

A Randomized Controlled Trial Comparing Injection Polidocanol, with Injection 50% D/W in Rectal Prolapse

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ABSTRACT

Background: Rectal prolapse manifests as the protrusion of the rectal mucosa through the anal opening. There can be partial or full thickness prolapse. It usually occurs before 4 years of age. Rectal prolapse in childhood tends to affect both males and females equally.

Aim: To compare Inj. Polidocanol with Inj 50% D/W in rectal prolapsed in this randomized controlled trial.

Methods: The study was conducted in the pediatric surgical ward of Mayo Hospital & King Edward Medical University Lahore, after receiving approval from the Hospital's Ethical Committee. There were 60 patients rectal prolapse with 30 patients in each group. Polidocanol was used in group A while 50% dextrose water was used in group B. The procedure was performed under general anesthesia. In the postoperative period children were observed for early complications like fever, anaphylaxis, diarrhea, hemorrhage, pain while defecating, mucosal edema and constipation. Results were analyzed with SPSS.

Results: Out of 60, 36 were male while 24 were female. Group A included 16 male and 14 females whereas group B had 20 males and 10 female children. Mean age was 5.35 years with SD of 2.7 and ranging from youngest child of 8 months till eldest of 12 years. In group A mean age was 5.44 while mean age of group B was 5.26 years. All 30 patients in group A were relieved of their symptoms after single session of Polidocanol so giving 100% of success rate while 28 patients (93.33%) in group B were relieved of their symptoms while 2(6.66%) patients developed recurrence with no significant difference. The complications observed in the study were post-operative constipation in 3(10%) patients in group A, however no patient developed postoperative stricture, infection or adverse drug reaction. In group B no patient developed any post-operative complication.

Practical Implication: This comparative study helps us to find more effective and better drug available as a sclerosing agent to treat rectal prolapse in pediatric population. It's also cost effective and with fewer side effects and easily available.

Conclusion: In conclusion, injection sclerotherapy using polidocanol emerges as an equally successful procedure for managing RP in children. This medication demonstrates enhanced efficacy, safety, and accessibility. The process is not only less time-consuming but also entails minimal complications.

Keywords: Rectal Prolapse Manifests, Protrusion, Mucosa, Chronic Constipation, Hirschsprung's Disease,

INTRODUCTION

Rectal prolapse manifests as the protrusion of the rectum through the anal opening. Partial rectal prolapse involves only the mucosa and appears as radial folds protruding between half an inch to one inch from the anal verge. Conversely, complete or full-thickness rectal prolapse entails the protrusion of the entire rectal wall through the anal canal. This is visualized as circular folds of mucosa, typically extending more than 2 inches from the anal verge. It commonly occurs before the age of 4 due to anatomical variations in children. These include a low position and vertical course of the rectum, increased mobility of the sigmoid colon, loose attachment of the rectal mucosa to the muscularis, absence of Houston's valves, a flatter coccyx, and inadequate levator support. These anatomical nuances collectively heighten the risk of rectal prolapse in children².

Rectal prolapse in childhood tends to affect both males and females equally¹. Its clinical presentation typically coincides with defecation, characterized by the painless protrusion of a mass and a sensation of incomplete evacuation or tenesmus. While most affected children do not exhibit specific predisposing factors, rectal prolapse can be associated with certain contributing factors^{1,2}. These may include chronic constipation (observed in up to 3% of cases), cystic fibrosis, neurologic disorders like myelomeningocele, and bladder extrophy. Additionally, rectal prolapse has been documented in children with severe malnutrition, failure to thrive, connective tissue disorders, rectal polyps, and following pull-through procedures for anorectal malformations or Hirschsprung's disease, albeit less frequently³.

The diagnosis of rectal prolapse primarily relies on history-taking and clinical examination. The vast majority of cases resolve spontaneously without the need for surgical intervention. Often, the prolapse reduces spontaneously, making it challenging to observe in an office setting after the event. However, some patients may require manual reduction if the prolapse persists⁴. For cases that do not resolve spontaneously, various therapeutic options exist. Medical management, particularly addressing underlying constipation, remains the cornerstone of treatment, significantly reducing straining and prolapse incidents⁵. Surgical intervention becomes necessary for cases of intractable prolapse. Less invasive techniques such as injection sclerotherapy, mucosal cauterization, and submucosal suture placement have been described. Surgical approaches include laparoscopic or open rectopexy, sigmoid resection, and rectal resection^{5,7}.

Sclerosing agents, crucial for treating rectal prolapse, may be inaccessible or expensive. Various agents have been utilized with differing outcomes, including 15% saline, 30% saline, 70-98% ethyl alcohol, 50% dextrose, 5% phenol in almond oil, cow's milk, and the novel drug polidocanol. These agents induce intense inflammation and fibrosis between the rectal mucosa and submucosal tissue to prevent prolapse⁴.

The use of 5% phenol in almond oil as a sclerosing agent is a traditional and long-standing technique, yielding satisfactory yet variable results. In one study, its efficacy for rectal prolapse reached up to 73.3% with a recurrence rate of 26.7%. In contrast, the use of polidocanol as a sclerosing agent is relatively new and is gaining popularity due to fewer complications and favorable outcomes. In one study, its effectiveness resulted in a 100% recovery from prolapse, while another study reported success rates up to 95%.

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Sing N et al (2019) compared efficacy of polidocanol injection vs. polidocanol combined with Thierch stitch for rectal prolapse⁸. The study comprised of total 30 patients with mean age of 5.71 years. Patients were followed for 12 weeks. All the patients in group A and group B were relieved of their symptoms with success rate of 100%. On long-term follow up no recurrence was observed⁸.

Al-Hamadani⁶ conducted retrospective study on effectiveness of injection 50% dextrose water for rectal prolapse. There was total 28 patients with mean age of 4.5 years. Patients were followed for 18 months. Sclerotherapy was successful in 96.5% patients after 1 session. Three cases required two sessions to improve. Failure of treatment was seen in one patient ($p < 0.0001$)⁶.

Limited data is available on comparison of both Sclerosing agents in treatment of rectal prolapse in children. Moreover, polidocanol is relatively novel drug and cost effective. Therefore, we conducted this comparative study between these two Sclerosing agents so that clinical evidence could be generated locally which would further guide us to opt better drug selection for rectal prolapse in paediatric population.

MATERIAL AND METHODS

A study was conducted involving patients of pediatric age up to 14 years with mucosal/partial/intermittent rectal prolapse which got reduced on its own after defecation/straining and underwent elective treatment of early rectal prolapse using a sclerosing agent. The study was conducted in the pediatric surgical ward of Mayo Hospital, Lahore, after receiving approval from the hospital's Ethical Committee. The parents/guardian of potential candidates for this study was educated preoperatively regarding the use of Sclerosing agents and their effectiveness, outcomes, side effects, and complications and informed consent was taken. Two groups of children were formed in order to determine the course of treatment. Polidocanol injection as a sclerosing agent is Group "A"'s approach. 50% D/W as a sclerosing agent for group "B" After being admitted to the ward, patients had pertinent investigations, comprehensive blood counts, and thorough stool examinations. Every patient was prescribed oral metronidazole. Preoperative care in the ward involved a 12-hour liquid diet, bowel preparation with an enema the night before and early on the day of surgery, and routine saline washings on both occasions. During the surgery, general anaesthesia was used. The perineal region was cleansed and wrapped while the patient was positioned in a lithotomy posture. The dosage of polidocanol injectable solution varied between 3-5mg/kg Birth Weight, based on the baby's weight. One unilock syringe was used to draw the solution, and it was connected to a three-way stopcock along with another unilock syringe that was loaded with air. After combining the two, the mixture was injected into the submucosal plane using a 22G spinal needle for older children and a 22G hypodermic needle for smaller children. The first step was a digital rectal examination. The needle was inserted into the submucosal plane, just above the mucocutaneous junction, using the left index finger as guide. The needle's length varied depending on the patient's age, from 4-6 cm. The substance was gently withdrawn from the needle after being administered from above. While subcutaneously administering the remedy. Children were monitored for early problems such as fever, allergy, diarrhoea, bleeding, discomfort during defecation, mucosal edoema, and constipation throughout the postoperative period. If there were no complications and the patients had passed stool, they were released from the hospital after 48 hours following surgery. For three months, every patient was monitored for symptom relief and prolapse recurrence. SPSS Version was used to analyse the results. A P-value of less than 0.0001 was deemed statistically significant.

RESULTS

In table 1, A total 60 patients with rectal prolapse were included in the study with 30 patients in each group. Out of 60, 36 were male while 24 were female. Group A included 16 male and 14 females whereas group B had 20 males and 10 female children. Mean age was 5.35years with SD of 2.7 and ranging from youngest child of 8 months till eldest of 12 years.

Table 1: Gender distribution report

		Gender		Total
		Male	Female	
Group A	Count	16	14	30
	%within group	53.3%	46.7%	100%
Group B	Count	20	19	30
	%within group	66.7%	33.3%	100%
Total	Count	36	24	60
	%within group	60.0%	40.0%	100%

Table 2: Age stratification

Group	Mean	N	Std. Deviation
A	5.4433	30	2.75427
B	5.2667	30	2.88795
Total	5.3550	60	2.79930

In group A mean age was 5.44 while mean age of group B was 5.26 years. Majority of children belonged to urban areas. In group A 22 children had partial prolapse and 8 children presented with full thickness rectal prolapse. While in group B 25 patients presented with partial thickness and 5 with full thickness prolapse with non-significant p value (0.88). All the patients were followed for 6 months for any recurrence of prolapse after sclerotherapy. After only one Polidocanol session, all 30 patients in group A experienced complete symptom relief, yielding a 100% success rate. In group B, 28 patients (93.33%) experienced complete symptom relief, while 2 patients (6.66%) experienced recurrence with no discernible change. Three patients in group A (10%) experienced post-operative constipation, which was one of the study's problems; no patients experienced postoperative stricture, infection, or adverse medication response. No patient in group B experienced any complications following surgery.

Table 3: Degree Cross tabulation

		Degree		Total
		Partial	Full thickness	
Group A	Count	22	8	30
	%within group	73.3%	26.7%	100%
Group B	Count	25	5	30
	%within group	83.3%	16.7%	100%
Total	Count	47	13	60
	%within group	78.3%	21.7%	100%

DISCUSSION

Rectal prolapse is a common problem in children living in developing countries like Pakistan. There are several medicinal and surgical therapeutic options for the management of rectal prolapse in pediatric patients, with a high percentage of possible resolution. In addition, when the underlying cause is addressed, spontaneous resolution of the rectal prolapse is recorded¹. Decision-making in the management of rectal prolapse becomes complex due to several factors. It is challenging to determine when surgical intervention is necessary, especially when conservative treatment options show promise². In rural areas with limited healthcare resources, parents and children encounter various difficulties during conservative treatment. In some cases, reducing the prolapse proves arduous and causes distress to parents, prompting them to seek intervention promptly. Sclerotherapy, known for its effectiveness in treating rectal prolapse, becomes the preferred surgical option after conservative methods fail.

The use of 50% dextrose water is cheap and easily available sclerosing agent used for treatment of rectal prolapse. Polidocanol (hydroxyl-proethoxydodecane) is a compound formed by ethoxylation of fatty alcohol dodecanol (C₁₂H₂₆O). Polidocanol, a sclerosant, has been applied in diverse concentrations across various surgical contexts in both pediatric and adult patients. These include conditions such as hemorrhoids, vascular malformations, non-variceal gastrointestinal bleeding, varicose veins in adults, and aneurysmal bone cysts. Polidocanol represents a relatively recent addition to sclerosing agents. Reports regarding its application in rectal prolapse treatment among children are scarce, highlighting its emerging role in this particular condition^{2,3}.

To our knowledge, there is no randomized control study for comparison between 50% dextrose water and polidocanol for treatment of rectal prolapse in children.

In our study total 60 patients with rectal prolapse were included with 30 patients in each group. 36 were male while 24 were female. Group A included 16 male and 14 females whereas group B had 20 males and 10 female children (Table 1). Mean age was 5.35 years with SD of 2.7 and ranging from youngest child of 8 months till eldest of 12 years. In group A mean age was 5.44 while mean age of group B was 5.26 years (Table 2). The children were mostly from metropolitan regions. Table 3 shows that of the children in group A, eight had full thickness rectal prolapse and twenty-two had partial prolapse. After just one Polidocanol session, all 30 patients in group A had symptom relief, yielding a 100% success rate. The effectiveness of polidocanol injection versus polidocanol paired with a Thierch stitch for rectal prolapse was studied by Sing N et al. (2019)⁸. There were 8(26.67%) female patients and 22(73.3%) male patients. The oldest patient was 12 years old, and the youngest was 1.5 years old, with a mean age of 5.71 years. Thirteen (43.3%) of Group A's patients were youngsters, and Group B's patients numbered seventeen (56.67%). The procedure took an average of 5.23 minutes (4 to 7 mm) for group "A" and 10.70 minutes (7 to 15 mm) for group "B." The research had a 100% success rate as all 13 patients in group "A" and all 17 patients in group "B" experienced symptom relief throughout the follow-up period. Three patients (10%) experienced postoperative constipation. These study's findings are similar to those of our investigation with the injection of polidocanol.

In rectal prolapse, Kadhim et al (2015) showed that 50% dextrose water was beneficial. A ten-year prospective study was conducted on 28 patients who had anterior rectal mucosal prolapse and had been treated with a submucosal injection of 50% Dextrose water. Up to 18 months of patient follow-up were conducted. The number of injection settings for each instance, the patients' reaction, complications, and recurrences were also assessed.

There were 4(14.28%) girls and 24(85.71%) men in the age range of 4 to 45. In 96.5% of cases, sclerosing with 50% dextrose water was effective. One session resulted in improvement for 24 patients, two sessions were needed for 3 cases to improve, and 1 case failed (P value < 0.001). For rectal prolapse, sclerosing using 50% DW is an easy, safe, and efficient treatment⁶.

In a study of 13 paediatric patients with RP, Khan et al 2008 (17) also described the combined method utilising chromic catgut and 5% phenol in almond oil as sclerosant. Three of the research participants experienced recurrence, which was resolved with further sclerotherapy. Three individuals' perianal abscess development was the only complication¹¹.

Results of alcohol injection treatment for rectal prolapse in children were examined by Bahadur et al. From nine months to six years, 153 patients were monitored. One hundred and six patients, or 69.3%, had prolapse for three to seven months. Seven patients had prolapsed for more than a year, and forty patients (26.1%) had

done so for more than seven months. 96 percent of the patients, or 117 out of 153, reacted to a single shot. It was necessary to give three of the kids another shot. Three individuals who were older than 13 did not get better after receiving therapy. There were no signs of an infectious consequence or recurrence¹¹.

CONCLUSION

In conclusion, injection sclerotherapy using polidocanol emerges as an equally successful procedure for managing RP in children. This medication demonstrates enhanced efficacy, safety, and accessibility. The process is not only less time-consuming but also entails minimal complications. Furthermore, adopting this approach holds the potential to reduce morbidity, cut down treatment expenses, and mitigate any enduring psychological effects on both children and their parents. However, given the limited number of patients and the relatively short-term follow-up in current studies, further research involving a larger patient cohort and an extended follow-up period is imperative to establish and standardize the effectiveness of this approach.

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1. Conception and design of or acquisition of data or analysis and interpretation of data.
2. Drafting the manuscript or revising it critically for important intellectual content.
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