

The definition of renal impairment in primary studies (where reported) varied widely, as did duration of follow up and outcomes measures used. None of the studies included in meta-analysis measured creatinine clearance directly. Some studies reported outcomes at infrequent intervals (for example, to the nearest three months). Few reported details of potential confounders (such as pre-existing renal impairment, diabetes, volume of contrast used). The review investigated not only the association between post-operative renal dysfunction and type of fixation but also the association between post-operative renal dysfunction and pre-operative renal impairment. The median duration of follow-up among patients included in the meta-analysis was 33 months.

The authors stated neither how relevant studies were selected for the review nor how many reviewers performed the selection.

Assessment of study quality
Study validity was measured using the Downs and Black score, a quality checklist for both randomised and non-randomised studies. No further details were reported.

Data extraction
Due to marked heterogeneity between the studies (evident on preliminary assessment) a post hoc decision was made to conduct a meta-analysis of individual patient data. Original data were obtained from primary investigators and were reclassified for each participant using standardised criteria (defined in the review) for pre-operative and post-operative renal impairment. Creatinine clearance was calculated using the Cockcroft Gault equation. Patient data were censored when renal impairment occurred or at last hospital contact. Some patients were excluded from analysis due to incomplete data sets.
Methods of synthesis
Individual patient data were pooled and Kaplan-Meier survival curves were generated showing the incidence of post-operative renal impairment in the comparison groups. The curves were compared using the log-rank test. A sensitivity analysis examined the effect of excluding patients with a follow up of less than one month for the primary outcome. Differences between the studies were investigated using a hierarchic Weibull regression model fitted in open Bayesian inference using Gibbs sampling and a random effects approach to calculate pooled hazard ratios (HRs) and 95% confidence intervals. Modelling was repeated with and without an outlying study.

Results of the review
No randomised controlled trials (RCTs) were found. Eleven cohort studies were initially eligible for inclusion (n=2,445), five prospective and six retrospective, but only five of these (three prospective and two retrospective) supplied suitable individual patient data for meta-analysis (n=1,065 with complete data sets).

Quality (11 studies). Only the prospective studies (n=5) had consecutive participant enrolment. Overall quality was moderate, with scores of 12 to 22 (out of a maximum of 31). More than half the studies failed to define renal impairment. Most did not adequately report confounding factors. Less than half used appropriate statistical techniques to deal with losses to follow up.

Kaplan Meier survival analyses showed that the median time free from post-operative renal impairment was significantly longer in the infrarenal fixation group than the suprarenal fixation group (38.5 months, 95% CI: 33.8, 43.4 versus 32.4 months, 95% CI: 28.3 to 36.5, p=0.0038; n=1,065). Median survival free of postoperative decline in renal function was significantly longer in patients with pre-operative renal impairment than in those without pre-operative renal impairment (39.5 versus 32.4 months, p<0.0001). However, neither of these effects persisted in the Weibull regression analyses: the pooled HR for deterioration of renal function after suprarenal fixation was 1.6 [abstract says 0.6 in error] (95% CI: 0.3, 10).

Exclusion from Kaplan-Meier analysis of patients with less than one month's follow up resulted in median renal-impairment-free survival times of 45.2 months (95% CI: 38.9, 51.4) in the infrarenal group versus 37.3 months (95% CI: 34.4, 40.02) in the suprarenal group (p=0.0385).

Authors’ conclusions
There was insufficient evidence to determine precisely how the use of suprarenal fixation in endovascular abdominal aortic aneurysm repair affects medium-term renal function. More research was needed.

CRD commentary
The review objectives and inclusion criteria were clear. The decision to modify the original intention of the review (that is, to include only individual patient data in meta-analysis) appeared appropriate. Relevant sources were searched. It appeared that specific attempts were made to locate unpublished studies, although it was not stated whether there was any restriction by publication or language.

It was unclear whether steps were taken to minimise the risk of bias and error in review processes by having more than one reviewer undertake study selection data extraction and validity assessment. The results of validity assessment were not reported in detail. It was unclear to what extent the original trial investigators collaborated in the process of re-analysis of the patient-level data. Appropriate statistical techniques appeared to be used to pool studies and explore heterogeneity. The processes used were described in some detail in the paper. The authors discussed the problems associated with poor study design overall and in particular with the interval-censored data in the meta-analysis. They highlighted that only 44 per cent of the potential sample was analysed and that there were insufficient data to investigate other potentially confounding variables. Potential causes of heterogeneity and of the counterintuitive finding with respect to pre-operative renal function were well addressed in the text. Despite some limitations in reporting of methods in the review, the authors’ conclusions are appropriately cautious and appear reliable.

Implications of the review for practice and research
Practice: the authors did not make any recommendations for practice.
Research: the authors stated that a large RCT of suprarenal versus infrarenal fixation was needed to provide conclusive evidence in this area.

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