772

Zangone M[1], Olmedo T[2], Palma P[3], Riccetto C L Z[3], Tamanini J T N[4]
1. *Hospital Bernardino Rivadavia. Buenos Aires, Argentina,* ***2.*** *Hospital San José - University of Chile. Santiago, Chile,* ***3.*** *University of Campinas - UNICAMP,* ***4.*** *Female Urology Reference Center - Bauru - Brazil*

TRANSURETHRAL BULKING AGENT INJECTION: PROMISSORY RESULTS USING THE NEW "OPSYS" POLYACRYLATE POLYALCOHOL COPOLYMER IN THE TREATMENT OF STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study

Assess clinical effectiveness of the transurethral bulking agent injection Opsys in the treatment of Stress Urinary Incontinence (SUI) when ISD is the main factor.

Study design, materials and methods

Polyacrylate polyalcohol copolymer is a permanent, non absorbable material (1) used in children to treat vesicourethral reflux condition (2).

A total of 40 women with SUI due to intrinsic sphincter deficiency, a mean age of 60.2 years, and a mean body mass index (BMI) of 31.6 kg/m^2 were prospectively included in this non-randomized open multicenter study after having signed an informed consent. Before procedure, patients were evaluated through a physical examination, a 24 hours pad test, a Q-Tip test, valsalva leak point pressure, an urodynamic study and an ICIQ-SF questionnaire final score, ranging from 0 to 21.

Patients with urinary incontinence due to idiopatic detrusor hyperactivity, hypermobility of the bladder neck, urethral fibrosis, urinary tract infection, cystocele, rectocele and vaginal prolapse were excluded.

Opsys was implanted with 21 gauge needle through transurethral technique using general or local anesthesia. The injection site was at hours 2, 6, and 10, one centimeter distal from bladder neck in the submucosal region of the proximal urethra, using a mean volume of 4.8 ml. Patients were monitored by 1, 3, 6, 12 and 24 months follow up.

The following urine loss classification was used to evaluate the 24-hour pad test: Dry patients, those with losses under 4 gr in 24 hours, improved patients, those with a reduction of over 50% from its initial condition and failed patients, those who are not included in this classification

Results

In an average 18 months follow up (1-24), the preoperative 24-hour pad test compared to the postoperative pad test showed 25 (62.5%) dry patients, 9 (22.5%) improved patients and 6 (15%) failed.

The ICIQ-SF final score (figure 1) showed a significant improvement when comparing the results prior and after implantation.

Of the 40 patients, 5 (12.5%) had reimplantation 90 days after the first procedure: 2 patients were dry, 1 showed improvement and 2 failed. Eight (20%) patients had urine retention in the first 48 hours and intermittent sterile catheterization had to be performed during such period. Urinary tract infection (UTI) was present in 4 (10%) patients, urgency in 2 (5%), and dysuria in 4 (10%).

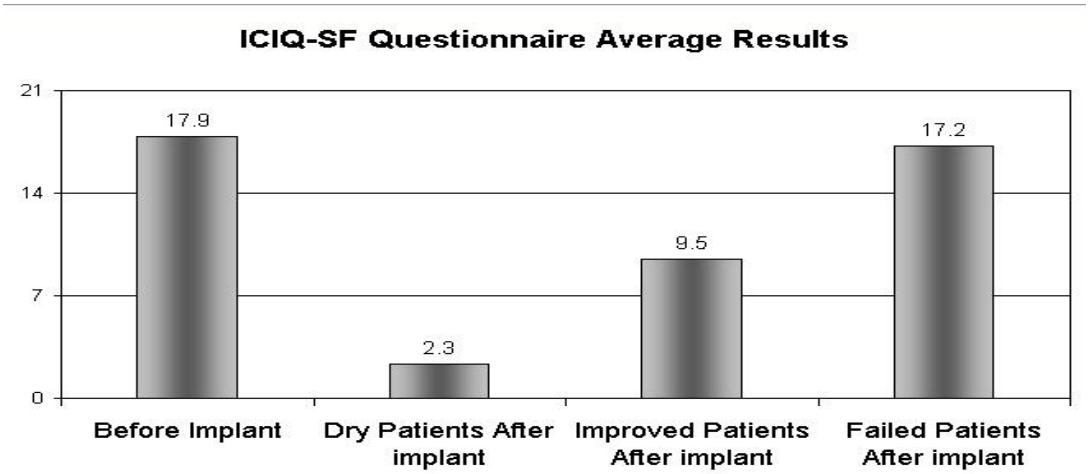

Figure 1: Average results from the incontinence ICIQ-SF questionnaire before and after the implant procedure for patients recruited for the study and divided into groups according to the incontinence classification of the 24-hour pad test

Interpretation of results

Opsys, is a non absorbable bulking agent, a polyacrylate polyalcohol copolymer hydrated in a 40% Glycerol carrier solution. This substance was implanted in 40 patients with SUI due to ISD who were monitored at 1, 3, 6, 12 and 24 months allowed us to verify the results obtained and prove treatment effectiveness.
None of the implanted patients presented adverse reactions to the bulking agent. 32 patients of this series did not show problems in micturation after the treatment. Eight patients developed acute urinary retention and required intermittent catheterization for less than 48 hs. To verify the impact of the procedure on the patients perception, the ICIQ-SF questionnaire final score was evaluated with mean values before the implant of 17.9 and after implant of 2.3 dry patients, 9.5 improved patients, and 17.2 failed patients. This reduction indicates the degree of significant improvement produced by the treatment in the patients everyday life.
Among women seeking for less invasive treatments for SUI, according to these results, Opsys offer a remarkable improvement in their quality of life to 85% of them. Also a large group of them (62,5 %) are complete dry.

Concluding message

Within an already identified tendency toward less invasive procedures, a detailed analysis of these clinical results lead to consider Opsys as a valid alternative to treat SUI in women, and to have verified the stability of the results up to 24 months follow-up.

References

1. Ormaechea M, et al . VANTRIS®, a biocompatible, synthetic, non-biodegradable, bulking substance, easy to inject. Evaluation of local tissular reaction, localized migration and long-distance migration. Arch. Esp. Urol. 2008, 61, 2 (263-268).
2. Ormaechea M, Ruiz E, Denes E, Gimenez F, Dénes FT, Moldes J, Amarante A, Pioner G, Dekermacher S, de Badiola F. New tissue bulking agent (polyacrylate polyalcohol) for treating vesicoureteral reflux: preliminary results in children. J Urol. 2010 Feb;183(2):714-7.

Specify source of funding or grant	**Promedon, Argentina**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Commitee of the University of Campinas School of Medicine**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**