



# Urethral bulking agents for the treatment of female stress urinary incontinence

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In the current general scenario on the use of mesh surgery for the treatment of pelvic floor dysfunction, the role of traditional mid-urethral slings (MUS) for the treatment of female stress urinary incontinence (SUI) is highly debated [1]. However, despite the warning published in 2018 in the UK and the NICE guidelines proposed a few months ago, it is evident that placement of MUS can be considered the gold standard for the treatment of SUI [2]. MUS show a long-lasting efficacy well demonstrated also with a long-term follow-up, with a relatively low complication rate [3, 4]. In 2018, a very large original study published in JAMA using a national population-based retrospective cohort of 90,057 women from the National Health Service in England found a low sling removal rate (3.3%) and a low SUI recurrence rate (4.5%) after MUS insertion even after 9 years.

Nevertheless, the debate on the use of synthetic tapes for SUI has allowed us to re-evaluate another useful and safe minimally invasive surgical procedure for treating female SUI, urethral bulking agents [5, 6].

First described by Murlless in 1938, it was widely used only with the development of more suitable materials for injection. Advantages of bulking agents include the ability to perform the injection in the office with the use of local anesthesia and minimal complication rate. Since 1938, several materials have been used trying to improve efficacy and safety in terms of biocompatibility of the bulk-enhancing agents. The last update of the Cochrane Library concluded that available

evidence remains insufficient to provide a conclusive evaluation of the pros and cons of bulking agents [7]. However, several studies have shown that this procedure can represent a good compromise among acceptable efficacy, negligible intra- and post-operative complications, and high subjective satisfaction rate [8]. In 2015, a meta-analysis published by Umberto Leone Roberti Maggiore et al. showed that bulking agents are characterized by a lower objective cure rate than traditional surgical procedures for the treatment of SUI, but with a similar subjective satisfaction rate in the two groups and with a significantly lower complication rate, in particular in terms of voiding dysfunction and urinary tract infections. Other medium- and long-term studies showed that the efficacy of injectable materials can also be long-lasting. The real problem with bulking agents is to identify which patients could benefit from this treatment. A possible answer comes from a recent study that found that women aged 60 or older with fewer than 2.5 daily SUI episodes were the best patients for urethral injection therapy with a success rate of 90%.

The role of urethral bulking agents should not be to replace MUS in the treatment of female SUI, but to offer a valid alternative in case of several subgroups of women with SUI, such as in case of patients who require a low-risk procedure such as elderly patients or subjects with severe comorbidities and young women who might want a pregnancy [9]. Counseling is the pivot on which the success of all treatments for SUI turns [10]. Counseling for bulking agents should include the minimal risks of the procedure and the cure, or improvement, in terms of continence. The potential need for repeat injections should be clearly discussed as a limitation of the procedure.

The last version of the International Consultation on Incontinence recommendations included bulking agents in the group of the first-line surgical treatments for SUI [11]. The guidelines on urinary incontinence published this year by the European Association of Urology recommend offering bulking agents to women with SUI who request treatment with a low risk of complications while understanding the limitations of this treatment modality [12].

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Bulking agents, with their low complication rate and an adequate and not negligible cure rate, may be able to respect the famous sentence declared by Hippocrates more than 2000 years ago, “primum non nocere,” and the aphorism created by Nelson Mandela, “May your choices reflect your hopes, not only your fears.”

### Compliance with ethical standards

**Conflict of interest** None.

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