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PERIURETHRAL INJECTION OF POLYACRYLAMID HYDROGEL AS A SALVAGE THERAPY FOR SEVERE STRESS URINARY INCONTINENCE IN WOMEN"

Hypothesis / aims of study:
Our aim was to assess clinical efficacy of a new bulking agent, polyacrylamid hydrogel (PAHG), for treatment of severe, complex cases of stress urinary incontinence (SUI) in women without urethral hypermobility after failed previous surgical management.

Study design, materials and methods
A prospective, observational evaluation was conducted from May 2008 to November 2010 in a tertiary reference center. Patients who presented with SUI after pelvic surgery or recurrence of SUI after surgical management were included. The following data were preoperatively collected: age, complete medical history, results of clinical examination with cough test, TVT and Bonney test, and preoperative urodynamics. All patients had SUI with a fixed urethra at clinical examination. 12 patients had associated OAB symptoms treated by anticholinergics. 36/50 patients had a maximal urethral closure pressure less than 30cm H20 (mean 25 cm H20 ±12 [3-58]). No patient had pelvic organ prolapse. All patients had underwent prior surgical procedure involving urogynecological disease (table 1). Median number of previous pelvic procedures 3 [1-12].
Methods: All surgical procedures were conducted under local anesthesia on an outpatient basis, by one very experienced surgeon. One milliliter of PAHG was injected in the urethral submucosa, one centimeter distal to the vesicourethral junction, under urethroscopy at 3, 6 and 9 o'clock. Patients were not catheterized and discharged six hours later. A second procedure (re-injection) was conducted for patients unsatisfied of the results at the first evaluation at one month. Patient global impression of improvement (PGI-I) scale, pad usage, reports of SUI episodes on bladder diary and stress test at clinical examination were assessed at 1, 3, 6, 12 months and yearly thereafter. Patients were defined as cured for SUI when wearing no pads, having no stress-related leakage and presenting a PGI-I score of one or two, as improved in case of reduction of pad usage > 50% and reduction of reported leakage episodes > 50%, associated to satisfaction level of one, two or three. Otherwise patients were classified as failur. In case of re-injection, patients were followed according to the same protocol starting form the second procedure. Post-operative pain according to visual pain scale, bleeding, post-operative urinary retention, and any adverse event were recorded. Durability of the results was assessed by a Kaplan-Meier analysis about recurrence of pad use or SUI episodes during the follow-up period

Results
Operating time was 10 minutes and blood loss was minimal for all patients. All patients described their immediate post-operative pain as under 5/10 on visual pain scale. One patient developed a postoperative urinary retention that was managed by urinary catheter during 24 hours. No patient was rehospitalized during the first post-operative month. 17 patients (34%) had two injection procedures. The median post-operative follow-up was 19±6 [10-30] months. At last follow-up, 17 patients (34%) were cured, 16 patients (32%) were improved, and 17 patients (34%) were not improved after the procedure. Survival without recurrence of pad usage is illustrated in figure 1. Pad usage was significantly reduced ($p<0.0001$).. All presenting with OAB symptoms before surgery were still experiencing urgency during follow-up, managed by anticholinergics. Four patients experienced urinary tract infection during follow-up managed by antibiotics,

Interventions	**Number of patients concerned**
Hysterectomy	12
Colposuspension	22
Mid urethral tape	30
Peri-urethral injections	9
Ajustable continence therapy (ACT)	4
Prolapse surgery	21
Artificial urinary sphincter	4
Urethro vaginal fistula	4
Cystectomy + neobladder	1
Stem cell therapy	1
Urethrolysis	3

Table 1. Previous surgical interventions underwent by patients

Interpretation of results
All patients treated were referred to our tertiary referral center on the basis of previous surgical failure of incontinence or urogynecological procedures, having led to severe SUI, needing a salvage therapy. Pre-operative evaluation showed that patients used 4.2 pads/day and had undergone several pelvic procedures. MUCP was low in this population and associated to a fixed urethra. Despite these challenging data, an overall success of 62% (including 38% of cure and 28% of improvement) was obtained after a median follow-up of 11.2 months. Furthermore, all procedures were conducted on an outpatient basis

under local anesthesia, and thus fit to all patients whatever the medical history. The technique was safe and could be repeated when insufficient. No extensive work has been published about results of periurethral injection procedures for SUI persistent after urethral or periurethral surgery. Isom-Batz et al. reported the use of collagen injection after periurethral surgery in a retrospective work [5]. In this series of 31 patients presenting SUI after periurethral surgery (sling procedure in 4 women, bladder neck suspension in 21, urethrolysis in 2, diverticulum repair in 2 and urethrovaginal fistula repair in 2), authors obtained an overall success of 80%, based only on subjective patient satisfaction.
Some limitations certainly apply to our evaluation. First, follow-up is limited. Then, to reflect clinical practice, we evaluated all the cases operated on in our unit, generating various profiles of patients, even if their common status was advanced therapeutic failure. Given the limited number of patients in this situation, no control group was available. Furthermore, cost-effectiveness of this option remains to be assessed.

Concluding message

With an overall success rate of 66%, PAHG is a safe and useful option in severe, multi-operated cases of women SUI with low MUCP and a fixed urethra. These short term results have to be confirmed by larger studies.

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**Bulkamid injections have recognied indiations of use.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**