

## Original Research Article

# Evaluation of the role of cyanoacrylate glue in the management of fistula-in-ano

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## ABSTRACT

**Background:** Fistula in ano is a common problem in patients presenting to surgical OPD. Various procedures have been described for the treatment of anal fistula, including fistulectomy, fistulotomy and use of a cutting seton. Surgical treatment of anal fistula is associated with a significant risk of recurrence and faecal incontinence due to damage to anal sphincter. The introduction of cyanoacrylate glue to close fistula tracts using an occlusive material and with no risk of incontinence (as there is no sphincter damage). The study was designed to evaluate the role of cyanoacrylate glue in the management of fistula in ano.

**Methods:** Here, 40 patients were enrolled in study as day cases. Patients were examined clinically and subjected to MRI pelvis where internal opening couldn't be palpated on digital rectal examination (DRE). Fistula tract was mapped using fistula probe and washed with diluted hydrogen peroxide and normal saline. The excess granulation tissue at the external opening was curetted. The glue was then injected slowly into fistulous tract through 8 F infant feeding tube. Patients were further examined in the OPD until 6-months.

**Results:** Here, 32 patients got healed after first instillation of glue with stoppage of discharge from the fistulous tract. The other 2 patients required second instillation of glue and showed no signs of discharge thereafter. While 6/40 continued to discharge even after instillation of glue.

**Conclusions:** Cyanoacrylate glue can be offered as a sphincter sparing alternative to conventional procedure in patients with anal fistula.

**Keywords:** Cyanoacrylate glue, Faecal incontinence, Fistula in ano

## INTRODUCTION

Fistula-in-ano is of oldest condition ailing mankind is a common problem presenting to the surgical outpatient department.<sup>1</sup> Inefficiency of medical management and high recurrence rate in various surgical procedures has been a motivation for evolution of new different methods of treatment however no method of treatment is perfect and ideal method is yet to be described till date.

Patients with fistula-in-ano have been found to have a reduced quality of life (QOL), worse in those with recurrent disease and secondary extensions.<sup>2</sup>

Various procedures have been advocated and described for the treatment of fistula-in-ano including fistulectomy, fistulotomy and the use of cutting seton. Newer technique like fibrin plug, anal fistula plug, Ligation of Intersphincteric fistula tract (LIFT), fistula laser closure (FiLaCTM) and Video Assisted Anal Fistula Treatment (VAAFT) have recently been added to the armamentarium of these treatment options. Surgical treatment of fistula-in-ano is associated with a significance risk of recurrence and a high risk of faecal incontinence due to damage to anal sphincter. The risk of incontinence is associated more with proximal location of the internal opening in the anal canal.<sup>3</sup>

The high risk of recurrence and faecal incontinence associated with the traditional surgical techniques led to the development of various other new procedures, with low morbidity and high patient satisfaction.<sup>4</sup>

The introduction of fibrin glue in the 1990s was seen as sound concept to close fistula tracts using an occlusive material and with minimal risk of incontinence (as there is no sphincteric injury). Fibrin glue held great promise for closing anorectal fistulas with minimal complications; however, reported success rate dwindled from 80% in the early years to <50% in more recent reports.<sup>5,6</sup> Due to high cost of fibrin glue and requirements of expert personnel to prepare it with limited shelf life after preparation (6 hrs), its use has not gain popularity. Cyanoacrylate glue, can obviate problems associated with fibrin glue because it is more economical and is available in vials with long shelf life and doesn't require prior preparation.<sup>7</sup>

Cyanoacrylate glue was first used in surgery in 1959 by Coover. It belongs to a class of synthetic glue and is a good alternative to fibrin glue.<sup>7</sup>

The current study was planned to evaluate the efficacy of cyanoacrylate glue in the management of fistula-in-ano with a follow up of 6 months.

## METHODS

The present study was a prospective interventional study in which Forty consecutive patients who presented with fistula-in-ano in the outpatient department of General surgery, from November 2016 to November 2018 at Lok Nayak Hospital, New Delhi were enrolled in the study.

Permission for the study was taken from the ethical committee of the institute. Patients were informed about the procedure, and a written informed consent was taken. Fistula-in-ano with one or two external openings were included in the study. Patients with recurrent fistula, fistula with more than two external opening and fistula with active pus discharge were excluded from the study.

Preoperatively, all the patients included were evaluated after taking proper history and through clinical examination. Digital Rectal Examinations (DRE) was done in all of them to identify and record the internal opening, distance of opening from anal verge. MRI pelvis was done in all patients where internal opening could not be palpated on digital rectal examinations. No bowel preparations were given. Patients were treated as day care cases without any type of anaesthesia.

In the operative room, the patient was placed in dorsal lithotomy position, and the peri anal skin cleaned and draped. Fistula tract was mapped using fistula probe to know the direction of fistula and the length of fistula. The internal and external opening was carefully identified, and the tract was thoroughly washed with diluted hydrogen peroxide and normal saline using infant feeding

tube. The excess granulation tissue at external opening was curetted and debrided. An 8 F infant feeding tube was inserted through the external opening and advanced until the point it reached easily in case of high fistula-in-ano or tip could be palpated at the internal opening. 1.0-3.0 ml of N-butyl cyanoacrylate glue (depending upon the length of fistula) was injected slowly through infant feeding tube. The infant feeding tube was slowly withdrawn while the glue still be injected until the tip of infant feeding tube appears at the external opening and the end point of insertion of glue was till it got plugged at the level of external opening. Polymerization of the glue occurred within 30s during which patient felt a little discomfort in the form of heat.

Patients were made ambulatory immediately after the procedure. A postoperative course of antibiotic was given in the form of tablet Amoxicillin Clavulanic acid 625 mg thrice daily for 7 days as presence of infection retards the polymerization of Cyanoacrylate glue. The patients were asked to keep the area dry and clean and use of tissue paper to clean the perianal area after defecation keeping in mind the normal toilet habits of Indians. Patients were asked to report for follow up in outpatient department at 2<sup>nd</sup>, 4<sup>th</sup>, 12<sup>th</sup> and 24<sup>th</sup> weeks when they were asked about their complaints if any like- burning sensation, foreign body sensation and presence of pus discharge. A thorough examination was done. Patients were again taken up for repeat injections if the symptoms recurred at any follow-up visit. Persistence or recurrence of symptoms after second injection was taken as failure of procedure.

## Statistical analysis

All the data was transferred and entered in MS Excel sheet and analysis was done using SPSS version 17. Quantitative data was expressed by mean and standard deviation. Qualitative data was expressed by percentages.

## RESULTS

Forty patients were enrolled in the study (30 males and 10 females). The mean age at diagnosis was 36 years. 4 out of 40 patients (10%) had two external openings while 36 out of 40 patients (90%) had single external opening.

Thirty-two patients healed after first instillation of glue and two patients after second instillation of glue making a total of thirty-four (85%) and remained free from symptoms at the end of six months.

Three patients required repeat injection of glue, one at 6th week and others at 13<sup>th</sup> and 14<sup>th</sup> week of follow-up. Two of them remained symptom free until the end of six months. The average time of healing of fistula tract came out to be 15 days.

Few patients, 15 out of 40 (37.5%) reported heat sensation immediately after instillation of glue which is

due to chemical reaction occurring at the fistula site due to glue which was managed conservatively. 13 out of 40 (32.5%) patients complained of foreign body sensation at first visit only which was not reported in next follow-up visits.

None of the patients presented with any intolerance to glue or incontinence. The patients were overtly satisfied with the treatment and returned to work the very next day. None of the patients required analgesics in the post-operative period. The results are summarized in Table 1.

**Table 1: Patient details and results.**

Details and outcomes	Number (%)
<b>No. of patients</b>	40
<b>Male</b>	30 (75)
<b>Female</b>	10 (25)
<b>Mean age in years at diagnosis</b>	36
<b>Two external opening</b>	4 (10)
<b>One external opening</b>	36 (90)
<b>Average distance from anal verge (cms)</b>	1.98
<b>Heat sensation immediately after surgery</b>	15 (37.5)
<b>Patients healed after one instillation</b>	32 (80)
<b>Patients healed after two instillations</b>	2 (5)
<b>Recurrence after first instillation (n=40)</b>	5 (12.5)
<b>Recurrence after second instillation (n=3)</b>	1 (33.3)
<b>Average time to heal (in days)</b>	15
<b>Cumulative healing percentage after second application of glue</b>	85

## DISCUSSION

The fistula-in-ano has a common surgical ailment reported since the time of Hippocrates. Recently a new modality with injection of cyanoacrylate glue in the management of fistula-in-ano has been described which is a sphincter saving procedure with faster wound healing time, early return to work, no post-operative hospital stays and decreased recurrence rate.

Cyanoacrylate glue has been earlier used in various surgical branches like orthopaedics, urology, endoscopy, ophthalmology, neurosurgery etc. It has been recently employed in the management of varicose veins as a non-tumescent technique. Cyanoacrylate glue is a synthetic glue that rapidly solidify on contact with weak bases like water and blood.<sup>7</sup> The active compound present in the glue (N-butyl-Cyanoacrylate) polymerize with an exothermic reaction on coming in contact with biological tissue to form an elastic membrane with high tensile strength and adheres to tissue. This membrane is totally resistant to blood and organic fluids. The process of

polymerization starts in 1-2 s and is mostly completed in 60 s.

The new modality has advantage over previous surgical procedures like fistulectomy or fistulotomy in terms of no risk of faecal incontinence as it is a sphincter sparing procedure, lesser chances of wound infection, rapid healing and no hospital stay as it was a day care procedure.

It has advantages over the other sealants like fibrin glue as it is less dense, cheaper, available in premade collapsible tubes, doesn't require expertise to prepare it, longer shelf life and can be stored at room temperature.

In this study, the healing after first instillation of glue was 80% and after second instillation, it was 85%. These results compared favourably with an earlier study conducted by Jain et al evaluating the role of cyanoacrylate glue in the management of low fistula-in-ano in 20 patients. The healing rate after first injection was 85% and after more than one injection, was 95%. In a study conducted by Barillari et al reported a success rate of 71.4% after primary treatment and a cumulative success rate of 90.2% after more than one injection.<sup>8</sup> These results were also comparable to a study conducted by Shivashankar et al where 30 patients were administered cyanoacrylate glue, where healing rate after primary application of cyanoacrylate glue was 73.3% and cumulative healing rate after two sessions of cyanoacrylate glue application was 80%.<sup>9</sup>

## CONCLUSION

Cyanoacrylate glue can be offered as an effective alternative to patients with fistula-in-ano, as it is easy to perform, cost effective, non-invasive and safe. However, studies with large sample size and longer follow-up are needed to establish the efficacy of this procedure.

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