Non-animal hyaluronic acid/dextranomer gel (Deflux®) for endoscopic treatment of grade IV vesicoureteral reflux: long-term outcomes based on patient records

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Disclosures

• Göran Läckgren: Speaker at teaching courses for Ferring AB, Sweden; Medical adviser and speaker at instructional courses for Palette AB, Sweden

• All other authors: None
Background

• Prior to 1993 all patients with persistent grade IV-VUR underwent open surgery. Even today grade IV is considered, in some centers, as an indication for open surgery.

• From 1993 all patients with grade IV reflux were treated consequitively with endoscopic Deflux®
Spontaneous resolution of VUR becomes less likely with increased severity of reflux

Swedish children, 1–2 years of age

![Graph showing probability of reflux over years of follow up for reflux grades 3 and 4-5.](image-url)
Material

- All patients diagnosed with grade IV VUR after a febrile UTI who had persistent dilating reflux documented by a new VCUG after >1 year of antibiotic prophylaxis (mean 22mths) were treated with Deflux® (NASHA/Dx gel) from 1993-2003

- Charts from Uppsala University Hospital and local county hospitals were studied, and post-treatment VCUG results were analyzed

- Duration of follow-up: 15-25 years
Results

• Total number of patients: 185 (69 boys, 116 girls)
  • Total number of grade IV ureters: 237
  • Duplex systems: 55 ureters

• Mean age at treatment:
  • Boys: 35 months
  • Girls: 45 months

• Mean number of endoscopic treatments per patient: 1.46

• Mean volume of Deflux® injected: 0.72 mL/ureter

• Follow-up VCUG after the last treatment was performed in 173 patients (222 ureters)
Results overall

Reflux grade at the last VCUG per ureter

Ureters (%; N=222)

Grade 0–I: 69% (Girls), 70% (Boys)
Grade II: 8% (Girls), 6% (Boys)
Grade ≥III: 23% (Girls), 24% (Boys)
Results single vs duplex

Reflux grade at the last VCUG per ureter

<table>
<thead>
<tr>
<th>Grade</th>
<th>Single</th>
<th>Duplex</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 0–I</td>
<td>74%</td>
<td>55%</td>
</tr>
<tr>
<td>Grade II</td>
<td>5%</td>
<td>13%</td>
</tr>
<tr>
<td>Grade ≥III</td>
<td>20%</td>
<td>32%</td>
</tr>
</tbody>
</table>

p<0.0225

p<0.05
Results

• 41 patients (22%) had persistent VUR grade III–V and were submitted to open surgery (ureteral reimplantation)

• There was a decrease of the number of reimplantations in the second 5 year period
  • 34 (1993-1998)
Long term results

• Only 5 patients (3%) underwent late ureteric reimplantation (6–10 years after Deflux® treatment)

  • one female: late obstruction and pyelonephritis 10 years after the last VCUG
  • two females: obstructive refluxing megaureter at the time of Deflux® treatment (now a contraindication)
  • one male and one female: initially cured, recurrent lower UTIs and bladder dysfunction, VCUG ➔ dilating reflux

One male: incidental finding of calcification around the Deflux® implantation site observed on routine examination 2 years after endoscopic treatment; no intervention required
Conclusions

• Longest follow-up of VUR patients undergoing endoscopic treatment with Deflux® (15–25 years)

• Treatment with NASHA/Dx gel was effective and durable
  • 75% of patients did not need open surgery
  • Low incidence of late complications (UTI, persistent VUR, need for open surgery)

• We recommend endoscopic injection of Deflux® in patients with grade IV reflux, even in those with duplex systems