Role of bulking agents in improving continence postoperatively in patients with Hirschsprung’s disease

Background: The bulking agents have provided an effective means of treating adults with internal sphincter (IS) incompetence. The damages to IS in pull-through operation and in those who had hypermotile proximal bowel segments have increased the need for increasing the IS pressure. Materials and Methods: 35 children with fecal incontinence after pull-through, who presented to our unit from January 2008 to February 2012, were enrolled in the study and investigated with endoanal sonography and anorectal manometry. The bulking agent was injected into the sub-mucosal anal plane of IS. The assessments undertaken were clinical assessment of the functional score and anorectal manometry for 6-12 months. Data were analyzed with IBM SPSS version 21 using repeated measure analysis of variance (ANOVA). Friedman test was used for analyzing soilage score changes during the study. Results: Manometry readings before and 6 months after intervention were 21.8 ± 4.2 and 25.2 ± 4.7 mmH₂O, respectively. High-pressure zone area changed from 1.98 ± 0.63 to 2.8 ± 0.75 cm² (P < 0.0001). Before intervention, all the patients had complaints of soilage and complete incontinency. However, after intervention and 6-12 month follow-up, nearly 60% of patients were continent without significant soilage. However, there was a significant improvement in the overall continence grading scale scores post bulking from baseline to 6-12 months, but no change in the mean squeeze pressures at any time interval. Conclusion: Bulking of internal anal sphincter defects causes an improvement in fecal continence and the function.

Key words: Anal sphincter, bulking agent, fecal continence, Hirschsprung’s disease

INTRODUCTION

Hirschspring's disease (HD) operation is associated with a high rate of either constipation or incontinence or both (30%). Anorectal manometry shows a significantly lower resting anal pressure in the incontinent group. Therefore, fecal incontinence can be secondary to poor compliance and elevated rectal pressure in the presence of normal or low anal sphincter resting pressure.[1-7] Reports of the use of injectable bulking agents for fecal incontinence are currently confined to a small number of pilot studies, while fecal incontinence can have a profound impact on all aspects of quality of life.[8] It has been shown that disruption of the internal anal sphincter muscle fibers correlates significantly to impaired function and symptoms of passive fecal leakage.[9] The use of injectable perianal internal sphincter (IS) bulking agents has provided an effective, minimally invasive treatment as an alternative in Patients with IS incompetence.

The aim of this study was to evaluate the short-term efficacy of an anal sphincter bulking agent (Opsys/promedon/argentina) in patients who underwent post pull-through operation for HD with internal anal sphincter dysfunction that was refractory to conservative management.

MATERIALS AND METHODS

Thirty-five children who referred to our unit for management of fecal incontinence after surgery for HD IS dysfunction between January 2008 and February 2012 were enrolled in this study. Their mean ± SD age was 4.9 ± 1.8 years (range: 2-9 years). The surgery was performed by one surgeon.
All had Ethics Committee granted ethical approval and all patients gave their written informed consent.

We classified patients the according to their symptoms as follows:\(^1\)
1. none; 2. occasional (<3/week); 3. frequent (≥3/week); 4. daily; and 5. incontinent.

We investigated all the patients with endoanal sonography and anorectal manometry. Endoanal sonography was performed to assess the thickness and integrity of the internal and the external anal sphincters. We used B and K axial endonic probe type 1850 of 7 MHz with a diameter of 1.7 cm and the plastic cone was covered with a condom lubricated with gel. We assessed anorectal function by manometry study with midazolam oral sedation using a 14-cm anal probe built in our unit.\(^2\) All patients had previously tried a range of conservative measures, including dietary and fluid manipulation, anti-diarrheal medication, and stool bulking. All patients were treated in the out-patient department under general anesthesia, and antibiotic cover with Opsys (promedon/argentina), a hydrogel polyacrylate for stress urinary incontinence in women, was administered with a 21-gauge needle.

Patients were positioned in the left lateral position. Sterile, preloaded, 1-ml syringes were used for the drug. Opsys was injected into the sub mucosal anal plane at the site of the defect at 3, 6, and 9 o’clock positions and anal sphincter symmetry was restored.

The following assessments were undertaken to clinically assess the function. The anorectal physiology and continence scores were measured before and 3 and 6-12 months after injection. The mean normal reference values for maximal resting squeeze and cough pressures were measured with “pull-through technique”. Our laboratory standard for squeeze and cough pressure are $\geq 80$ cm H2O and $\geq 120$ cm H2O, respectively.\(^3\) [Figures 1 and 2].

Statistical analysis

Data were analyzed with IBM SPSS version 21 using repeated measure analysis of variance (ANOVA) for manometry and high-pressure zone measurements. Friedman test was used for soilage score changes during study.

RESULTS

All patients tolerated the Opsys injection well. A mean volume of 2.1 ml (range: 1.5–4 ml) was injected at one to three sites, which was the maximum volume injected in one patient at a single site to restore anal canal symmetry.

Ten patients reported mild anal discomfort for 2-3 days post procedure, which resolved spontaneously with sedative. Fifteen patients reported a slight rise in core temperatures for 3 days post procedure, which resolved with anti-inflammatory drugs.

Manometry and high-pressure zone measurements for internal anal sphincter during 6-12 months are presented in Figures 3 and 4. Manometry readings before and 6-12 months after intervention were 21.8 ± 4.2 and 25.2 ± 4.7 mmH2O, respectively. The manometry reading during 6-12 months after intervention was significant [Table 1]. High-pressure zone area changed from 1.98 ± 0.63 cm to 2.8 ± 0.75 cm ($P < 0.0001$) [Table 1]. Before intervention, all patients had a history of soilage and incontinency. However, after intervention and 6-month follow-up, nearly 60% of patients were continent without significant soilage [Table 2]. However, there was a significant improvement in the overall continence grading scale scores post bulking from baseline to 6-12 months, but no change in the mean squeeze pressures at any time interval.

DISCUSSION

Fecal incontinence post pull-through operation may be secondary to sphincter damage or overflow soiling, which can be identified by clinical examination and biopsy, anorectal manometry, and intestinal transit studies and imaging of anal sphincter complex.\(^4\)

Imaging is especially relevant in HD operations where the internal anal sphincter cannot be expected to be normal, the rectum has been removed, and the proximal large bowel may persist to be hypermobile or hypoactive after a technically perfect operation.\(^5\)

Current treatment options for the management of fecal incontinence include simple measures such as dietary and fluid volume changes, the correct use of stool bulking and/or anti-diarrheal agents, bowel retraining techniques, and targeted anal sphincter exercises with biofeedback.\(^6\)

Anal sphincter bulking with Opsys is a safe and well-tolerated, minimally invasive procedure that can be performed easily in the out-patient setting. Our results showed that there is improvement in continence function in the short term as well as long term.

More importantly, there appears to be mild attenuation of effect in the long term. However, there is a reported significant improvement by

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Table 1: Comparison between manometry and high-pressure zone measurements during 6 months

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before intervention</th>
<th>1 month</th>
<th>3 months</th>
<th>6-12 months</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manometry (mmH2O)</td>
<td>21.8±4.2</td>
<td>29.2±5.1</td>
<td>27.6±5.2</td>
<td>25.2±4.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>High-pressure zone (cm)</td>
<td>2±0.63</td>
<td>2.8±0.65</td>
<td>2.7±0.71</td>
<td>2.8±0.75</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Table 2: Comparison between soilage scores during 6 months

<table>
<thead>
<tr>
<th>Variables</th>
<th>Soilage score before intervention</th>
<th>Soilage score at 1 month</th>
<th>Soilage score at 3 months</th>
<th>Soilage score during 6-12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>21 (60)</td>
<td>20 (57.1)</td>
<td>23 (65.7)</td>
</tr>
<tr>
<td>2</td>
<td>21 (60)</td>
<td>14 (40)</td>
<td>11 (31.4)</td>
<td>9 (25.7)</td>
</tr>
<tr>
<td>3</td>
<td>11 (31.4)</td>
<td>-</td>
<td>4 (11.5)</td>
<td>3 (8.6)</td>
</tr>
<tr>
<td>4</td>
<td>1 (2.9)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>2 (5.7)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
and in the final continence score.

In this study, the sites injected were uniformly spread around the anal circumference. Post injection, endoanal ultrasound confirmed the presence of Opsys at the injection site in all but four patients. In these four patients, the Opsys leaked out immediately from the injection site and was noticed on the toilet paper and mixed with stool. This agent generally does not have the problems of migration or absorption as has been previously reported with other sphincter bulking agents.[9,10]

The mechanism of action of bulking with Opsys is multifactorial. Mechanical obliteration of the sphincter probably helps to keep the anal canal closed.

It has previously been reported that there is a combined defect of the internal and external anal sphincters in incontinence.[11]

Resting pressures in our patients were just below the normal values, whereas the squeeze pressures were normal. The injection corrected anal canal asymmetry, and continued remodeling of the bulking site over time may provide another mechanism for improvement.

Also, the length of high-pressure zone was increased in all, which is important for improving the continence.

We found that bulking of internal anal sphincter defects with Opsys causes an improvement in fecal continence and also function, but prolonged follow-up is needed to know whether it would be maintained over time or not. We recommend the noninvasive method as the preferred treatment for this group of patients with incontinence.

REFERENCES

5. Foroutan HR, Hosseini SM, Banani SA, Bahador A, Sabet B, Zeraatian S.


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Announcement

Android App

A free application to browse and search the journal’s content is now available for Android based mobiles and devices. The application provides “Table of Contents” of the latest issues, which are stored on the device for future offline browsing. Internet connection is required to access the back issues and search facility. The application is compatible with all the versions of Android. The application can be downloaded from https://market.android.com/details?id=comm.app.medknow. For suggestions and comments do write back to us.