A randomized, controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence.

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Abstract

PURPOSE:
Mid urethral sling procedures have become the surgical treatment of choice for female stress urinary incontinence. Innovative modifications of mid urethral sling procedures were recently introduced with the claim of offering similar efficacy and decreased morbidity. We compared the efficacy and morbidity of an innovative single incision mid urethral tape and an established transobturator procedure.

MATERIALS AND METHODS:
We performed a prospective, randomized, controlled trial in 6 teaching hospitals in Belgium and The Netherlands between 2007 and 2009. A total of 96 patients received a TVT Secur™ single incision sling and 98 received a TVT™ Obturator System. We collected data on patient characteristics, surgery related parameters, adverse events, clinical followup, Urogenital Distress Inventory and SF-36® scores, validated questionnaires on daily life activities and visual analog scores objectifying pain. Followup was 1 year.

RESULTS:
One-year followup was available for 75 single incision sling and 85 obturator system cases. Stress urinary incontinence could be objectified in 16.4% of the patients with a single incision sling and in 2.4% with an obturator system (p <0.05). Stress urinary incontinence was subjectively reported by 24% of single incision sling and 8% of obturator system patients (p <0.05). One year after surgery the mean ± SD UDI incontinence domain score in the single incision sling and obturator system groups was 21 ± 24 and 13 ± 21, respectively (p <0.01). Patients with a single incision sling experienced significantly less pain during the first 2 weeks after surgery (p <0.05) and returned significantly earlier to normal daily activity. The OR of re-intervention for stress urinary incontinence 1 year after receiving a single incision sling vs an obturator system was 2.3 (95% CI 1.9-2.7).

CONCLUSIONS:
The single incision sling procedure is associated with less postoperative pain and a lower objective cure rate than the obturator system procedure.

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