POSTOPERATIVE PAIN IN PATIENTS WHO UNDERWENT TVT-O (INSIDE-OUT) SUBURETHRAL SLING FOR STRESS URINARY INCONTINENCE: A PROSPECTIVE STUDY OF 108 PATIENTS

Hypothesis / aims of study
To assess postoperative pain in patients with stress urinary incontinence (SUI) who underwent a transobturator vaginal tape inside-out (TVT-O®).

Study design, materials and methods
An isolated TVT-O® (Ethicon, Gynecare, Somerville, USA) procedure was carried out in 108 consecutive patients complaining of pure SUI (62 patients) or mixed incontinence (46 patients). Procedure was performed according to a modified DeLeval [1] technique (exit points of the helical needles were located in the thigh folds at the clitoris level) under local (84.2%), spinal (11.1%) or general (4.7%) anaesthesia. Patients were prospectively enrolled with verbal consent obtained for all patients. A verbal scale and a visual analog scale were used to record pain before and after surgery (6-12 hours (H6–H12) after procedure, at 1 month (M1) and 3-6 months (M3 – M6) follow-up).

Results
Mean age was 60.1 years [37-82]. Eight patients () had a previous SUI surgery and 18 () a previous pelvic organ prolapse surgery. Sixty-two patients (57.4%) complained of pure SUI while 46 (42.6%) complaining of mixed incontinence. Intraoperative complications were 3 vaginal injuries (2.7%) recognized and repaired at surgery. Postoperative pain scores are reported in Table 1. At one month follow-up 3 patients complained of an occasional unilateral thigh low pain during effort (VAS 4). No patients required medication for pain. At 3-6 months, 3 patients reported residual thigh discomfort with none having a score > 3 and none requiring medication for pain. One hundred and four patients (96.3%) attended the 3-6 months follow-up. Overall 94 patients (90.4%) were cured for SUI, while 7 (6.7%) were significantly improved. Among the forty-six patients with mixed incontinence, overactive bladder symptoms were cured or improved in 30 patients (65.2%).

Interpretation of results
Anatomical studies have suggested an increased risk of nerve damage with inside-out procedure compared to out-in [2]. These published results have supported the theory that inside-out procedure was more likely to result in postoperative thigh pain than out-in procedure. With these small changes in the initial technique, needle passages are similar to those performed when choosing an out-in procedure.

Concluding message
This prospective study demonstrates that modified TVT-O is a safe painless procedure. Only three patients (2.8 %) reported occasional discomfort at 3-6 months. Nevertheless, care must be taken at surgery to avoid a too lateral passage of the needle in the thigh that may increase the risk of postoperative pain.

Table 1:

<table>
<thead>
<tr>
<th></th>
<th>H3 – H6</th>
<th>M1</th>
<th>M3 – M6</th>
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<tbody>
<tr>
<td>n</td>
<td>106</td>
<td></td>
<td>104</td>
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<tr>
<td>VAS 1-2-3</td>
<td>38</td>
<td>6</td>
<td>3</td>
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<td>VAS 4-5</td>
<td>15</td>
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<td>VAS 6-7</td>
<td>8</td>
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<tr>
<td>VAS 8-9-10</td>
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<tr>
<td>Overall</td>
<td>62</td>
<td>9</td>
<td>3</td>
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</table>

References

Specify source of funding or grant
No disclosure

Is this a clinical trial? Yes

Is this study registered in a public clinical trials registry? 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 Only postoperative pain assessment with autoadministered questionnaires. In addition, TVT-O is a worldwide performed procedure which has been proven to be safe and effective.

Was the Declaration of Helsinki followed? Yes

Was informed consent obtained from the patients? Yes