The thermo-expandable metallic stent for managing benign prostatic hyperplasia: a systematic review

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CRD summary
The review assessed the effectiveness, safety and durability of the Memokath stent in patients with benign prostatic hyperplasia (BPH) who are unfit for surgery. The authors’ conclusion, that the Memokath stent is a safe and effective treatment for BPH in men at high operative risk, seems somewhat overstated given the paucity and quality of the available data.

Authors' objectives
To determine the effectiveness, safety and durability of a self-expanding metallic prostatic stent (Memokath stent) in patients with benign prostatic hyperplasia (BPH) who are not fit for surgery.

Searching
MEDLINE and EMBASE were searched from 1992 to March 2005 without any language restrictions; further details are available on request. In addition, the reference lists from relevant articles and recent reviews were checked and the stent manufacturer was contacted. Published and unpublished studies were eligible for inclusion.

Study selection
Studies of any design which evaluated the second generation Memokath stent in men with BPH were eligible for inclusion. Where reported, stents were inserted for lower urinary tract symptoms or urinary retention. In the majority of studies the pathogenesis of bladder outlet obstruction was BPH. Five studies included some patients with prostatic carcinoma (≤28% were reported). All of the included participants were at high operative risk, with ages ranging from 54 to 103 years (where reported). The primary outcomes were treatment failure (stent removal, replacement or repositioning) and urological symptom scores. The secondary outcomes were urodynamic indices and minor complications not requiring stent removal.

Two reviewers independently assessed studies for inclusion in the review. Any disagreements were resolved through consensus or by referral to a third reviewer.

Assessment of study quality
The quality of the included studies was assessed using criteria developed from published frameworks (Downs and Black 1998; Khan et al. 2001; Lohr 2004). Two reviewers independently assessed the quality of the primary studies. Any disagreements were resolved through consensus or by referral to a third reviewer.

Data extraction
Two reviewers independently extracted the data from the included studies. Any disagreements were resolved through consensus or by referral to a third reviewer. The authors of the primary studies were contacted for additional information, where required.

Methods of synthesis
The studies were combined in a narrative, grouped by outcome. Any differences between the individual studies were highlighted in the text.

Results of the review
Fourteen case series (n=839) were included in the review.

The studies were small with less than 50 participants in 11 of the included case series. Most of the included studies were deemed to be of a poor quality with often unclear or inadequate follow-up. Only 5 studies provided estimates of the statistical uncertainty of their results.
All 14 studies reported treatment failure; immediate failure occurred in 4% (11 out of 311) of patients. The frequency of subsequent failure could not be established because of insufficient information. Treatment failure rates ranged from 0 to 48%, but the duration of follow-up was often unclear. Seven studies reported changes in urological symptom score (using at least two different measures and at different times after stent placement); all studies reported a reduction in symptoms after stenting. All 7 studies reporting on maximum urinary flow rates found that these increased. All 4 studies reporting on residual urine volume found a decrease. The most commonly reported minor complications were urinary incontinence, infection and haematuria. However, complications were inconsistently reported and little information was given about the timing of these events.

**Authors' conclusions**
The Memokath stent appears to be an effective and safe treatment for BPH in men at high operative risk. However, it is difficult to draw firm conclusions about stent durability due to inadequate follow-up data.

**CRD commentary**
This review addressed a focused question and was supported by clear inclusion criteria. The literature search was limited to two databases, although the search was not restricted by language and some attempt was made to locate unpublished studies. Appropriate steps were taken to minimise the possibility of error or bias when selecting studies, extracting the data and assessing validity. The narrative synthesis seems appropriate given the differences in follow-up (where reported), outcome measures and timing of assessment, as well as the included populations. The authors' conclusions about effectiveness and safety are perhaps overstated given the paucity of the available evidence. Whilst a consistency between studies in symptom improvement was shown with the insertion of a stent, study design, small data sets, lack of and inconsistent data on safety, and the poor quality of the included studies preclude firm conclusions.

**Implications of the review for practice and research**
Practice: The authors did not state any implications for practice.

Research: The authors stated that further research is required. They suggested a high-quality observational study to provide information on the timing of treatment failure, which would enable an assessment of the durability of the Memokath stent. In addition, the authors stated that the collection of more detailed information pertaining to patient characteristics before stent insertion would help identify the patients who would most benefit from a Memokath stent. The authors also indicated the benefit of a randomised controlled trial to determine the safety and effectiveness of a stent compared with other treatments.

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