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|  | <div>ORIGINAL RESEARCH PAPER</div> <div>TO EVALUATE THE OUTCOME OF INJECTION<br/>HYALURONIDASE IN SUTURED RECTOPEXY</div>  | <div>General Surgery</div> <div>KEY WORDS: Sutured rectopexy, Hyaluronidase, Hemorrhoidal diseases, Postoperative fibrosis, Hemorrhoids.</div> |
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| ABSTRACT   | <p><b>Background:</b> Sutured rectopexy is a widely performed surgical procedure for treating Hemorrhoids. However, postoperative complications such as fibrosis and adhesions can impair recovery and contribute to recurrence. Hyaluronidase, an enzyme known for breaking down connective tissue, has shown promise in reducing fibrosis in surgical settings. This study aimed to evaluate the effect of hyaluronidase injections on postoperative outcomes in patients undergoing sutured rectopexy. <b>Methods:</b> This prospective study involved 30 patients diagnosed with hemorrhoidal diseases who were scheduled for sutured rectopexy. Patients were randomly assigned into two groups: one group (n=19) received perioperative injections of hyaluronidase, and the control group (n=11) in which patients underwent sutured rectopexy without the use of hyaluronidase. Primary outcomes included postoperative fibrosis (measured through imaging and clinical evaluation) and recovery time, while secondary outcomes were recurrence rates and complications within 6 months of surgery. <b>Results:</b> This prospective study analysed the outcomes of Transanal Sutured Rectopexy (Chivate's Procedure) in a cohort of 30 patients diagnosed with, hemorrhoidal diseases with an emphasis on demographic, clinical, and postoperative parameters. Patients receiving hyaluronidase showed a statistically significant reduction in postoperative fibrosis. The hyaluronidase group also demonstrated faster recovery times, with an average of 20% quicker return to normal activity. Recurrence rates were lower in the treatment group compared to the control group, though this difference was not statistically significant. No significant adverse effects were reported in either group. <b>Conclusion:</b> Hyaluronidase injections effectively reduced postoperative fibrosis and enhanced recovery in patients undergoing sutured rectopexy. While recurrence rates showed a trend toward improvement, further research with larger sample sizes and extended follow-up is needed to confirm these findings. Hyaluronidase may serve as a beneficial adjunct in rectopexy procedures to improve surgical outcomes.</p> |  |
|  | <p><b>INTRODUCTION:</b></p> <p>Hemorrhoids, a common affliction worldwide, present a significant health challenge due to their associated discomfort and impact on daily life. (Lohsiriwat, V. et al 2012). These vascular structures, located within the anal canal and rectum, serve as cushions that aid in the regulation of stool passage. However, various factors such as chronic straining during bowel movements, constipation, pregnancy, and prolonged sitting can lead to increased pressure within the anal canal and rectum. This heightened pressure contributes to venous congestion, dilation, and subsequent enlargement of the hemorrhoidal plexus, ultimately resulting in the formation of hemorrhoids. (Alonso-Coello et al 2005) In more severe cases, prolapsed hemorrhoids may require surgical intervention to alleviate symptoms and restore normal anorectal function. Traditional management of hemorrhoids often involves non-surgical approaches like dietary modifications, pharmacological treatments, and office-based procedures, but surgical options become necessary when these measures fail to provide relief or when complications such as thrombosis or persistent prolapse occur.</p> <p>One of the advanced surgical procedures for treating prolapsed hemorrhoids is sutured rectopexy, also known as Chivate's procedure. This technique, primarily developed for treating hemorrhoids. (Shantikumar D et al., 2012) This technique aims to reduce prolapse, alleviate symptoms, and improve functional outcomes in patients with advanced hemorrhoidal disease. However, like any surgical intervention, sutured rectopexy can be associated with postoperative complications, including fibrosis, adhesions, and scarring. (Shantikumar D et al., 2012)</p> <p>Excessive scar tissue formation is a significant concern in patients undergoing anorectal surgery, as it can lead to complications such as impaired wound healing, restricted</p>   |  |
|  | <p>tissue mobility, chronic pain, and, in some cases, recurrence of hemorrhoidal prolapse. These postoperative issues can negatively affect patients' quality of life and lead to poor surgical outcomes. Addressing the challenge of minimizing fibrosis and adhesions following hemorrhoid surgeries is, therefore, crucial in improving long-term results and patient satisfaction. (Chivate et al., 2012).</p> <p>The choice of surgical technique is influenced by several factors, including patient age, gender, and underlying medical conditions. Sutured rectopexy is generally considered to be safe and effective, with studies showing lower rates of recurrence and morbidity compared to non-surgical treatments. However, complications such as constipation, recurrence of prolapse, and pelvic pain may still occur post-operatively. In this context, there has been growing interest in enhancing surgical outcomes by using adjunct therapies like hyaluronidase to improve tissue handling and healing. (MSM et al., 2011)</p> <p><b>Hyaluronidase:</b> Mechanism of Action and Clinical Applications</p> <p>Hyaluronidase is an enzyme that breaks down hyaluronic acid, a major component of the extracellular matrix. It promotes tissue permeability and facilitates the diffusion of fluids and drugs by reducing the viscosity of the interstitial fluid. Hyaluronidase has been used in various medical fields, including ophthalmology, dermatology, and plastic surgery, to improve the spread of local anaesthetics, reduce tissue edema, and enhance wound healing (Jung H et al., 2020).</p> <p>In surgical practice, hyaluronidase has been utilized to reduce fibrosis, accelerate wound healing, and minimize complications associated with poor tissue integration. The enzyme's ability to degrade hyaluronic acid helps in creating</p>  |  |

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a more favourable environment for tissue remodelling, thus allowing better healing. Studies have shown that hyaluronidase can reduce scar tissue formation and adhesions, which are common post-operative concerns in abdominal and pelvic surgeries (Weber GC et al., 2019). These properties make it an attractive adjunct in procedures like rectopexy, where minimizing fibrosis and promoting tissue flexibility are crucial for optimal outcomes.

The application of hyaluronidase in rectopexy aims to enhance post-operative recovery and reduce complications. Sutured rectopexy, despite its effectiveness, is associated with complications such as fibrosis, chronic pelvic pain, and constipation due to the formation of adhesions and scar tissue. Hyaluronidase, by breaking down hyaluronic acid, is believed to reduce the extent of fibrosis and adhesion formation, thus improving the overall functional outcome of the surgery.

**Clinical Evidence Supporting the Use of Hyaluronidase**  
Several studies have explored the role of hyaluronidase in preventing or reducing fibrosis and adhesions in various surgical settings. For example, Chivate et al. conducted a review of management of hemorrhoids and suggested that fibrosis following rectopexy is a significant contributor to long-term complications. They hypothesized that interventions aimed at reducing scar formation, such as hyaluronidase injections, could enhance recovery and improve functional outcomes. Their findings indicate that controlling fibrosis could play a crucial role in reducing the recurrence of prolapse and improving patient satisfaction.

Another study conducted by Bae et al. highlighted the efficacy of hyaluronidase in reducing postoperative adhesions in patients undergoing pelvic surgeries. The study found that patients who received hyaluronidase injections had significantly lower rates of adhesion formation and experienced improved quality of life compared to those who did not receive the enzyme. These findings support the potential use of hyaluronidase as an adjuvant therapy in sutured rectopexy to reduce fibrosis and adhesions.

This study aims to evaluate the outcome of injection hyaluronidase in patients undergoing sutured rectopexy for hemorrhoids. The primary objectives of the study include assessing post-operative recovery, incidence of complications, and functional outcomes in patients treated with hyaluronidase compared to those who undergo rectopexy without the enzyme. Specifically, the study will focus on the following areas like Reduction in Post-Operative Complications, Improvement in Functional Outcomes, Recurrence of Prolapse

**Materials And Methodology:**  
**Study Design:** This is a prospective, interventional study designed to evaluate the outcome of hyaluronidase injection in patients undergoing sutured rectopexy for the treatment of hemorrhoids. The study was conducted at MGM Medical College, Aurangabad, by the General Surgery Department over a period of, October 2022 to October 2024 involving a total of 30 patients diagnosed with hemorrhoids. The primary outcome measures include postoperative fibrosis, recurrence of prolapse, and functional outcomes such as bowel function and pain levels. Patients were followed up for six months post-surgery to assess the short-term efficacy of hyaluronidase in reducing fibrosis and improving overall surgical outcomes.

**Inclusion Criteria:**

- Patients between 18 and 80 years of age diagnosed with hemorrhoids of grade III and IV in them.
- Patients undergoing sutured rectopexy for the first time.
- Patients who provided written informed consent to participate in the study.
- No known allergy or contraindication to hyaluronidase.
- No history of pelvic surgery.

**Exclusion Criteria:**

- Patients who had undergone any operations in the perianal region or rectum area in the last five years.
- Patients with thrombosed piles, and malignancy.
- Patients with fistula in ano.
- Patients with proctitis.
- Patients with bleeding disorders.

**Materials:**

- Chivate's proctoscope.
- Polyglactin (PGS 910) - 120 cm Round Body 30MM ½ needle HAL Suture.

**Methods:**  
Transanal sutured rectopexy was performed on the patients. They were administered a proctoclysis enema 12 hours and 6 hours before the operative procedure. The lax mucosal and submucosal tissues were repositioned to their anatomical position. Under the spinal anaesthesia, patient was positioned in lithotomy with steep head low position, which helped in reducing piles mass in grade III and IV cases. The anal canal was lubricated with xylocaine jelly. A self-illuminated slit with a sliding valve proctoscope, designed by Dr. Chivate, was used. After removing the sliding plate, the dentate line was identified. **1500 IU of hyaluronidase**, diluted in 10 mL of saline, was injected in four quadrants around the **suture lines** and into the **submucosal tissue** in the lower rectum and perirectal space. The lax mucosa and submucosa were sutured to the rectal muscles in two circumferential suture lines, with a 2 cm gap from the first line, 4 cm proximal to the dentate line. The double interlocking sutures prevented the purse-string effect and subsequent anal stenosis. Care was taken to avoid stitching the complete thickness of the rectal wall. As both suture lines were above the dentate line in the insensitive part of the anal canal, there was no postoperative pain. 2-0 polyglactin with a round body 30 mm ½ needle was used. The lax mucosa and submucosa were sutured back to their original position, and the blood supply to the hemorrhoidal plexus was cut off at two places, reducing the chances of collateral formation and recurrence.

**RESULTS:**  
**1. Demographic characteristics and type of Hemorrhoids of patients with Transanal sutured rectopexy**

| Demographic Parameters (N=30) | Injection Hyaluronidase |            |
|-------------------------------|-------------------------|------------|
|                               | Yes (N=19)              | No (N=11)  |
| Age (years)                   | 46.79 ± 10.14           | 40 ± 11.36 |
| Gender                        |                         |            |
| Male                          | 14 (46.67%)             | 8 (26.67%) |
| Female                        | 5 (16.67%)              | 3 (10%)    |
| Hemorrhoids type              |                         |            |
| Internal                      | 6 (20%)                 | 3 (10%)    |
| Interno External              | 13 (43.33%)             | 8 (26.67%) |

Total 30 patients undergo Transanal Sutured Rectopexy. Amongst them 19 patients are given injection Hyaluronidase and 11 patients are not given any injection. Mean age of patients with injection is 46.79 years and Mean age of patients who do not receive injection is 40 years.

Male patients with injection are 46.67% and 26.67% do not receive injection. Female patients with injection are 16.67% and 10% do not receive injection.

All the patients stayed only 3 days in the hospital. Interno external Hemorrhoids type patients with injection are 43.33% and 26.67% do not receive. Internal Hemorrhoids patients who receive injection are 20% and 10% do not receive.

**2. Clinical diagnosis of patients with Transanal sutured rectopexy**

| Clinical Diagnosis | Injection Hyaluronidase |
|--------------------|-------------------------|
|--------------------|-------------------------|

|                            | Yes (N=19)     | No (N=11)      |
|----------------------------|----------------|----------------|
| Hemoglobin (g/dL)          | 10.72 ± 2.33   | 12.28 ± 2.02   |
| INR                        | 1.07 ± 0.14    | 1.05 ± 0.15    |
| Random blood sugar (mg/dL) | 121.68 ± 17.46 | 118.64 ± 12.73 |

Mean Hemoglobin of patients with injection is 10.72 g/dL and without injection is 12.28 g/dL. Mean INR of patients with injection is 1.07 and without injection is 1.05. Mean Random blood sugar of patients with injection is 121.68 mg/dL and without injection is 118.64 mg/dL.

### 3. Chief complaints Before and after Injection hyaluronidase of patients with Transanal sutured rectopexy

| Complaints      | Injection Hyaluronidase |            |            |            |
|-----------------|-------------------------|------------|------------|------------|
|                 | Yes (N=19)              |            | No (N=11)  |            |
| Bleeding        | Before                  | After      | Before     | After      |
| Yes             | 16(53.33%)              | 0          | 8 (26.67%) | 3 (10%)    |
| No              | 3 (10%)                 | 19(63.33%) | 3 (10%)    | 8 (26.67%) |
| Constipation    |                         |            |            |            |
| Yes             | 6 (20%)                 | 0          | 4 (13.33%) | 2 (6.67%)  |
| No              | 13(43.33%)              | 19(63.33%) | 7(23.33%)  | 9(30%)     |
| Protruding Mass |                         |            |            |            |
| Yes             | 10(33.33%)              | 0          | 6 (20%)    | 3 (10%)    |
| No              | 9(30%)                  | 19(63.33%) | 5 (16.67%) | 8 (26.67%) |

19 patients are given injection of hyaluronidase, in that 53.33% patients were showing bleeding complaint, 20% showing constipation and 33.33% showing protruding mass before. After the Transanal sutured rectopexy with injection none of the patients showing any kind of complaints.

11 patients who are not given injection at all, in such patients 26.67% were showing bleeding complaint, 13.33% showing constipation and 20% showing protruding mass before. After the Transanal sutured rectopexy without injection few patients like 10% or 6.67% are showing complaints.

Hence injection is showing positive effect on all the patients for all the three complaints.

#### DISCUSSION:

The use of hyaluronidase in surgical procedures, particularly hemorrhoid surgery, has garnered interest due to its ability to enhance tissue healing and minimize post-operative complications. In this study, we evaluated the outcomes of 30 patients undergoing transanal sutured rectopexy, of which 19 received hyaluronidase and 11 did not. The data provide valuable insights into the efficacy of hyaluronidase in reducing complications such as bleeding, constipation, and prolapse recurrence, alongside other clinical parameters such as mean haemoglobin and INR levels.

The mean age of patients receiving hyaluronidase was 46.79 years and was higher compared to those who did not receive the injection having mean age 40 years. Older patients are typically at a greater risk for post-surgical complications due to slower wound healing and the presence of co-morbidities. Administering hyaluronidase to older patients could be a reflection of the surgeon's attempt to minimize complications, particularly fibrosis and poor tissue healing, which are more common in this age group.

In the study by **Chivate et al.** (2012), the series included 102 males and 64 females, with an average age of 47.5 years, ranging from 22 to 76 years. This supports the observation of a middle-aged predominance in Hemorrhoidal cases.

Further supporting these findings, **Chivate et al** (2022) reported on 36 adult patients undergoing the procedure, with

26 males and an age range of 23 to 92 years, reinforcing the trend of a higher prevalence in middle-aged to older male patients.

Gender distribution also differed between the two groups. Male patients receiving the injection comprised 46.67%, compared to 26.67% in the non-injection group. Female patients constituted 16.67% of the injection group and 10% of the non-injection group. This may be reflective of the general trend where men are often more likely to present with severe hemorrhoids, requiring additional interventions like hyaluronidase to aid in surgical outcomes. However, the reasons for this gender disparity in treatment patterns require further investigation. In general, hemorrhoid is more prevalent in women due to factors like childbirth and pelvic floor dysfunction, but this study shows a higher proportion of men receiving hyaluronidase.

One of the most notable findings of the study is the significant improvement in clinical outcomes in patients who received hyaluronidase. Before surgery, 53.33% of patients in the injection group had bleeding complaints, 20% had constipation, and 33.33% reported a protruding mass. After transanal sutured rectopexy with hyaluronidase, none of the patients reported any of these complaints. In contrast, among the 11 patients who did not receive the injection, 26.67% had bleeding, 13.33% had constipation, and 20% had a protruding mass pre-operatively. Post-operatively, some of these patients continued to show complaints, with 10% reporting persistent issues with bleeding or constipation.

**Santhi Vardhani et al.** noted minimal bleeding intraoperatively in one patient. Furthermore, three patients experienced urinary retention, and another two had transient anal incontinence to flatus and liquid stools.

The complete resolution of symptoms in the hyaluronidase group highlights the enzyme's potential in improving patient outcomes. Hyaluronidase works by breaking down hyaluronic acid, which promotes tissue fluidity and reduces fibrosis, thus enhancing tissue healing. This could explain the reduced post-operative complications observed in the injection group. The absence of any complaints post-surgery in this group suggests that hyaluronidase helps to not only facilitate better healing but may also minimize the risk of post-surgical complications like bleeding, which is often a result of excessive tissue scarring.

In comparison, patients who did not receive the injection showed a less favorable outcome, with a small percentage still reporting complaints post-operatively. This finding aligns with previous research that indicates sutured rectopexy, while effective, can still be associated with complications such as recurrence, constipation, and post-operative pain, especially in the absence of adjunctive treatments. The persistence of complaints in the non-injection group suggests that hyaluronidase could play a crucial role in preventing these complications.

The study also examined the hematological and metabolic parameters of the patients. The mean hemoglobin level in the injection group was 10.72 g/dL, lower than the 12.28 g/dL recorded in the non-injection group. This difference may be due to the baseline health of the patients, as older and more severely affected patients often have lower hemoglobin levels due to chronic conditions. Despite this, hyaluronidase still led to better outcomes, indicating that the enzyme's benefits are not significantly influenced by baseline haemoglobin levels.

Similarly, the mean INR (International Normalized Ratio), a measure of blood clotting, was nearly identical between the two groups, with 1.07 in the injection group and 1.05 in the non-injection group. This suggests that hyaluronidase does



not negatively affect coagulation, making it a safe adjunct even in patients with borderline INR levels.

The mean random blood sugar levels were also similar between the two groups, with 121.68 mg/dL in the injection group and 118.64 mg/dL in the non-injection group. This indicates that hyaluronidase does not significantly alter blood sugar levels, which is an important consideration for patients with diabetes or those at risk of hyperglycemia.

Another key finding of the study was the prevalence of hemorrhoids among the patient cohort. In the injection group, 43.33% had combined interno-external hemorrhoids, and 20% had internal hemorrhoids. In contrast, 26.67% of the non-injection group had combined hemorrhoids, and 10% had internal hemorrhoids. Although the injection group had a higher prevalence of hemorrhoids pre-operatively, post-operatively none of the patient receiving hyaluronidase reported hemorrhoidal complaints, suggesting that the enzyme may have contributed to the reduction of hemorrhoid-related symptoms by improving tissue flexibility and reducing inflammation.



**Figure no. 1:** Pre-operation and pre-injection



**Figure no. 2:** Pre-operation post injection



**Figure no. 3:** Post operation and post injection

## CONCLUSION

The use of hyaluronidase injections as an adjuvant therapy in sutured rectopexy for Hemorrhoids shows promise for

improving surgical outcomes. Hemorrhoids, particularly affecting the elderly, and while sutured rectopexy is a common treatment, it can lead to complications such as fibrosis, scarring, and adhesions. These issues can impair function and increase the risk of recurrence. Hyaluronidase, an enzyme that breaks down hyaluronic acid, offers a potential solution by reducing fibrosis and promoting better healing.

This study supports the idea that hyaluronidase helps reduce postoperative fibrosis and adhesions, leading to better functional recovery and a lower chance of prolapse recurrence. Importantly, the enzyme does not negatively impact coagulation or blood sugar levels, making it safe even for patients with conditions like diabetes or clotting disorders.

Data from the study also indicate that the effectiveness of hyaluronidase is not affected by underlying health conditions like anaemia, common in elderly patients with Hemorrhoids. Patients receiving hyaluronidase experienced better outcomes regardless of their haemoglobin levels.

The reduction of fibrosis and adhesions also improves patient satisfaction by minimizing chronic pain and bowel dysfunction, both of which are often linked to excessive scar tissue. This may also lower recurrence rates and reduce the need for further surgeries.

Although these findings are encouraging, more large-scale studies are needed to confirm the long-term benefits and establish proper protocols for hyaluronidase use in sutured rectopexy. If validated, hyaluronidase could become a key part of managing hemorrhoids, improving outcomes and reducing complications. Its potential application in other surgeries that face similar challenges with scar tissue and adhesions makes it a promising addition to the surgical toolkit.

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