

FIRST DUTCH SHORT-TERM RESULTS OF UROLASTIC, A NEW BULKAGENT FOR STRESS URINARY INCONTINENCE IN WOMEN.

Hypothesis / aims of study

To determine the efficacy of a new bulkagent Urolastic (Urogyn BV, NL) vinyl dimethyl polydimethylsiloxane (PDMS) on stress urinary incontinence (SUI) in woman with one or more failed SUI surgeries and/ or comorbidities.

Study design, materials and methods

Twenty-three women with SUI were treated with PDMS. Twenty women had a fixed urethra. Two women did not receive any previous SUI surgery, five had one previous SUI surgical procedure, six women had 2 previous procedures, three women had 3 previous procedures and eight women had > 3 previous procedures for SUI. Concomitant diseases included: mitochondrial disease & muscle weakness, vulvar radiotherapy, Lichen Sclerosus at Atrophican, detrusor hypocontractility, cervical complete spinal cord injury, sacral agenesis with intrinsic sphincter deficiency (ISD), cystectomy with neobladder, and overactive bladder syndrome with/without detrusor overactivity. PDMS was injected paraurethraly and midurethraly under local anesthesia. The volume of PDMS injected was 3,2-4,4 ml. Patients were asked to subjectively describe their improvement of their SUI.

Results

After two months follow up 57% (13/23) of the women were dry, 4% (1/23) had an improvement of 90%, 4% (1/23) had an improvement of 80%, 4% (1/23) had an improvement of 50%, 13% (3/23) had an improvement of 30%, and 17% (4/23) had no improvement.

Complications: temporary de novo retention in 30% (7/23), treated with an indwelling catheter or CIC (for a maximum of 6 days). Partial removal of the material due to vaginal exposure in 13% (3/23) of the patients, due to bladderneck erosion in 4% (1/23) of the patients, and due to deterioration of the incontinence in 4% (1/23) of the patients. In 4% (1/23) the material was partially injected into the bladder and removed immediately after injection. De novo urge was found in 4% (1/23) of the patients. Infection treated with antibiotics in 4% (1/23) of the patients. All patients experienced pain after the treatment during 2 – 14 days.

Interpretation of results

This study shows good short term result of treatment with PDMS for SUI in a group of patients who are very difficult to treat. This bulkagent is suitable for patients with SUI and a fixed urethra, suggestive of ISD. Complications seen after treatment are erosion, exposure, temporary retention, pain, infection, and de novo urgency incontinence.

Concluding message

In a difficult to treat group of women with SUI and a fixed urethra, PDMS shows good short term result, but with a complication rate of 22%. Longer follow up is needed to show the duration of the achieved results.

References

1. None

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** This are the results of our centre of an existing CE marked therapy. **Helsinki:** Yes **Informed Consent:** No