



Management of Fistula in Ano with Biodegradable Glue vs Conventional Fistulectomy - A Comparative Study

Siddharth Mishra¹, Swopna Sagar Das^{2*}, Rudra Prasad Mahapatra³

1. Senior Resident, Department of General Surgery, Govt. Medical College and Hospital, Sundergarh, Odisha, India.
2. Assistant Professor, Department of General Surgery, IMS and SUM Hospital, K8, Kalinga Nagar Bhubaneswar, Odisha, India.
3. Senior Resident, Department of General Surgery, Govt. Medical College and Hospital, Sundergarh, Odisha, India.

*Corresponding author's E-mail: swopna008@gmail.com

Received: 11-04-2024; Revised: 26-05-2024; Accepted: 08-06-2024; Published on: 15-06-2024.

ABSTRACT

Background: Fistula in ano is one of the common conditions that bring the patient to a surgery clinic. It is often difficult to manage because of its propensity for recurrence and post operative complications like incontinence.

Aim: To compare conventional fistulectomy with cyanoacrylate glue in terms of post operative pain, mean hospital stay, incidence of incontinence and recurrence.

Method: The study was a prospective, double blind, randomized study conducted in the department of general surgery, Ispat General Hospital, Rourkela. A total of 40 patients above 18 years and admitted for treatment of fistula in ano were included in this study. The data were collected in the post operative period and statistical analysis was done using SPSS 18.0 and R environment ver.3.2.2. P value <0.05 was considered significant.

Result: All patients in the fistulectomy group needed analgesics in the post operative period compared to only 20% (4/20) patients in the glue group. The mean hospitalization duration was 7.1 ± 2.64 days and 1.45 ± 0.49 days in the fistulectomy group and glue group respectively. 20% (4/20) of the patients developed major and 25% (5/20) developed minor incontinence in the fistulectomy group whereas no such complications seen in the glue group. The recurrence rate was 35% (7/20) and 25% (5/20) in the glue group and the fistulectomy group respectively.

Conclusion: cyanoacrylate glue is a cost effective, safe and hence can be offered as an alternative to fistulectomy in patients with complex anal fistula where chances of sphincter damage following surgery is high.

Keywords: Fistulectomy, Cyanoacrylate glue, Incontinence, Recurrence of fistula in ano.

INTRODUCTION

Fistula in ano is a commonly encountered surgical problem with a prevalence of 1.2-2.8 cases/10,000 population¹. By definition it is an abnormal communication that runs from the anal canal to the perianal skin or perineum. Anal fistula may be found in association with a variety of conditions like Crohn's disease, tuberculosis, malignancy of anorectum, HIV, radiation exposure, lymphogranuloma venerum etc. but most are nonspecific and due to infection of anal glands in the intersphincteric plane. Despite the ease of diagnosis establishing cure is problematic due to significant percentage of cases persisting or recurring when the right modality of intervention is not adopted. The treatment must be navigated by surgeon's experience and judgment after careful considering the extent of sphincter division, post-operative healing rate and functional loss².

Most of the fistula in ano has been conventionally treated by either fistulotomy or fistulectomy⁴. The overall rate of recurrence by these procedures is low at around 4%^{5,6} and the reported incontinence rate is up to 45%. This mainly occurs after fistulectomy, due to damage to the anal sphincter. One of other methods in treating perianal fistula is use of biodegradable glue, which obliterates fistula

opening and tracts. This method avoids the extensive dissection of other techniques and the reported success rates for complex fistulas vary from 14 to 60%⁷⁻⁹.

Majority of the literature supported the use of biodegradable with a variable success rate. But there are very few studies comparing the efficacy of biodegradable glue with the common surgical procedures practiced widely like fistulectomy. In this study we compared the outcome of cyanoacrylate glue therapy and fistulectomy surgery in the management of anal fistulas.

MATERIALS AND METHODS

The study was a prospective, double blind, randomized study conducted in the department of general surgery, Ispat General Hospital, Rourkela between October 2017 to April 2019. Keeping the confidence interval 5% and confidence level of 95%, by applying sample size calculator software from <http://www.raosoft.com/samplesize.html>, the sample size calculated as 40. Informed consent was taken from all patients and Clearance required from research and ethical committee was obtained. All patients above 18 years admitted to Ispat General Hospital, Rourkela for treatment of fistula in ano were included in this study. Patients with acute infection of anal gland, with pre-existing anal incontinence, with diagnosed intestinal



tuberculosis, anorectal neoplasm, inflammatory bowel disease, with age less than 18 years and more than 65 years and those not willing for follow up were excluded.

The patients were allocated into 2 groups, named as Group A (patients undergoing cyanoacrylate glue therapy) and Group B (patients undergoing fistulectomy) randomly by using standard randomization method. All patients were admitted one day before surgery. All surgeries were performed under spinal anesthesia by the same surgeon who has performed more than 200 cases of fistulectomy as per standard steps. **In Group A:** after delineating the fistulous tract, cyanoacrylate glue was injected through it until it is seen exuding from the internal opening. Patients were discharged on the evening of the surgery or the next day morning with laxatives, oral antibiotics and analgesics.

In Group B: The entire tract was excised after delineation along with some surrounding tissue. The wound was left open to be allowed to heal by secondary intention. Patients were discharged when the wound appeared healthy with no signs of infection and the pain decreased. The perianal area of both group of patients were inspected at the time of discharge and they were advised to come for follow up weekly for six weeks and then monthly up to six months. The following data were collected from each group patients during the follow up time: Recurrence of symptoms like perianal soiling, perianal pain, pruritus ani, Any degree of anal incontinence, Mean hospital stay (in days). Statistical analysis was done using SPSS 18.0 and R environment ver.3.2.2. P value <0.05 was considered significant.

RESULTS

In our study, glue and fistulectomy group were matched with respect to the age of the patients with mean age of glue group being 42.5 ± 11.44 and that of fistulectomy group being 44 ± 11.94 . Maximum numbers of patient were in 41-50 years of age group, mean age of presentation being 43.25 ± 11.72 . Youngest patient was a 27 years old male and the oldest patient was a 64 years old male. In our study, male:female ratio in glue group was 3:1 whereas in fistulectomy group it was 4:1.

All the patients were complaining of soiling in perianal region. 12 patients in glue group and 10 patients in fistulectomy group were complaining of perianal pain while 5 patients in glue group and 6 patients in fistulectomy were complaining of pruritus ani.

Out of the 20 patients of glue group 8 patients had recurrent fistula, 1 female patient had anterior fistula and rest 11 patients had primary fistula. Similarly, out of the 20 patients of fistulectomy group 6 patients had recurrent fistula, 2 female patients had anterior fistula and rest 12 patients had primary fistula.

Out of the 20 patients in glue group, the internal opening of the fistula tract was identified in 15 patients by DRE, fistulogram and during procedure whereas in 5 patients it could not be identified. Similarly, in fistulectomy group the internal opening was identified in 14 patients whereas in 6

patients it could not be identified during surgical exploration also.

Out of the 20 patients in glue group 6 patients had low transsphincteric tract, 9 patients had high transsphincteric tract, 3 patients had intersphincteric tract and 2 patients had suprasphincteric tract. Similarly, out of 20 patients in fistulectomy group 5 patients had low transsphincteric tract, 9 patients had high transsphincteric tract, 4 patients had intersphincteric tract and 2 patients had suprasphincteric tract. Out of 20 patients in glue group secondary extension of the fistula tract was found in 5 patients whereas in fistulectomy group it was found in 4 patients.

DISCUSSION

Fistula in ano is one of the commonly encountered surgical problems known to mankind with considerable discomfort and morbidity. Historically various surgical techniques have been described e.g. fistulotomy, fistulectomy, seton placement etc, but every surgical procedure is associated with variable degree of success rate and post operative complications like anal incontinence which is catastrophic on the part of the patients. It is yet unclear which factors affect the outcome of the surgical treatment.

Appropriate treatment of a perianal fistula is based on 3 tenets: control of sepsis, closure of fistula tract, maintenance of continence. The classical technique described throughout history and which carries worldwide popularity is fistulectomy and fistulotomy, but the healing time is long and a study by Van Tets et al concluded that impaired continence is not uncommon after these surgeries¹⁸. Fistulectomy done for simple low fistulas reported incontinence to flatus in up to 50% of the cases¹⁹. On the contrary there are many sphincter preserving procedures being described in literature. One being the anal fistula plug which is safe and a long term with success rate of 24-88%. The failure may be due to extrusion of the plug from the fistula tract. FiLac and video assisted anal fistula treatment procedures are expensive and are yet to be assessed¹¹. Over the past 20 years, fibrin glue treatment for anal fistula has become increasingly popular²⁰. A study done by Lindsey et al concluded that the fibrin glue healed more complex fistulas than conventional treatment and with a higher patient satisfaction¹².

In our study, we have used cyanoacrylate glue which is a straw colored and clear liquid, contained in ready to use vials, usually stored at 4°C. On contact with biological tissue in a moist environment, it polymerizes to create a thin elastic film of high tensile strength, thereby adhering to the tissues. It begins solidification within 2 seconds and completes the process in 60-90 seconds¹³. The healing rate after application of cyanoacrylate glue in perianal fistula was 65%, which is slightly lower than the other studies and was in the lower range of that reported in literature, which may be due to small sample size and type 1 error. However, few other studies done by Barillaeri et al¹³ and Shivashankar et al¹⁶ show a success rate of 71.4% and



73.3% respectively. There is no reliable data regarding the efficacy of cyanoacrylate glue application over conventional surgery like fistulectomy in terms of success and incontinence rate in hospitals in the developing world. The efficacy of cyanoacrylate glue in healing complex anal fistula varies from 14-75 %^{7,8}. Such a wide variation is due to the fact that studies differed in various aspects like difference in study design (retrospective, non-randomised versus prospective, randomized), surveillance methods (surgical team versus independent observer), duration of follow up etc.

Post-operative pain

We found in our study that in the cyanoacrylate glue group, most of the patients (80%) did not experience any kind of pain at all. But in the fistulectomy group all patients experienced moderate to severe pain postoperatively, the difference was statistically significant ($P < 0.05$). This finding is comparable to the results of the study conducted by Lindsey et al¹² in which the 30% patients experienced pain following administration of cyanoacrylate glue whereas 100% patients experienced pain following conventional fistulectomy.

Table 1: Postoperative pain in both groups of patients

Postoperative pain requiring analgesic	Glue group n = 20	Fistulectomy group - n = 20
Present	4(20%)	20(100%)
Absent	16(80%)	0(0%)

$P < 0.05$, Significant.

Mean hospitalization days

The mean hospital stays following a surgical procedure depends upon various factors like severity of postoperative pain, condition of the surgical wound, ambulation following surgery etc. In the present study we found significant difference in the mean postoperative hospital stay between 2 groups ($P < 0.05$). This may be comparable to the study done by Shivshankar et al¹⁶. The increased hospital stay in fistulectomy group may be due to variable degree of postoperative anal incontinence.

Table 2: Mean hospitalization days in both groups

Studied groups	Glue group	Fistulectomy group
Mean hospitalization days \pm SD	1.45 \pm 0.49 days	7.1 \pm 2.64 days

P value < 0.05 , Significant

Incidence of incontinence

Post procedural anal incontinence is a dreaded complication following perianal surgeries. The incidence is higher in complex anal fistula in comparison to simple fistulas. In our study we did not find any form of incontinence in cyanoacrylate glue group with similar results obtained by Studies done by Shivshankar et al¹⁶,

Lindsey et al¹², Swinscoe et al²¹, Damin Dc et al¹⁴, Witte ME et al¹⁷. This is well expected as there is no damage to the anal sphincter complex during the application of cyanoacrylate glue.

In contrast to this, 4 patients (20%) developed major incontinence (incontinence to solid stool) and 5 patients (25%) developed minor incontinence (incontinence to gas and liquid stool) following fistulectomy. This high rate of incontinence may be explained by the fact that 14 patients (70%) in our study were having transsphincteric fistula. Hence excision of the complex anal fistula tract could lead to damage of the anal sphincter intraoperatively. These findings are comparable with the study done by Garcia Aguilar et al³ where there was minor incontinence in 50% of patients and major incontinence in 24% of cases. The difference in the incidence of incontinence between the two groups is statistically significant ($P < 0.05$).

Table 3: Incidence of incontinence among both groups

Type of incontinence	Major	Minor
Glue group (n = 20)	0 (0%)	0 (0%)
Fistulectomy group (n = 20)	4 (20%)	5 (25%)

P value < 0.05 , Significant

Recurrence of symptoms

Recurrence is a major problem associated with treatment of perianal fistula. The reason for recurrence may be due to persistent infection of the anal glands, non-identification of the internal opening and failure of delineation of the fistula tract during surgery, faulty surgical technique by an inexperienced surgeon. In application of cyanoacrylate glue the recurrence may be due to premature expulsion of the glue before it gets organized inside the fistula tract. In our study 7 patients (35%) developed recurrence of symptoms like perianal soiling, perianal pain and pruritus ani within a mean follow up period of 6 months. This is comparable with the study conducted by Shivshankar et al¹⁶, Barrilleri et al¹³, Dhanraj et al¹⁵ and Lindsey et al¹². Jain et al¹⁰ in their study found that the healing rate of 85% occurred following primary instillation of cyanoacrylate glue. The slight difference in the success rate in our study may be due to the fact that we have included patients with complex anal fistula in whom scarring from previous procedure may have led to not complete delineation of the tract.

Similarly, in the fistulectomy group, 5 patients (25%) had recurrence of symptoms like perianal soiling, perianal pain and pruritus ani during a mean follow up period of 6 months. Our results are comparable to the study performed by Lindsey et al¹² in which the recurrence rate following conventional surgery is around 30%. The difference in success and recurrence rate between the two groups is not statistically significant ($P 0.328$).



Table 4: Incidence of recurrence of symptoms among both groups

Recurrence of symptoms	Glue group (n=20)	Fistulectomy group (n=20)
Present	7(35%)	5(25%)
Absent	13(65%)	15(75%)

P value = 0.328

CONCLUSION

The present study is a prospective, double blind, randomized study between cyanoacrylate glue and fistulectomy group. The study was conducted in an intention to observe the efficacy of biodegradable glue (cyanoacrylate) in comparison to conventional surgery like fistulectomy in the management of anal fistulas. The patients were followed up in the postoperative period weekly for six weeks and then monthly for six months. Patients were assessed for anal incontinence and recurrence of symptoms in the postoperative period.

In our study we found that the postoperative hospital stay was significantly lower in glue application in comparison to fistulectomy and it can be performed as a day care procedure also. Rate of incontinence was significantly high following fistulectomy where risk of damage to the anal sphincter is high. In contrast there was no incontinence related complications following glue application. The success rate following glue application was 65% and following fistulectomy 75% at the end of the study. This indicates cyanoacrylate glue is a cost effective, safe and hence can be offered as an alternative to fistulectomy in patients with complex anal fistula where chances of sphincter damage following surgery is high.

There are few limitations to our study including small sample size, short term follow up period, financial constrain not allowing sophisticated investigations to perform to correctly identify the anatomy of the fistula tract and moreover no data was obtained regarding the economic burden on the patients related to longer duration of postoperative hospital stay and further treatment of anal incontinence.

Source of Support: The author(s) received no financial support for the research, authorship, and/or publication of this article

Conflict of Interest: The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

REFERENCES

- Zanotti C, matinez PC, Pascual I HD and GD. Fistula in ano its incidence and prevalence. *Int J Colorectal Dis.* 2007;22:1459–62.
- Hamalainen KP SA. Cutting seton for anal fistulas: high risk for minor control of defects. *Dis Colon Rectum.* 1997;44:722–7.
- Garcia-Augilar J, Davey CS, Le CT, Lowry AC R DA. Patients satisfaction after surgical treatment for fistula in ano. *Dis Colon Rectum.* 2000;43:1206–12.
- Isbister WH AS. Cutting seton : an experience at King Faisal specialist Hospital. *Dis Colon Rectum.* 2001;44:722–7.
- Garcia-Aguilar J, Belmonte C, Wong WD, Goldberg SM MR. Anal fistula surgery, factors associated with recurrence and in continence. *Dis Colon Rectum.* 1996;39:723–9.
- Malouf AJ, Buchanana GN, Carapeti EA, Rao S, Guy RJ, Wetcott E, Thomson JP CC. Prospective audit of fistula in ano at St. Mark's hospital. *Dis Colon Rectum.* 2002;4:13–9.
- Loungnarath R, Dietz DW, Mutch MG, Birnbaum EH, Kodner IJ FJ. Fibrin glue treatment of complex anal fistulas has low success rate. *Dis Colon Rectum.* 2004;68:615–8.
- Lamont JP, Hooker G, Espenschied JR, Lichliter WE FE. Closure of proximal colorectal fistulas using fibrin sealant. *Am Surg.* 2002;68(7):615–8.
- Zmora O, Mizrahi N, Rotholtz N, Pikarsky AJ, Weiss EG, Noguera JJ WS. Fibrin glue sealing in the treatment of perianal fistulas. *Dis Colon Rectum.* 2003;46:584–9.
- Jain SK, Kaza RC, Pahwa M BS. Role of cyanoacrylate glue in the management of low fistula in ano: prospective study. *Int J Colorectal Dis.* 2008;23(4):355–8.
- Limura E GP. Modern management of anal fistula. *World J Gastroenterol.* 2015;21(1):12–20.
- Lindsey I, Smilgin Humphreys M, Cunnigham, Chris, Mortensen NJ. A randomised controlled trial of fibrin glue vs. conventional treatment for anal fistula. *Dis Colon Rectum.* 2002;45(12):1608–15.
- Barillari P, Basso L, Larcinese A, Paolo Gozzo MI. Cyanoacrylate glue in the treatment of ano-rectal fistulas. *Int J Colorectal Dis.* 2006;21(8):791–4.
- Damin DC, Rosito MA, Contu PC TC. Fibrin glue in the management of complex anal fistula. *Arq Gasroenterologica.* 2009;46(4):300–3.
- Dhanraj N, Meenakshisundaram N, Vinodh Duraisami VR. Comparison of various techniques in the management of fistula in ano. *Int Arch Integr Med.* 2018;5(5):14–20.
- Shivashankar Sc, Nayaka ANN, Manangi M, Rao S MS. Efficacy of cyanoacrylate glue in anal fistulas. *Int Surg J.* 2019;6(4):1352–5.
- Witte ME, klaase JM, Gerritsen JJ KE. Fibrin glue treatment for simple and complex anal fistula. *Hepatogastroenterology.* 2007;54(76):1071–3.
- Van Tets WF KH. Continence disorder after anal fistulotomy. *Dis Colon Rectum.* 1994;37:1194–7.
- Lunniss PJ, Kamm MA PR. Factors affecting continence after surgery for anal fistulas. *Br J Surg.* 1994;81:1382–5.
- Hammond TM, Grahn MF LP. Fibrin glue in the management of anal fistulae. *Color Dis.* 2004;6(5):308–19.
- Swinscoe MT, Ventakasubramaniam AK JD. Fibrin glue for fistula in ano: the evidence reviewed. *Tech Coloproctol.* 2005;9:89–94.

For any questions related to this article, please reach us at: globalresearchonline@rediffmail.com

New manuscripts for publication can be submitted at: submit@globalresearchonline.net and submit_ijpsrr@rediffmail.com

