Endoscopic injection of submucosal bulking agents for the management of incontinent catheterizable channels

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Abstract Background: Urinary and fecal continence can be achieved by constructing catheterizable continent channels that provide access to the bladder and bowel. Some patients develop persistent stomal leakage. A minimally invasive method of injection with a bulking agent for treatment of stomal incontinence was evaluated.

Methods: A retrospective review identified patients with incontinence of their catheterizable continent urinary channel (CUC) and/or antegrade continence enema (ACE). All patients underwent circumferential endoscopic sub-mucosal injection of the channel with a bulking agent, performed at the level of the continence mechanism. The type of injected material, number of procedures required, and success rates were evaluated.

Results: Out of 157 patients with a CUC and/or ACE (total of 164 stomas), eight patients underwent the minimally invasive therapy (total of nine stomas). The initial reconstructive procedure was appendicovesicostomy in one patient, ileovesicostomy (Monti) in seven patients, and ACE in two patients. Amount of bulking agent injected varied from 1.4 to 7 cc (mean 3.72 cc). Follow up ranged from 1 to 39 months (median 15 months). Two patients received multiple injections. One patient had injection of both a CUC and ACE. At the time of final follow up, 6/7 (86%) patients with a CUC and 1/2 (50%) with an ACE were continent per catheterizable channel.

Conclusion: Injection of a bulking agent provides an excellent minimally invasive treatment alternative for incontinence of a catheterizable channel.

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Introduction

The success of reconstructive procedures used to attain bladder and bowel continence is often dependent on access

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to the bladder and bowel through continent catheterizable channels. These channels may be created from bladder, small bowel or appendix. The Mitrofanoff principle, creation of a flap valve mechanism, has become, for many, the preferred means of creating a continent urinary channel (CUC) [1]. Antegrade continence enemas (ACEs) allow direct access into the cecum which permits easier administration of enemas. The channel employed for the creation of an ACE is in-situ appendix which may or may not be supported by imbricated cecum. Continent channels can be employed along with bladder or bowel reconstruction, or may be used as an isolated procedure. Regardless of the type of stoma created or the reason for its construction, stomal continence is important for overall patient health and quality of life. Incontinence of a flap valve stoma is usually secondary to an inadequate valve mechanism and tends to present in the early postoperative period [2].

Formal management of stomal incontinence would require recreation of the original continence mechanism. A minimally invasive approach to address stomal incontinence could spare these patients an additional open surgery. Recent advances in the use of, and familiarity with, injectable bulking agents for treatment of VUR and stress urinary incontinence have made these materials an offset pediatric 10-Fr cystoscope (Wolf, Germany) was placed retrograde through the stoma. Injections with a 3.7-Fr injection needle were targeted to the area of the continence mechanism (buttressed appendicoccecal valve for patients with an ACE, submucosal tunnel for patients with a CUC) and were placed submucosally at the 12, 3, 6 and 9 o’clock positions. Sufficient material was injected to cause mucosal coaptation under direct vision. Patients resumed their catheterization schedule immediately postoperatively. Materials used varied and included cross-linked bovine collagen (Contigen®, Bard, Covington, GA, USA), polytetrafluoroethylene (Teflon®, DuPont, Wilmington, DE, USA) and dextranomer/hyaluronic acid (Deflux® Ixion Biotechnology, Inc., Alachua, FL, USA).

**Results**

Between 1996 and 2007 a total of 157 patients with either a CUC or ACE were followed at our institution and a total of 164 stomas were identified. Eight patients with a total of nine stomas underwent endoscopic management for stomal incontinence. The types of continent channel created in this group consisted of one appendicoccecalostomy, seven ileovesicostomies (Monti) and two ACEs. Two channels were injected with cross-linked bovine collagen, two channels were injected with polytetrafluoroethylene, and five channels were injected with dextranomer/hyaluronic acid. The mean injected volume was 3.72 cc (see Table 1). Two patients underwent planned minor open revision of the stoma (consisting of supra-fascial correction of the channel angle) in the same setting. One patient each with an appendicoccecalostomy and an ACE failed endoscopic management. Both of these patients underwent successful open revision. One patient with an ACE required two injections and was continent following the second procedure. Follow up ranged from 1 to 39 months (median 15 months). At the time of last follow up, six of the seven patients (86%) with a CUC were continent and one of the two patients (50%) with an ACE was continent. There were no complications as a result of endoscopic injection of the bulking agent.

**Discussion**

Minimally invasive techniques to treat a variety of urological conditions have become widespread and familiar to many practicing urologists. The safety and efficacy of submucosal bulking agents to aid in coaptation of the ureter and urethra have been well established [3]. Catheterizable urinary and fecal channels are commonly created as part of reconstructive surgery in patients with bladder and bowel dysfunction. Overall continence rates in patients undergoing creation of a CUC are reported to be 82—93%; however, patients who are affected with persistent stomal incontinence show a marked decrease in overall quality of life [2,4]. Like CUCs, there are technical variations in the creation of ACEs, although overall fecal continence rates per the stoma have been reported to be 97% [5]. Many patients who require creation of CCCs have complex congenital anomalies and have undergone multiple intra-abdominal procedures. When incontinence develops in these challenging patients, multiple procedures may be required in more than 50% of patients to correct stomal
incontinence [2]. Patients who require repeat open surgery to correct a lower urinary tract problem are often subjected to inpatient hospitalization, long operative times, and significant morbidity due to abdominal adhesions and aberrant anatomy. A minimally invasive therapy with a high success rate and low morbidity would be an ideal approach to manage stomal incontinence in this patient population.

Endoscopic injection of incontinent catheterizable urinary channels was first introduced by Kaefer et al. in 1997 when they successfully used collagen to salvage an incontinent urinary stoma in one patient [6]. Since that time, larger series with various injectable agents have been reported. Guys et al. utilized polymethylsiloxane to salvage continence in four of six patients with incontinent catheterizable urinary stomas [7]. Halachmi et al. also used polymethylsiloxane to correct urinary incontinence via a catheterizable channel in three of five patients [8]. The largest series to date utilized dextranomer/hyaluronic acid in 14 patients with an incontinent urinary channel. This multi-institutional study reported by Prieto et al. achieved a 79% overall continence rate with a mean injection volume of 3.7 cc with only one patient requiring a second injection [9]. Guys et al. and Prieto et al. both directed injections at the area of the continence mechanism and additional sites along the channel to achieve maximal coaptation [7,9]. Additionally, Prieto et al. managed their patients with a diverting urethral catheter or suprapubic tube in order to avoid catheterizing the channel for the first 10–14 days after injection [9].

Endoscopic management of incontinent frenal channels has been previously reported. Koivusalo et al. utilized injections of dextranomer/hyaluronic acid in nine patients with fecal incontinence per their ACE [10]. The site of the injection was the appendicovesical valve in eight patients, and the skin site and appendicoccal valve in one patient. An indwelling catheter was left per the channel for 4–7 days. The authors report that 38% of patients had a good result with cessation of fecal leakage for 3 months or more.

In a large review of 236 patients undergoing an ACE, Bani-Hani et al. attempted endoscopic salvage in five patients with fecal incontinence per their stoma [5]. The authors utilized dextranomer/hyaluronic acid and were able to correct the incontinence in one of the five patients. They concluded that endoscopic injection was ineffective in this patient population and should be reserved for patients refusing open ACE revision.

Endoscopic techniques for the injection of submucosal bulking agents in a catheterizable channel have not been standardized. Technical variation in the creation of the continent channels and the difference in the continence mechanism between CUCs and ACEs may limit one technique from being applied to all incontinent channels. Some authors report injection at the area of the continence mechanism and at various sites along the channel [7,9,10]. We report our technique that concentrates the bulking agent into the area of the failed continence mechanism. These channels are constructed with a valve mechanism that creates external compression of the channel lumen. The external compression causes outflow resistance. If the outflow resistance is higher than the storage pressure, continence is achieved. We feel that the most efficacious injections are those that are placed in the area of maximal outflow resistance—the area of the continence mechanism. Larger series of patients and standardized injection protocols will be required to demonstrate any difference between the reported techniques.

Stomal incontinence is a troubling issue to surgeons and patients alike. The time and energy focused on successful reconstruction makes any suboptimal outcome more pronounced. Stomal incontinence, while only a minor complication in the scheme of reconstructive surgery, is often viewed by the patients and their families as an indicator of failed reconstruction. Any therapy that improves overall outcomes in these patients has enormous potential. Based on our results, we feel that in properly identified patients endoscopic treatment of stomal incontinence should be attempted before open channel revision is performed. None of our patients experienced any complications from the procedure. While some patients will require multiple injections, a majority of our patients became continent following a single injection and remained so over the follow-up period. In our experience, a previously injected bulking agent did not add any significant difficulty to later open revision.

### Table 1: Details of injected stomas.

<table>
<thead>
<tr>
<th>Stoma Number</th>
<th>Stoma Type</th>
<th>Injected Material</th>
<th>Injected Volume</th>
<th>Success</th>
<th>Repeat Injection</th>
<th>Injected Volume</th>
<th>Success</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Continent Urinary Channel</strong></td>
<td>1</td>
<td>AV</td>
<td>DH</td>
<td>3.0 cc</td>
<td>No&lt;sup&gt;a&lt;/sup&gt;</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Monti</td>
<td>Collagen</td>
<td>2.0 cc</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Monti</td>
<td>Collagen</td>
<td>7.0 cc</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Monti</td>
<td>PTFE</td>
<td>1.5 cc</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Monti</td>
<td>DH</td>
<td>3.0 cc</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Monti</td>
<td>DH</td>
<td>1.4 cc</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Monti</td>
<td>PTFE/DH</td>
<td>4.0 cc</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Antegrade Continence Enema</strong></td>
<td>1</td>
<td>IA</td>
<td>DH</td>
<td>4.0 cc</td>
<td>No</td>
<td>Yes</td>
<td>7.0 cc</td>
</tr>
<tr>
<td>2</td>
<td>IA</td>
<td>DH</td>
<td>5.0 cc</td>
<td>No</td>
<td>Yes</td>
<td>3.0 cc</td>
<td>No&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>


<sup>a</sup> Dry after open revision.
Our study is limited by a relatively low number of patients and lack of long-term follow up. The lack of permanence of injectable agents is a well recognized limitation of injectable therapy. It is likely that some of these patients may require repeat injections in the future. It is believed, though not proven, that these patients would benefit from additional injections. The use of multiple injectable agents limits our ability to conclude that our success rate can be attributed to any one particular agent. The use of dextranomer/hyaluronic acid for the treatment of VUR has led to a familiarity with this injectable agent, and this agent will be utilized for the future endoscopic management of incontinent channels. Incontinence per a CUC or ACE cannot be generalized as the same entity and more experience will be needed to determine if endoscopic injection for an incontinent ACE will reach the success rate currently observed for endoscopic management of an incontinent CUC.

Conclusion

Stomal incontinence following reconstructive surgery can significantly impact on patient quality of life. Submucosal injection of bulking agents into incontinent CUCs has been shown to be a viable, minimally invasive solution to stomal incontinence. Our success rate of 86% compares favorably with previously reported series. In addition, similar treatment of ACE incontinence is feasible and has been performed successfully; however, more clinical data is needed before the role of this therapy in patients with an incontinent ACE can be defined.

Conflict of interest

No author has a conflict or interest.

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References