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A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF USE OF POLIDOCANOL VS OPEN HAEMORRHOIDECTOMY IN THE TREATMENT OF GRADE 3 INTERNAL HAEMORRHOIDS.

General Surgery

Nirmal Mishra* PG. Trainee, Department Of General Surgery, G.S.V.M. Medical College, Kanpur *Corresponding Author

Raj Kumar Singh Professor, Department Of General Surgery, G.S.V.M. Medical College, Kanpur

Ashish Kumar Chaudhary Professor, Department Of General Surgery, G.S.V.M. Medical College, Kanpur

Priyesh Shukla Assistant Professor, Department Of General Surgery, G.S.V.M. Medical College, Kanpur

ABSTRACT

Introduction: Haemorrhoidal disease (HD), with its different manifestations, is one of the commonest referrals to the surgical outpatient departments. Our study aims to compare efficacy of use of injection sclerotherapy via 3% Polidocanol vs Open Haemorrhoidectomy in treatment of Grade 3 Internal Haemorrhoids. Sclerotherapy with 3.0% polidocanol foam induces an inflammatory reaction with sclerosis of the submucosal tissue; moreover, the obliteration of the vascular support may lead to a reduction in the Haemorrhoidal volume. **Objectives:** To compare the early, late complications as well as safety profile of both the procedures. **Methods:** The study was conducted on patients who would be admitted in the Department of Surgery of LLR Hospital, GSVM Medical College Kanpur. The Sample size being 120 cases: 60 for injection sclerotherapy, 60 for Open Haemorrhoidectomy. **Results:** In our study, On day 1st and day 7th, (OH) Arm experienced higher pain levels in comparison to (IS) Arm. Infection rates and incontinence were significantly higher in the OH Arm. Ulceration rates were higher in the IS Arm. IS Arm patients experienced recurrence significantly earlier compared to OH Arm. OH Arm had a significantly longer recovery time compared to IS Arm. The Patient satisfaction scores were significantly higher in IS Arm. **Conclusion:** Injection sclerotherapy, being minimally invasive, offers a quicker recovery time, less post-operative pain, and can be performed on an outpatient basis, making it a suitable option for patients with significant comorbidities or those seeking a less aggressive intervention. On the other hand, open Haemorrhoidectomy, though more invasive and associated with a longer recovery period, provides a more definitive treatment with lower recurrence rates, which may be particularly beneficial for patients with severe or recurrent Haemorrhoidal disease.

KEYWORDS

Injection sclerotherapy; Polidocanol foam sclerotherapy; Open Haemorrhoidectomy; Recurrence; Post operative pain.

INTRODUCTION

Haemorrhoidal disease (HD) is one of the most common conditions encountered in surgical practice, affecting millions globally and significantly impacting the quality of life. The prevalence of Haemorrhoidal disease varies widely across studies, ranging from 2.9% to 50%, with approximately 20–30% of affected individuals seeking medical intervention. HD is most prevalent in males aged 45 to 65 years, occurring 2–3 times more frequently in men than in women. Haemorrhoids are vascular cushions located within the anal canal, comprising blood vessels, smooth muscle, and connective tissue. Classified into internal, external, and mixed types, internal Haemorrhoids are further graded based on the degree of prolapse: Grade I: No prolapse but bleeding during defecation; Grade II: Prolapse that reduces spontaneously; Grade III: Prolapse requiring manual reduction; Grade IV: Irreducible prolapse. Grade III Haemorrhoids are particularly challenging to treat as conservative measures often fail, necessitating minimally invasive or surgical interventions. Open Haemorrhoidectomy, often performed using the Milligan-Morgan or Ferguson technique, remains the gold standard for severe cases. However, it is associated with significant postoperative pain, complications such as urinary retention and anal stenosis, and longer recovery times. In contrast, injection sclerotherapy with polidocanol foam has emerged as a minimally invasive outpatient alternative, offering reduced pain and fewer complications. Polidocanol induces sclerosis of the vascular tissue, leading to a reduction in haemorrhoid size and bleeding. While studies suggest its safety and efficacy, questions remain regarding its effectiveness for Grade III haemorrhoids and long-term outcomes compared to open haemorrhoidectomy. Haemorrhoids are normal anatomical structures arising from the Haemorrhoidal plexus, which comprises arteriovenous anastomoses, smooth muscle, and connective tissue. The internal Haemorrhoidal plexus is located above the dentate line and receives blood from the superior and middle rectal arteries. These vascular cushions contribute to anal continence by sealing the anal canal during resting states and aiding in sensing rectal contents.

The pathophysiology of Haemorrhoidal disease is associated with the downward displacement of these vascular cushions, which leads to increased vascular congestion, prolapse, and symptoms such as bleeding and discomfort. Risk factors include constipation, prolonged straining, aging, pregnancy, and increased intra-abdominal pressure. Polidocanol, a sclerosing agent, induces sclerosis through endothelial damage and thrombus formation. Foam formulations enhance efficacy by maximizing the contact time with the vascular walls, leading to reduced hemorrhoid size and bleeding. Studies by Salgueiro et al. (2022) and Lisi et al. (2022) have demonstrated the safety and efficacy of polidocanol foam in Grades I–III Haemorrhoids, although recurrence rates remain a concern.

The Milligan-Morgan and Ferguson techniques are widely recognized as the gold standards for treating Grade III and IV Haemorrhoids. Despite high efficacy and low recurrence rates, these procedures are associated with significant morbidity, including severe postoperative pain, urinary retention, and anal stenosis. While polidocanol sclerotherapy offers a promising minimally invasive alternative, its efficacy in Grade III Haemorrhoids remains underexplored. Furthermore, there is a lack of comparative studies assessing long-term outcomes, recurrence rates, and patient satisfaction between polidocanol sclerotherapy and open Haemorrhoidectomy. This study addresses these gaps by providing a detailed analysis of the comparative outcomes, complications, and patient experiences associated with these two treatment modalities for Grade III Haemorrhoids.

Aims And Objectives

Aims Of Study:

- To evaluate the efficacy between injection sclerotherapy and Open Haemorrhoidectomy for grade III internal Haemorrhoids.

Objectives:

- To evaluate the early complications including pain and bleeding at 3 days, 2 weeks, and 3 months.
- To evaluate the late complications including recurrence and recovery at 18 months.
- To compare safety profile of both procedures.

MATERIAL AND METHODS

Study Design

This prospective comparative study enrolled 120 patients with Grade III internal Haemorrhoids at GSVM Medical College, Kanpur. Participants were randomly assigned to Group A (polidocanol sclerotherapy) or Group B (open Haemorrhoidectomy) after obtaining

consent.

Inclusion Criteria
- Age 18–60 years
- Willingness for follow-up
- Written informed consent

Exclusion Criteria
- Pregnancy
- Thrombophilia
- Inflammatory bowel disease
- Portal hypertension
- Acute thrombosis

Methodology:
Every patient who was included had a thorough history obtained, which included information on their age, sex, occupation, and daily activities. a thorough medical history that includes information on the kind and length of the complaints, a history of any prior treatments, family history, and personal history. A thorough examination of the whole abdomen, a digital and rectal examination, proctoscopy were done.

Procedures
Our research groups determined that the patients were suitable candidates for Injection Sclerotherapy and Open haemorrhoidectomy. The gastrointestinal, respiratory, and cardiovascular systems were all thoroughly examined. Proctoscopic assessment, digital rectal examination, and local examination were carried out. Haemoglobin levels, TLC, DLC, urine routine, X-ray chest, blood urea, blood sugar, and ECG were performed to evaluate the patient's overall health. The cases were assigned at random to one of the two therapy groups after assessment.

Group A; Injection Sclerotherapy (IS) Arm: 60 patients underwent Injection Sclerotherapy either one or two sessions 2 weeks apart using 3% polidocanol foam. Foam was injected above the dentate line to minimize pain.

Group B; Open Haemorrhoidectomy (OH) Arm: 60 patients underwent Open Haemorrhoidectomy which was conducted under spinal anesthesia. A Kelly clamp was placed over one Haemorrhoidal pedicle. The external skin was incised in a V-shaped manner, followed by dissection of the Haemorrhoidal plexus in a good plane without any muscle injury using scissor and diathermy towards the clamped pedicle. A Vicryl 2/0 suture was used to ligate the pedicle that was cut at the end and left open to heal. The procedure was repeated for the remaining hemorrhoid pedicles. Diclofenac suppository was used, and then gauze impregnated in local anaesthetic (Lignocaine jelly) with Betadine Solution was put into the anus as packing. Patients were discharged home after the removal of the anal pack and ensuring hemostasis. Any postoperative complication was reported based on clinical findings, especially pain, bleeding, urine retention, recurrence, wound infection, and fecal incontinence. To assess pain, we used a 10-cm linear Universal Pain Assessment Tool (UPAT) starting from 0 (where there was no pain at all) to 10 (the worst pain ever experienced). The low anterior resection syndrome (LARS) score was used to evaluate incontinence: Flatus incontinence was scored as 0–7, liquid stool incontinence was scored as 0-5, re-evacuation was scored as 0–11, and evacuation urgency was scored as 0–16 (0–20 no LARS, 21–29 light LARS, and 30–42 strong LARS).

OBSERVATION AND RESULTS
The analysis begins with the distribution of patients based on age. IS Arm had a mean age of 49.32±9.7 years, while OH Arm had a significantly younger mean age of 43.60±12.1 years (p=0.006). This suggests that the conditions being studied might have a broader impact on middle-aged individuals. In IS Arm, the majority of patients (53.3%) were between 51-60 years old, whereas OH Arm had a more even distribution, with the largest subset (38.3%) in the 51-60 age range as well. The notable difference in the 18-30 age group, with OH Arm having 12 (20.0%) patients compared to just 2 (3.3%) in IS Arm (p=0.008), indicates a significant demographic difference that might affect treatment outcomes and responses.

Haemoglobin levels were significantly higher in OH Arm (11.8±0.95 mg/dl) compared to IS Arm (10.4±1.8 mg/dl) (p<0.001). This discrepancy might reflect underlying health differences between the groups, possibly influencing their overall recovery and response to treatments. Both groups had a similar gender distribution, with no significant difference (p=0.849). IS Arm had 38 males (63.3%) and 22 females (36.7%), while OH Arm had 39 males (65.0%) and 21 females (35.0%). This parity ensures that gender does not confound the results and that any observed differences between the groups are more likely due to the interventions rather than gender-based physiological differences. A stark contrast was observed in the fitness for surgery, with all patients in OH Arm (100.0%) being fit for surgery compared to only 58.3% in IS Arm (p<0.001). This suggests that OH Arm patients were generally healthier or had fewer complications making them eligible for surgery. The remaining 41.7% in IS Arm were not fit for surgery, possibly due to severe comorbidities or poor overall health. IS Arm had a higher prevalence of comorbidities, with 18.3% having diabetes mellitus and 20.0% having hypertension. OH Arm had comorbidities, with 11.7% having diabetes mellitus and 15.0% having hypertension. Additionally, chronic obstructive pulmonary disease (COPD) was present in 3.3% of IS Arm but not in OH Arm. These differences (p<0.0.05) indicate that IS Arm patients had more complex health profiles, which could affect treatment outcomes. A significant difference was found in the number of sittings required for treatment (p<0.001). OH Arm patients predominantly required only one sitting (98.3%), compared to 40.0% in IS Arm. This suggests that the treatment protocol or the patient health profile in OH Arm was more effective or patients had a better response to the initial treatment. There was recurrence in one patient in OH Arm which was subjected to Injection Sclerotherapy

On the first day post-treatment, OH Arm experienced higher pain levels. Only 1.7% reported mild pain (1-3) compared to 71.7% in IS Arm (p<0.001). Conversely, 75.0% of OH Arm experienced moderate pain (4-6) and 23.3% severe pain (7-10), compared to 26.7% and 1.7% respectively in IS Arm. By day seven, OH Arm showed significant pain improvement, with 88.3% reporting mild pain (1-3) compared to 51.7% in IS Arm (p<0.001). However, 10.0% in OH Arm still reported moderate pain, while none in IS Arm did, indicating a longer recovery timeline for some in OH Arm.

Table 1: Distribution Of The Studied Patients Based On The Pain Score On Day 1 In Both Groups

Pain score in Day 1	Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
Mild Pain (1-3)	43 (71.7%)	1 (1.7%)	<0.001
Moderate Pain (4-6)	16 (26.7%)	45 (75.0%)	
Severe Pain (7-10)	1 (1.7%)	14 (23.3%)	

Day 7 Pain Score:
Table 2: Distribution of the studied patients based on the pain score on day 7 in both groups

Pain score in Day 7	Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
No Pain (0)	29 (48.3%)	1 (1.7%)	<0.001
Mild Pain (1-3)	31 (51.7%)	53 (88.3%)	
Moderate Pain (4-6)	0 (0.0%)	6 (10.0%)	

Infection rates were compared between IS Arm and OH Arm. IS Arm reported 9 cases (17.64%) while OH Arm had 8 cases (15.38%). The p value of 1.0 signifies that there is no statistically difference in infection rates between the two groups, suggesting that the risk of infection is similar regardless of the group.

Table 3: Distribution Of The Studied Patients Based On Infection And Abscess Formation In Both Groups

		Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
Infection	Yes	9 (17.64%)	8 (15.38%)	1.0
	No	51 (85.0%)	52 (86.7%)	

Bleeding rates were similar between the groups (p=0.697), with 5.0% in IS Arm and 6.7% in OH Arm.

Ulceration was more prevalent in IS Arm compared to none in OH Arm, though this was not statistically significant (p=0.079).

Incontinence was significantly more common in OH Arm (11.7%)

compared to IS Arm (1.7%) (p=0.028). This highlights a potential downside of the treatment protocol or health status of OH Arm. Incontinence was transient and was graded according to LARS score; Light LARS (21-29) in both groups and it was managed symptomatically. No active surgical intervention was required.

Recurrence And Recovery

Recurrence Rates:

Recurrence was significantly lower in OH Arm (10.0%) compared to IS Arm (31.7%) (p=0.003). This suggests that the treatment protocol or patient health profile in OH Arm was more effective in achieving long-term remission.

Table 4: Distribution of the studied patients based on recurrence in both groups

Recurrence	Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
Yes	19 (31.7%)	6 (10.0%)	0.003
No	41 (68.3%)	54 (90.0%)	

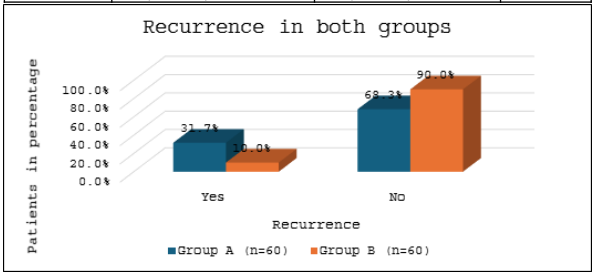

Figure 1: Distribution of the studied patients based on recurrence in both groups

The time to recurrence differed significantly (p<0.05). IS Arm patients experienced recurrence earlier (mean 6.94±2.2 months) compared to OH Arm (mean 11.5±6.5 months), indicating a more sustained treatment effect in OH Arm.

Table 5: Distribution Of The Studied Patients Based On Time Of Recurrence In Both Groups

Time of recurrence in months	Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
6 months	8 (42.1%)	2 (33.3%)	0.002
12 months	10 (52.6%)	0 (0.0%)	
18 months	1 (5.3%)	4 (66.7%)	
Mean ± SD	6.94±2.2	11.5±6.5	<0.001

OH Arm had a significantly longer recovery time (12.80±1.4 days) compared to IS Arm (4.12±2.0 days) (p<0.001). This could be due to more intensive treatment protocols in OH Arm, reflecting a trade-off between short-term recovery and long-term benefits.

Table 6: Details Of The Studied Patients Based On Recovery Time In Days In Both Groups

Recovery time in days (Mean±SD)	Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
	4.12±2.0	12.80±1.4	<0.001

Patient Satisfaction

Patient satisfaction scores were higher in OH Arm, with 61.7% rating their satisfaction at 7, compared to 23.3% in IS Arm. However, IS Arm had higher satisfaction scores in the range of 8 and 9 (71.7%) compared to OH Arm (33.4%). The overall p-value (<0.001) indicates a significant difference, suggesting that despite longer recovery times and higher initial pain, OH Arm patients were more satisfied with their treatment outcomes.

Table 7: Distribution Of The Studied Patients Based On Patient Satisfaction Score In Both Groups

Patient's satisfaction score	Group A (n=60) Injection Sclerotherapy	Group B (n=60) Open Haemorrhoidectomy	p-value
6	3 (5.0%)	3 (5.0%)	<0.001
7	14 (23.3%)	37 (61.7%)	
8	36 (60.0%)	19 (31.7%)	
9	7 (11.7%)	1 (1.7%)	

DISCUSSION

The aim of the present study was to compare the efficacy of use of polidocanol vs open Haemorrhoidectomy in treatment of grade 3 internal Haemorrhoids. **Gahlot N et al** did a hospital-based prospective comparative study of the sclerotherapy and Haemorrhoidectomy in second-degree Haemorrhoids and concluded that "the two surgical procedures employed in the study to treat Haemorrhoids sclerotherapy was found to have less complications, early ambulation, short post-operative hospital stay, and cost-effective." **Rathore RK** carried out a hospital-based prospective comparative study of the management of second- and third-degree Haemorrhoids with injection Sclerotherapy using Polidocanol and concluded that "the injection Sclerotherapy using Polidocanol elicits good results with less complications and low cost." **Badal RK & Sharma** MK conducted a clinical study of the assessment of cases of Haemorrhoids in adults and concluded that "the young age group was more prone to develop Haemorrhoids. Common symptoms were bleeding through rectum, mass through rectum, soiling of clothes, pain in defecation and pruritis."

Age Distribution

In our study, IS Arm had an older mean age (49.32±9.7 years) compared to OH Arm (43.60±12.1 years). Similar studies often report that older patients tend to have more complications and longer recovery times. **Gahltot N et al**[8] reported that "the mean age in H group was 38.56±7.8 years whereas 39.08±8.2 years in SCL group. (p>0.05) and both groups were socio-demographically comparable." Similarly, **Ammanagi AS & Mathew T** found that "the occurrence of Haemorrhoids was seen between the age In H group, maximum 76.00% were male whereas 80% in SCL group." Similarly, **Ammanagi AS & Mathew T**[11] in their study found that "out of 90 patients 52 were male and 38 were female." Our study was consistent with **Badal RK & Sharma** MK[10] found that "out of 87 patients, males were 53 and females were 34."

The pain score differences, with OH Arm experiencing more pain initially but improving significantly by day seven, reflect the intensity of the treatment protocol. **De A and Roy P** reported "the postoperative pain assessed on Visual analog score was 2.82 on 3rd day, 1.28 on 7th day and till 14th day was extremely low." **Saxena P and Bhakuni YS** found "postoperative pain assessed on Visual analog score was 2.82 on 3rd day, 1.28 on 7th day and till 14th day was extremely low." According to **Hoyuela C et al** "the mean postoperative pain was: VAS=2.6 after 6 h, VAS=1.7 after 24 h, VAS=1.7 on the seventh day and pain was practically non-existent (VAS=0.7) 1 month after the procedure." **Lopez FC et al** reported "the postoperative pain in patients was lower until the 15th postoperative day with statistically significant differences (p<0.05)."

Our study's infection rates were comparable between groups. **Gahltot N et al**[8] reported that "in OH group, maximum 96.00% were presented with bleeding, 84% constipation, 80% had a prolapse and 64% had anal pain whereas In SCL group, 96.00% were presented with bleeding, 84% had constipation, 80% had prolapse and 68% had anal pain (p>0.05)." Similarly, **Ammanagi AS & Mathew T**[11] found that "the most common presenting complaint was bleeding per rectum and mass per rectum in 33.33% of patients." **Salgueiro P et al** did a study on polidocanol foam sclerotherapy in the treatment of Haemorrhoidal disease and reported that "Complications occurred in 11.4% of the patients, with bleeding reported in 4.8%. The majority of complications were mild (96.2%). No significant differences between the two groups were observed for therapeutic success, recurrence, or complication rate." **Scheyer M et al** reported that "the short-term follow-up, 26.0% of patients reported recurrent or persistent prolapsing piles, while 21.0% of patients had recurrent bleeding. After long-term follow-up, 24.0% of patients reported prolapsing piles, 3.0% bleeding, 3.0% pruritus, and 2.0% anal pain, while 20.0% complained of persistent mixed symptoms."

The lower recurrence rate in OH Arm (10.0% vs. 31.7% in IS Arm) and the longer time to recurrence support the effectiveness of the treatment protocol used for OH Arm.. Many non-operative procedures are effective in controlling symptoms from the patients' perspective; however, they all share the common problem of recurrence. Sclerotherapy has the lowest recurrence rate compared to all types of

haemaroidectomy. According to **MacRae HM & McLeod RS** "at 12 months of follow-up, 92.0% of patients remained symptom free following injection sclerotherapy." "**Gahlot N et al** reported that the in-H group, maximum 74% were cured whereas 96% in the group SCL (p=0.005)." **Satzinger U et al** who observed the recurrence of prolapse at 12 months was low, with no re-prolapse being recorded in 89.0% of the patients. **Hoyuela C et al**[16] found that "after 24 months follow-up, recurrence of bleeding and prolapse was observed in only 1 patient." "**Saxena P and Bhakuni YS**[15] found that overall, 82.8% patients were free from symptoms at 1 year follow up after the procedure and only 7.8% of the patients had recurrence of bleeding or prolapse. 6.25% complained of recurrent bleeding per rectum for which injection sclerotherapy was done."

The higher satisfaction scores in OH Arm despite longer recovery times highlight the trade-off between short-term discomfort and long-term benefits. **De Vos M et al** reported that the satisfaction after HAL or HALRAR was 84.4%. **Satzinger U et al** study on recto anal repair and found that the patient satisfaction was consistently high (>90.0%) at all follow-up intervals and the complication rate was low. **Gahltot N et al** reported that "the two surgical procedures employed in the study to treat Haemorrhoids sclerotherapy was found to had less complications, early ambulation, short post-operative hospital stay, and cost-effective." **Shekhar R et al** reported that "the foam sclerotherapy is a new, innovative, effective, and safe non-surgical treatment option for Haemorrhoidal disease.

The advantage as we observed was simplicity of the procedure, less postoperative pain, insignificant bleeding during the procedure and postoperatively, and no need for costly and specialized instruments like Barron band ligator or Doppler ultrasound so it is cost effective."

Limitation:

The limitations of the study are worthy of mention, it is single centre study experience with a limited target population and lacking representation of the wider patient population, reducing their external validity. Multicentre studies allow for comparison of effects between centres, which provide insight into the generalizability of data and effects of the new procedures across hospitals.

CONCLUSION

In conclusion, this comparative study between injection sclerotherapy and open Haemorrhoidectomy for the treatment of grade three internal Haemorrhoids highlights the distinct advantages and limitations of each method. The data obtained by the study conducted at our institute emphasizes the importance of considering patient demographics, comorbidities, and treatment protocols. Injection sclerotherapy, being minimally invasive, offers a quicker recovery time, less postoperative pain, and can be performed on an outpatient basis, making it a suitable option for patients with significant comorbidities or those seeking a less aggressive intervention. On the other hand, open Haemorrhoidectomy, though more invasive and associated with a longer recovery period, provides a more definitive treatment with lower recurrence rates, which may be particularly beneficial for patients with severe or recurrent Haemorrhoidal disease. Also the more aggressive approach of treatment which is also a definitive one could be reserved for a younger subset of individuals who are healthier with little or no comorbidities. The choice between these treatments should be individualized, taking into consideration the patient's overall health, the severity of Haemorrhoidal symptoms, and the patient's preferences regarding recovery time and potential complications. Future studies with larger sample sizes and longer follow-up periods are recommended to further validate these findings and help refine treatment protocols for grade three internal Haemorrhoids. Also Injection sclerotherapy adds as a BRIDGE TREATMENT for those patients with severe co-morbidities who are awaiting a more definitive and permanent treatment.

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