LONG TIME FOLLOW UP RESULTS OF NON-ANIMAL STABILIZED DEXTRANOMER/Hyaluronic Acid (NASHA/DX) FOR POST-PROSTATECTOMY STRESS URINARY INCONTINENCE

Hypothesis / aims of study
Stress urinary incontinence is one of the most relevant complication after radical prostatectomy. The quality of life of these patients is dramatically decreased. Several therapies have been postulated so far. Bulking agents are minimally invasive treatment options, whether there are differences in tolerability, efficiency and adverse side effects.

One of these bulking agents is the non-animal stabilized dextranomer/hyaluronic acid (NASHA/DX) (Deflux®).

Study design, materials and methods
From 2003 till 2004, Deflux® injection was performed in 72 patients with postoperative urinary incontinence after radical prostatectomy (age range: 58 – 78 years, mean: 68 years).

Before the procedure, all the patients had a full urological examination including modified PAD – test, sonography and cystoscopy, followed by conventional videourodynamic.

After these procedures, the patients group was classified in 4 grades, depended on the intensity of stress urinary incontinence, based on the results of the modified PAD – test.

The definition of the different grades was the loss amount of urine per day:
- Grade 0: less than 15 g
- Grade I: 16 – 50 g
- Grade II: 51 – 250 g
- Grade III: more than 250 g

The submucosal injection of Deflux® was performed in local anaesthesia infrasphinctorial.

The modified PAD – test was performed 4 weeks, 3 months and 1 year after injection.

Table 1: Classification of the patient group

<table>
<thead>
<tr>
<th>Stress urinary incontinence grade</th>
<th>Number of patients (n=72)</th>
<th>Injected amount of Deflux®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0</td>
<td>5</td>
<td>1-2 ml</td>
</tr>
<tr>
<td>Grade I</td>
<td>19</td>
<td>2-3 ml</td>
</tr>
<tr>
<td>Grade II</td>
<td>36</td>
<td>2-3 ml</td>
</tr>
<tr>
<td>Grade III</td>
<td>12</td>
<td>3-4 ml</td>
</tr>
</tbody>
</table>

Results:
Immediately after injection, 45 of 72 patients were continent (grade 0: 5/5, grade I: 16/19, grade II: 21/36, grade III: 3/12).

Patients with low – grade stress urinary incontinence showed better effects after injection than patients with high – grade stress urinary incontinence.

Four weeks after injection, 33 out of 72 patients remain continent.

Three months after injection, 27 out of 72 patients showed continence.

One year after injection, there was no change in the continence rate of the patients. 27 out of 72 patients still remained continent.

From the patients group, who were incontinent 3 months after first injection (n=45), 38 patients underwent a reinjection.

Interpretation of results
Submucosal injection of non-animal stabilized dextranomer/hyaluronic acid (NASHA/DX) (Deflux®) in post prostatectomy patients is a minimally invasive treatment option in post operative stress urinary incontinence. Early results showed a high relapse rate, but patients, who were continent after 3 months, remain continent and showed no decrease in the effect of Deflux®. Because of the high tolerability and minimally invasive method, Deflux® injection can be repeated several times with no additional adverse side effects.

Concluding message
Deflux® injection is a minimally invasive and easy to do method in the treatment of post prostatectomy stress urinary incontinence.

If patients stay continent after the threshold time of 3 months, as far as observed so far remain continent.

References

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HUMAN SUBJECTS: This study did not need ethical approval because Due to the retrospective character neither a vote of the ethics committee nor informed consent of patients had to be obtained but followed the Declaration of Helsinki Informed consent was not obtained from the patients.