Injection Sclerotherapy Using Polidocanol in the Early Management of Rectal Prolapse in Children- At Tertiary Care Hospital

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Abstract

**Background:** Aim. The present study has been conducted to analyse the results of Injection sclerotherapy using Polidocanol alone or in combination with Thiersch’s Stitch in the early management of Rectal Prolapse (RP) in children. **MATERIAL AND METHOD:**-All the patient’s up to 14 years of age presenting with a diagnosis of idiopathic RP in the outpatient department or in the Emergency wing of the Govt Medical College Hospital Jammu for the first time were enrolled for the study. There were total 30 children and were divided into two groups for deciding the mode of treatment Group ‘A’ – children with mucosal/partial/intermittent RP which got reduced on its own after defecation / straining and Group ‘B’ – children with complete prolapse which had to be reduced manually after defecation or those children who came with persistent prolapse to the hospital.

Group A patients were given sclerotherapy only using polidocanol and in Group B children combined sclerotherapy with Thiersch’s Stitch procedure was performed. Polidocanol was injected submucosally at 3,6 and 9 o’clock position in a dose varying between 3-5 mg/kg body weight and in combined procedure in addition Thiersch’s Stitch using vicryl was applied. All Patients were admitted in the hospital for 72 hours and then followed up in the out patients department. **RESULTS:**- The study comprised of total 30 children with mean age of 5.71 years. There were 22 (73.3%) male and 8 (26.6%) female patients. Group A comprised of 13 (43.3%) children and group B 17 (56.67%). 27 (90%) patients (11 in Group A and 16 in Group B) were followed for 12 weeks and 3 (10%) patients (2 in Group A and 1 in Group B) were followed for 6 weeks. All the 13 patients in Group A and 17 patients in Group B were relieved of their symptoms with success rate of 100% of the approach in the study. Postoperative complications noted were constipation in 3(10%), mucosal protrusions in 1(3.33%) and slippage of ligature in 1(3.33%) patient. But there was no recurrence seen in these patients in follow up. **CONCLUSION:** We recommend that injection sclerotherapy using polidocanol alone or in combination with Thiersch’s Stitch is highly successful procedure in the management of rectal prolapse in children. The drug is more effective, safe, affordable and easily available.

**Key Words:** Rectal Prolapse, Injection Sclerotherapy, Polidocanol, Thiersch’s Stitch.
vascular stasis, ulceration and even gangrene in later stages, or chronic debilitating symptoms such as faecal incontinence and mucous discharge\(^5,4\). Traditionally the disease has been treated initially with the dietary modifications, laxatives, avoiding squatting and straining during defecation. The duration of conservative medical treatment and the optimal surgical approach required for paediatric RP has remained a controversial issue in the available literature\(^5\). Initial operative management if necessary should consist of less invasive procedures like injection sclerotherapy or Thiersch’s Stitch. Injection sclerotherapy with different agents has been described as the most popular and minimally invasive procedure for initial management of rectal prolapse in paediatric population\(^6,7,8\). The procedure is cost effective, simple, has low morbidity and can be used for both partial and complete RP\(^9\). Different types of sclerosants have been used for sclerotherapy in RP like hypertonic saline\(^1\), ethyl alcohol\(^6\), cow’s milk\(^9\), 5\% phenol in almond oil\(^10\), 50\% dextrose water\(^11\). Newer and safe agents like Sodium Morrhuate\(^12\), Deflux\(^12\) and Polidocanol\(^12\) are now being used more frequently and these have low complication rate. Upto 90\% success rate after sclerotherapy with few complications have been reported in different studies\(^13\). Other minimal invasive surgical procedures described in literature are Thiersch’s encirclement suture\(^14\), linear cauterization\(^15\) and packing of presacral space with various materials\(^16\). Since the optimal approach for the management of RP in children has been controversial, we report here our approach of early intervention in children with RP in a study of 30 patients who presented at our tertiary care referral hospital for the first time and were offered minimal invasive procedure where polidocanol as sclerosant alone or in combination with Thiersch’s Stitch procedure was performed as a primary mode of treatment. The effectiveness of the drug, its side effects, complications if any and outcome of the treatment were evaluated.

II. Material And Methods

The present study was conducted in the Paediatric Surgical Division of Department of Surgery Govt. Medical College Jammu which is a Tertiary Care Referral Hospital, over a period of 1 year (Nov2016-Oct2017). All the patients upto 14 year of age coming to hospital with history suggestive of rectal prolapse or there was rectal prolapse demonstrated or detected at the time of examination or those patients who presented in emergency wing with prolapsed rectum were included in the study. Children were divided into two groups for deciding the mode of treatment. Group ‘A’→ Children with mucosal/partial/intermittent rectal prolapse which got reduced on its own after defecation/straining. Group ‘B’→ Children with complete prolapse which has to be reduced manually after defecation/ those patients who presented with persistent prolapse in the hospital. All the patients were admitted in the hospital and relevant investigations were done. Preoperative preparation was given in the ward which included liquid diet for 12hrs, bowel preparation by giving enema on the previous night and in the morning on the day of surgery followed by normal saline washes both times. Preoperative antibiotics were administered intravenously half an hour before the operation. The procedure was performed under general anaesthesia. Group ‘A’ patients were subjected to sclerotherapy only using polidocanol solution and group ‘B’ patients were subjected to sclerotherapy combined with Thiersch’s Stitch procedure. Patient was placed in lithotomy position and perineal area was cleaned and draped (fig 1). Polidocanol injection 3\% solution was used according to weight of the baby with a dosage varying between 3-5mg/kgBW. The transparent solution was taken in one unlock syringe which was attached to a three way stopcock & the second unlock syringe filled with air was attached to the same stopcock. Both were mixed together to make foamy material which was then injected in submucosal plane using 22G hypodermic needle in small children and 22G spinal needle in older children by following methodology:-

- Digital rectal examination was performed and the needle was passed just above the mucocutaneous junction into submucosal plane under the guidance of the index finger of left hand for a distance varying between 4-6cm depending upon the age. The foamy material was injected starting from above and slowly withdrawing the needle while injecting the solution submucosally.
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The foamy material was injected at three positions first starting posteriorly at 6°Clock positions and then two lateral positions at 3°Clock and 9°Clock on both sides. About 50% of the drug was injected posteriorly and remaining 25% each on lateral positions. In combined procedure in group ‘B’ patients, firstly Thiersch’s Stitch procedure was performed using delayed absorbable suture vicryl 1/0 or No 1 depending upon the age and then sclerotherapy as described above was carried out. The suture knot was tied at the end taking care not to tighten it too tight by placing a finger in the anal canal (fig 2). At the end of the procedure anal canal and lower rectum was packed with gauge soaked betadine solution and xylocaine jelly for a period of 24hrs to avoid leakage of drug. Patients were kept in the ward and injectable antibiotics were continued for 48hrs and pack was removed after 24hrs on 1st postoperative day. Orals were allowed after 6hrs of surgery and patients were advised laxatives, analgesics and sitz bath in postoperative period. In the postoperative period children were observed for early complications like fever, anaphylaxis, diarrhoea, haemorrhage, pain while defecating, mucosal oedema.
and constipation. Patients were discharged after 48hrs of operation if no complications were present and had passed stools. All the patients were advised follow up in the outpatient department at 1st week, 3rd week and 6th week and subsequently as required. In follow up they were examined for complications like collections, ulceration, stenosis, constipation, incontinence and managed accordingly.

### III. Results

A total of 30 children up to the age of 12 years were studied. There were 22(73.3%) male and 8(26.67%) female patients. Mean age was 5.71 years with youngest patient 1.5 years and eldest patient 12 years of age. Group ‘A’ patients comprised of 13(43.3%) children and Group ‘B’ 17(56.67%) patients. 23(76.67%) patients were from far off hilly areas and 7(23.33%) from semi urban & urban areas. Group ‘A’ patients were early to present for treatment after the symptomatology on an average less than 2 months (mean 54.2 days) while group ‘B’ patients had duration of symptoms of more than 5 months (means 161.2 days). Mean operative time for the procedure in group ‘A’ was 5.23 minutes (4 to 7 mm) and in group ‘B’ 10.70 minutes (7 to 15 mm). The duration of hospital stay was 2 days for all 13 patients in group ‘A’ & in group ‘B’, 2 days for 16 patients and 3 days for 1 patient. 27(90%) patients (11 in group A & 16 in group B) were followed for 12 weeks and 3(10%) patients (2 in group A & 1 in group B) were followed upto 6 weeks only and all these were operated in later part of study. All 13 patients in group ‘A’ & 17 in group ‘B’ were relieved of their symptoms in the follow up period thus giving 100% success rate in the study. The complications observed in the study were postoperative constipation in 3 (10%) patients, 1(3.33%) patients in group ‘A’ had mucosal protruding which settled conservatively in subsequent follow up and 1(3.33%) patients in group ‘B’ had slippage of the ligature after 1 month of Surgery but there was no recurrence in this case later on.

<table>
<thead>
<tr>
<th>Group</th>
<th>Total Number of Patients</th>
<th>Sex</th>
<th>Mean Age</th>
<th>Mean Duration of Symptom</th>
<th>Distance from Hospital</th>
<th>Mean Operative Time</th>
<th>Follow up Period</th>
<th>Complications</th>
<th>Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Semi urban Hilly Areas</td>
<td></td>
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</tr>
<tr>
<td>A</td>
<td>13</td>
<td>Male-9 Female-4</td>
<td>4.8 years</td>
<td>54.2 days</td>
<td>2-11</td>
<td>5.23 Minutes (4-7 Mts)</td>
<td>2-11</td>
<td>Mucosal prolapse 1 patient</td>
<td>100%</td>
</tr>
<tr>
<td>B</td>
<td>17</td>
<td>Male-13 Female-4</td>
<td>5.7 years</td>
<td>162.4 days</td>
<td>5-12</td>
<td>10.10 Minutes (7-15 mts)</td>
<td>1-16</td>
<td>Slippage of ligature 1 patient</td>
<td>100%</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>Male-22 Female-8</td>
<td>--</td>
<td>--</td>
<td>7-23</td>
<td>--</td>
<td>3-27</td>
<td>--</td>
<td>100%</td>
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### IV. Discussion

Rectal Prolapse is a common problem in children living in developing countries like India. Conservative treatment has remained as mainstay of management to begin with, waiting for the spontaneous resolution to occur. The duration of conservative management has not been agreed upon and moreover we don’t know in how many of these patients, the partial prolapse will further progress to complete type during this period. During the conservative approach many problem are faced by the children and parents, particularly in hilly far off areas of a state like Jammu and Kashmir. Prolapse at times is very difficult to reduce and its presence is horrifying and alarming to many parents, who always request for some kind of intervention at the earliest\(^{(17)}\). We therefore decided to offer treatment to all the children with RP who came to our institution for consultation or presented in the emergency with persistant prolapse. The type of interventions required in RP has not been agreed upon by various authors \(^{(1,6,18)}\) and even the different sclerosants used and surgical procedures to be undertaken is also controversial\(^{(10)}\). However injection sclerotherapy has been described as the most popular mode of treatment in the available literature. Sahay R et al (2017)\(^{(10)}\) has suggested sclerotherapy using 5% phenol in almond oil as the first line treatment for RP in children refractory to medical management. Polidocanol (hydroxyl-protoxy dodecane) is a compound formed by ethoxylation of fatty alcohol dodecanol(C\(_{12}\)H\(_{25}\)). Polidocanol as a sclerosant has been used in various concentration in different surgical conditions both in children and adults such as haemorrhoids\(^{(19)}\), lymphangioma\(^{(20)}\), haemangioma\(^{(21)}\), non variceal GI bleeding\(^{(22)}\), varicose veins\(^{(23)}\), aneurysmal bone cyst\(^{(24)}\), bleeding after colon polypectomy\(^{(25)}\) and a few reports of RP in children\(^{(12)}\). The mechanism of action of polidocanol is possibly an aseptic chemical

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inflammation of the surrounding tissues leading to fibrosis and as a result the mucosa becomes adherent to the underlying muscle coat. The drug when mixed with air and prepared for injection forms a microfoam like a detergent and after injection spreads over a wide area in the submucosal plane. In our view this unique property makes polidocanol more effective as compared to other agents used for sclerotherapy. Besides this, it has also some anaesthetic action that reduces the postoperative pain and irritation. The compound is easily available in the market as clear solution and is very cheap. The commonly available preparation has 3% concentration that contains 60mg of the drug in a vial having 2ml solution. The dosage administered in our study varied between 3.5mg/kg/BW. We used this drug alone in patients with mucosal prolapse or those children who had intermittent prolapse which got reduced as its own. The basic requirement for the sclerosants to act effectively is that rectum should stay inside the anal canal in postoperative period. But in those patients who had complete RP requiring manual reductions or those children who had persistent prolapse, injection sclerotherapy was combined with Thiersch’s Stitch. The aim of the combination procedure is to manage the postoperative sclerotherapy time period in a more effective way. With the mechanical barrier of Thiersch’s Stitch, rectum stays inside the anal canal there by allowing the sterile inflammation caused by sclerotherapy and the formation of adhesions to occur more effectively 17,26. Khan et al 2008(17) has also reported the combination procedure using chromic catgut and 5% phenol in almond oil as sclerosant in a study of 13 paediatric patients having RP. There was recurrence in 3 patients in the study which settled with repeat sclerotherapy. Only complication was abscess formation in perianal area in 3 patients. They strongly recommended this approach for the management of RP in children. Flum AS et al 2010(7) also used the combination therapy using hypertonic saline or 25% dextrose with water, encirclement suture using No 1 PDS & linear cauterization. Their study included 29 Paediatric patients with RP refractory to conservative management. 90% patients had resolution of their prolapse following one or two combination procedures (67% following initial procedure and 23% in subsequent repeat sclerotherapy). They concluded that combination technique is likely to be more effective and reasonable approach for RP in children. Anmuth SA and Kottb MBM 2015(27) have also used combination technique in adult patients using ethanolamine olate and No 2 prolene encirclement suture. They repeated a success rate of 55% and concluded that their approach is simple and safe with reasonable outcome. In the present study all the 13 patients where sclerotherapy alone was used and 17 patients where combination therapy was performed were cured of their symptoms in the follow up period. Thus, the success rate in the present study was 100%. When a single agent has been used as sclerosant the success rate with different agents have been 95% with cow’s milk proteins9, 96% with ethyl alcohol38, 93.7% with 15% saline39, 100% with 5% phenol in almond oil40, 100% with 30% saline. The results of the present series using polidocanol as sclerosant are comparable. When combination procedure have been performed the success rate reported has been 97.6% by Khan D et al (17). 98% by Siafakas A et al(32) and 100% by Anato B et al (33) in their studies as compared to 100% in the present study. No major complications occurred in our study which was directly attributed to the drug polidocanol used. There were minor complications like faecal impaction in 2 patients & slippage of ligature in one patients. Both these problem had no implication on the final outcomes in these patients. However with 5% phenol in almond oil various complications have been seen like perianal abscess formation, mucosal sloughing, extensive necrotizing fascitis and anal stenosis3,17,34. Faecal incontinence, anal stenosis & neural injury have also been reported with hypertonic saline3,28.

In conclusion we say that injection sclerotherapy using polidocanol alone or in combination with Thiersch’s Stitch is highly successful procedure in the management of RP in children. The drug is more effective, safe, affordable and easily available. The procedure is less time consuming with minimum complications and without recurrence. We also recommend early surgical intervention with this methodology in paediatric RP at tertiary care hospital in all the symptomatic patients even with short history particularly those from the far off hilly areas without giving trial of conservative medical management. Moreover this approach will decrease the morbidity, cost of treatment and obviate any long term psychological effects on the children and parents.However, given the small number of patients and short term follow up, more number of patients and longer follow up is required to standardize this approach.

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