243

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A SYSTEMATIC REVIEW ON URETHRAL BULKING INJECTIONS USING POLYACRYLAMIDE GEL (BULKAMID®) FOR FEMALE STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study

Recent concerns on the adverse effects and complications of meshes used for the management of SUI have resulted in an increased interest in the use of urethral bulking agents as an alternative treatment.
The objective of this systematic review was to assess the efficacy and safety of polyacrylamide gel (Bulkamid®) for the treatment of female stress urinary incontinence.

Study design, materials and methods
A systematic review of the literature was undertaken in accordance with PRISMA guidelines. We searched Ovid, MEDLINE, Pubmed and Cochrane library databases from 2006 until January 2014 and checked the references of studies reporting on polyacrylamide gel (Bulkamid®) in women with SUI.

Inclusion and Exclusion criteria: We searched for published randomised controlled trials (RCTs), as well as observational prospective, retrospective cohort studies.
Case reports and animal studies were excluded. Injectables other than polyacrylamide gel (Bulkamid®) were also excluded.

Results
No RCTs were identified. A total of 413 patients from 9 studies were eligible for inclusion. Of those 9 studies, two were follow up studies of the same cohort but different time lengths.
The median age of patients varied between 54 and 84.5 years.
Two hundred and eighty seven women had a single injection. Fifty six women had previous continence procedures. One hundred and thirty six women had repeat injections. The range of follow up varied between 3 months and 9 years. The outcome measures used varied from cough test, ICIQ –UI SF, IIQ-7, PGI-I and urodynamics. Seven studies used subjective improvement as outcome measure. Cough test was used in two studies. Stamey scores, 24hour pad test were used as subjective outcome in two of the studies.
Short term success rate (3 - 12 months) varied between 60% and 74%. Subjective cure rates varied from 44% to 80%. The success rates at 3 months were much higher than those at 12 and 24 months. There was no statistically significant difference in subjective response rate at 12 and 24 months. No life threatening complications were mentioned in any of the studies. The common adverse effects were urinary tract infections (5-10%), pain at the injection site, haematuria, voiding difficulties. There was one case of abscess formation in the long term study(2). There were no reports of extrusion, migration, immune reaction.

Interpretation of results:
We did not identify any RCTs and the published studies had significant heterogeneity. There were only two long term studies. One was a two-year follow up and the other was 8 year follow up. In the two-year follow up study only 86 patients out of 135 completed the study. The 8 year follow up had only 15 patients of whom only 6 completed the study. A large number of women required repeat injections.
The outcome measures were mostly subjective rather than objective tests. There were no long term complications reported.

Concluding message
Urehtral bulking injections with polyacrylamide gel (Bulkamid®) is a treatment option for women with SUI. However, the efficacy of this treatment modality is variable in the current literature and repeat injections are often required. In this era of increasing litigation and debate on the use of meshes for stress incontinence, bulking agents appear to be an alternative option. This bulking agent appears to have no serious adverse effects. It can be administered under office based setting with local anaesthetic procedure for women who are not candidates for general anaesthesia, wish to consider future vaginal childbirth. Prospective well designed studies are needed to establish the efficacy of this, as well as other currently used urethral bulking agents. Future research on alternative bulking agents and tissue engineering may provide new techniques and materials with higher success rates.

References
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