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Simple Anal Fistula: Clinical Criteria for Diagnosis and Local Anesthesia with Conscious Sedation for Surgery - An Observational Study

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Abstract

Introduction: To evaluate (i) acceptability of surgery for simple anal fistula under local anesthesia with conscious sedation by the patients and (ii) accuracy of a set of clinical criteria for diagnosing the condition. **Methods:** Simple anal fistula was diagnosed using a set of clinical criteria. The patients underwent surgery under local anesthesia with conscious sedation. Intravenous paracetamol, diclofenac sodium, and midazolam were administered as adjuvants. Fistulotomy with/without marsupialization was performed in most patients. Clinical diagnosis was matched with operative findings.

Results: Among 193 patients presenting with anal fistula, 61 were diagnosed as simple anal fistula and were scheduled for surgery under local anesthesia. One patient was found to have a complex anal fistula during intraoperative assessment and surgery was deferred. The operation was completed under local anesthesia with conscious sedation for 58/60 (96.7%) patients. Acceptability of the procedure was assessed with the patients' satisfaction score on a visual analog scale (VAS) and their willingness to undergo fistula surgery under local anesthesia again if required. The median (interquartile range) VAS score for patients' satisfaction was 10 (9-10). All patients expressed willingness to undergo fistula surgery under local anesthesia again if required. The clinical criteria were successful in diagnosing simple anal fistula in 58/61 (95.1%) patients. The remaining three patients had a high intersphincteric fistula (1) or a blind sinus (2).

Conclusions: Acceptability of surgery for simple anal fistula under local anesthesia with conscious sedation was excellent. The proposed clinical criteria were highly accurate in diagnosing simple anal fistula.

Keywords: Fistula in ano, Intersphincteric anal fistula, Transsphinteric anal fistula, Complex anal fistula, Magnetic resonance scan, Operative surgery

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Introduction

nal fistula, in an individual patient, needs Acategorization into simple anal fistula (SAF) or complex anal fistula (CAF) because their treatments differ widely. A SAF usually consists of a low intersphincteric or transsphincteric subcutaneous tract and it can be cured by a simple operation fistulotomy or fistulectomy (1). It is characterized by a single external opening (EO), a single internal opening (IO), a completely palpable tract, and no palpable abnormality in the upper anal canal or the lower rectum (1-3). However, the accuracy of these clinical criteria has not been reported. Conventionally, anorectal surgery is conducted under regional anesthesia (RA) or general anesthesia (GA). These anesthetic techniques may be associated with complications like hypotension, urinary retention, post-spinal headache, and longer postoperative hospital stay. Furthermore, the waiting period for operations requiring administration of RA/GA by an anesthesiologist is usually longer in busy governmental hospitals. Local anesthesia (LA) is suitable for operations for hemorrhoids, anal fistulas, anal fissures, and perianal abscesses, boasting a high degree of acceptance among patients (4-7). However, comprehensive information on patient selection, anesthetic technique, pain during surgery, patients' acceptance, surgeons' satisfaction, healing, and recurrence in respect of surgery for SAF under LA is not available in the literature. We evaluated these parameters for surgery under local anesthesia with conscious sedation (LACS) in the present study. We also examined the accuracy of the clinical criteria used for diagnosing SAF.

Material and Methods

This prospective observational study was conducted in the Department of Surgery and Department of Anesthesiology and Critical Care of a teaching hospital in Delhi, India from November 2016 through April 2018. Ethical clearance was obtained from the Institutional Ethics Committee - Human Research. The study included 61 patients in whom anal fistula was diagnosed as SAF using a set of clinical criteria based on physical findings (Table 1). Written informed consent for inclusion in the study and for undergoing surgery under LACS/RA/GA was obtained from each patient. Patients having the following characteristics were excluded from the study: age <18 years, history of perianal surgery, local signs of acute inflammation like purulent discharge with erythema and induration around the

EO/fistula tract, additional anorectal pathology that may alter the scope of surgery, American Society of Anesthesiologists (ASA) grade III & IV, mental illnesses or disabilities, and allergy or sensitivity to drugs to be used for the treatment. The first and second authors assessed all the patients.

The clinical assessment of anal fistula included perineal inspection and palpation, digital rectal examination (DRE), and proctoscopy to assess suitability for inclusion in the study. Each patient underwent a pre-anesthetic check-up and the ASA grade was noted. All patients were advised to take bisacodyl (15 mg tablet) at bedtime for two successive days before the surgery, remain fasting from midnight before surgery, and to report to the operation theatre at 8 am of the day of operation with an adult attendant. The patients for whom it was not convenient to undergo the procedure on the same day as admission were admitted to the surgery ward one day prior to the operation.

In the operation theatre, vital signs monitors were applied. The patient was positioned in the lithotomy or prone jack-knife position. The LACS technique is described in Table 2 and Figure 1. The effect of anesthesia was checked after a few minutes by noting the absence of pain when pinching the skin gently with fine-tooth forceps. Time taken for the achievement of anesthesia was estimated by noting the time interval between commencement of infiltration of local anesthetic solution and achievement of anesthesia at the operative site.

The surgery started with placing the tip of a moist gauze piece in the anal canal. About 2 ml of 1.5% methylene blue was injected through the EO. Staining of the gauze with dye confirmed the patency of the fistula tract. Proctoscopy identified the location of the dye-stained IO. A malleable probe was passed into the EO of the fistula and gently negotiated through the tract and the IO. The fistula tract was laid open over the probe and the fistulotomy was done. The granulation tissue in the tract was curetted out. A search was made for any secondary tract that was also laid open. The edge of the open fistula tract was sutured to the skin on either side with interrupted 3-0 polyglactin/polyglycolic acid sutures. This procedure was termed 'fistulotomy with marsupialization'. Whenever EO was found to be obliterated at the time of surgery, a keyhole-like incision was made around the scarred EO and was deepened. The obliterated, scarred fistula tract was dissected toward the IO for one to two centimeters. When this cord-like tract was transacted, the patent lumen of the fistula tract was exposed. The proximal tract was cannulated to perform a dye test to confirm

 Table 1: Clinical criteria for the diagnosis of simple anal fistula.

1. A single external opening or two or more closely placed external openings on the same side (left/ right) of the anus.

2. A fistula tract palpable, under the skin, from its external opening toward the anal verge.

3. Internal opening present at or inferior to the dentate line in the anal canal and corresponding to the palpable tract.

4. No palpable abnormality (swelling or induration) in relation to the upper anal canal or lower rectum on digital rectal examination.

Table 2: Local anesthesia with conscious sedation technique for simple anal fistula.

Adjuvant medication	Intravenous (IV) paracetamol (15 mg/kg body weight up to maximum dose of 1.0 gm),			
	IV diclofenac sodium (75 mg), and			
	IV midazolam (0.03-0.05 mg/kg)			
	administered 15 minutes before surgery			
Composition of local anesthetic solution	15 ml of 0.5% bupivacaine mixed with 15 ml of 2% lignocaine with adrenaline (1:200000).			
Maximum safe dose	Maximum safe dose of local anesthetics not to be exceeded: lignocaine with adrenaline			
	(7mg/kg), bupivacaine (3mg/kg).			
Infiltration technique	Local infiltration of anesthetic solution around the external opening, fistula tract, and into the sphincter complex around the internal opening of the fistula (Figure 1).			
Ensuring patient comfort 7	Use of fine needle (26-30 gauge) for local infiltration.			
	Slow administration of solution.			
	Waiting patiently until anesthesia is achieved.			
Precautions	The fistula tract should not be pierced/punctured by the needle.			
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Figure 1: Extent of local anesthetic solution infiltration around the anal fistula tract (area colored yellow).

the patency of the tract and IO. A malleable probe was then passed in the tract and the fistulotomy was completed. This procedure was termed 'proximal fistulotomy with distal fistulectomy' (Figure 2 A to D). In some other cases, the proximal part of the fistula tract lying within the sphincters or the IO was not patent, and the probe could not be negotiated through the entire fistula tract. In such a situation, a fistulotomy of the distal patent tract was performed and the obliterated proximal part was excised by performing fistulectomy. This involved excising a small postage stamp-like portion of the internal sphincter at the site of the obliterated IO along with the obliterated proximal tract. The procedure was termed 'distal fistulotomy with proximal fistulectomy' (Figure 2 E to G).

The patient's response to the operative stimulus, in terms of complaint of pain and withdrawal movement of the body, was observed during surgery. If necessary, further infiltration of the local anesthetic solution was undertaken. If the patient still complained of pain, GA was to be administered by the anesthetist as a rescue. The surgeon expressed his satisfaction regarding the procedure on a visual analog scale (VAS) based on the effectiveness of LA and the patient's cooperation during surgery. In the VAS, 0 indicates minimum satisfaction and 10 indicates maximum satisfaction (8). Any intraoperative complication was noted.

In the postoperative room, each patient was asked about the perception of pain in the operative site during the operation. The response was recorded on the numerical rating scale (NRS) where 0 is no pain and 10 is the worst pain imaginable (9). The patient was also requested to quantify the pain in the operative site on the NRS at 30-minute intervals during the postoperative period. Any spontaneous complaint of pain was also noted and assessed on the NRS. If the NRS score was 4 or more, or if the patient demanded an analgesic, tramadol (1 mg/kg) and ondansetron (4 mg) were administered intravenously. After observing the patient for 3 hours in the postoperative room, the Post-Anesthetic Discharge Scoring System (PADSS) score was calculated, and the patient was discharged when a PADSS score of 9 was recorded (10). The patient was prescribed oral paracetamol 500 mg 6 hourly for three days for pain relief and lactulose syrup 15-30 ml at bedtime, as per requirement, to prevent constipation. Patients were advised to clean the perianal region with clean tap water after passing stool and during a bath, mop the area dry with a clean hand towel, keep the operative area covered with a commercially available sterile sanitary pad, and attend the surgery outpatient clinic on the fifth postoperative day. Patients were provided a phone number of the resident doctor for contact in case of any inconvenience.

During the follow-up visit, an inquiry was made regarding nausea and vomiting, retention of urine, fever, bleeding from the wound, wound discharge, anal incontinence, and any other postoperative complication. Acceptability for surgery for SAF under LA was based on the assessment of patients' satisfaction score on a VAS and their willingness to undergo surgery under LA again if required. The answer for the latter was recorded in the 'yes/no' format. The patients were followed up at two-week intervals up to three months after surgery. Analysis was performed using SPSS software version 20



Figures 2: A to D: Proximal fistulotomy with distal fistulectomy: (A) keyhole incision around obliterated external opening; (B) distal fistulectomy done, patent lumen exposed; (C) & (D) proximal tract laid open over a probe and marsupialization done. E to G: Distal fistulotomy with proximal fistulectomy: (E) malleable probe not negotiating through the proximal tract; (F) fistulotomy and marsupialization of patent distal fistula tract; (G) proximal obliterated tract excised with a small postage stamp-like portion of the internal sphincter.

(SPSS Inc., Chicago, IL., USA). Descriptive statistics were used to calculate number, percentage, mean (standard deviation), and median (interquartile range; IQR).

Results

Among 193 patients presenting with anal fistula, 61 patients were categorized as SAF according to the clinical criteria and were scheduled for surgery under LACS. Surgery was deferred in one patient who was found to have a CAF during intraoperative evaluation. The mean age of the patients was 33.6 ± 10.4 years with a male to female ratio of 9:1. Thirty-one (51.7%) patients had anterior tracts, while 29 (48.3%) patients had posterior tracts. No patient reported anal incontinence for flatus or feces during preoperative assessment.

The operative treatment of the patients was determined by the topography of the fistula as shown in Figure 3. The mean time for achievement of anesthesia was 5.3±1.5 minutes. The mean volume of local anesthetic solution used in surgery was 17.6 ± 3.8 ml. Fistulotomy with or without marsupialization was performed in 52/60 (86.7%) patients. In four (6.7%) patients, in whom part of the tract/EO/IO was obliterated, fistulotomy was combined with fistulectomy of the obliterated portion of the tract. In another four (6.7%) patients, in whom the fistula tract was not entering the anal sphincters, the blind sinus was laid open. The mean time taken for completion of surgery was 25.8±13.9 minutes. Only 2/60 (3.3%) patients required further local anesthetic infiltration to control pain during surgery. No patient required conversion to GA. No patient developed hypoxia or hypoventilation. No other intraoperative

complications were recorded among the 60 patients. The median (IQR) NRS for pain during surgery was 0 (0-1). During the postoperative observation period, six (10%) patients reported NRS scores of 4 or more, responding to tramadol administration. The median (IQR) VAS score for patients' satisfaction regarding surgery under LACS was 10 (9-10). Besides, all 60 patients expressed their willingness to undergo fistula surgery under LACS again, if required. The median (IQR) VAS score for the surgeons' satisfaction was also 10 (10-10).

No patient reported anal incontinence for flatus or feces following surgery. Surgical wounds healed completely within three months without any complication in 56/60 (93.3%) patients. Four (6.7%) patients developed complications, including failure of healing (n=2) and recurrence (n=2). Two of the four patients, in whom the blind sinus was laid open, complained of persistent discharge from the wound. The wound was explored under spinal anesthesia (SA). A patent low fistula tract leading to the anal canal was found in both patients and a fistulotomy was performed. Two other patients reported recurrence of pus discharge after initial healing. For these two cases, a second operation was done under LA during which a small residual secondary tract was laid open. In all four patients who required re-operation, the wound was found to have healed at three months. Two (3.3%) patients required SA for a second operation. Thus, operative treatment of SAF could be completed under LACS in 58/60 (96.7%) patients. Surgery was performed on a day-care basis in 23/60 (38.3%) patients. Following surgical exploration, 54 patients were confirmed as having low transsphincteric fistula, 4 patients as low intersphincteric anal fistula, and 2 patients as blind



Figure 3: Flow diagram showing surgery for simple anal fistula in 61 patients. SAF: Indicates simple anal fistula; EO: External opening; IO: Internal opening

Tab	le	3:]	Physica	l signs	of ana	l fistula.	
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Physical signs	Significance
Number and location of external opening (EO)	Bilateral, multiple, and/or distant EOs suggest the possibility of a complex fistula.
Number and location of internal opening (IO)	More than one IO or its location in the upper anal canal/rectum suggests complex fistula.
Palpate anal fistula tract	The tract of a simple fistula is usually superficial and it is easily palpable, under the skin, between the EO and anal verge. Sometimes, the proximal/medial part of the tract of a simple fistula may not be palpable when obscured by robust sphincter muscles. On digital rectal examination, a high intersphincteric tract may be occasionally palpable as a cord extending from the IO toward the anorectal junction (ARJ). The superior end of such a tract may be sometimes palpated as a small polyp/nodule in the rectum just above the ARJ.
Ridge-like induration posteriorly at the ARJ	Scarring in the case of a horseshoe tract may be felt as a firm ridge posteriorly at the ARJ.
Induration/ swelling in lower rectum abutting the ARJ	In case of a supralevator abscess or deep postanal space abscess, a swelling/indurated area can be palpated in the lower rectum abutting the ARJ.

sinus tract. In one patient, in whom a CAF was found during intraoperative assessment, a CT fistulogram later revealed a high intersphincteric fistula. Thus, in 58/61 (95.1%) patients, the preoperative diagnosis of SAF was proven correct when matched with operative findings. Thus, the clinical criteria had a diagnostic accuracy of 95.1% in diagnosing SAF. At the same time, these criteria were successful in excluding CAF in 60/61 (98.4%) patients.

Discussion

The physical examination can reveal several characteristics that may help in differentiating between a SAF and a CAF (3). These characteristics can be detected on a careful and thorough perineal examination (inspection, palpation, and DRE) and should be christened as physical signs of anal fistulae. These physical signs reveal the topography and

complexity of the anal fistula (Table 3) (1, 3). During the DRE, the attention of the surgeon is usually focused on identifying the IO; other important findings are generally not looked for or are missed. It is interesting to note that little attention has been, often, paid to the description of these physical signs and their significance in anal fistula literature (11-17). The SICCR position statement on evaluation of and management of perianal abscess and anal fistula mentions only Goodsall's Rule while referring to the physical examination (13).

The proposed set of clinical criteria for the diagnosis of a SAF is based on the physical signs mentioned in Table 3. A SAF is diagnosed by documenting the presence of specific signs of SAF and the absence of those of CAF (Table 1). Such criteria had a diagnostic accuracy of 95.1% in diagnosing SAF in our study. At the same time, these criteria were successful in excluding CAF in 98.4% of patients. The evaluation of a set of clinical criteria based on physical findings for differentiating between SAF and CAF has not previously been reported in the literature. Magnetic resonance imaging (MRI) has been reported to add significant information about unsuspecting complex parameters that were missed on history and clinical examination in more than one-third (34.6%) of simple fistulae (12). Failure to note the specific signs of CAF during the clinical examination is the main reason for clinical under-diagnosis of CAF. MRI is a costly investigation; the equipment, as well as the expertise, has limited accessibility particularly to socio-economically challenged members of society. Awareness of various physical signs that differentiate between SAF and CAF and the use of this knowledge in day-to-day practice is a simple and more costeffective alternative to MRI. An MRI should be reserved for fistulae that do not fulfill the clinical criteria for SAF. The sensitivity and specificity of the clinical criteria used to diagnose SAF could not be determined because the data of patients who did not fulfill these criteria were not available for analysis. This is a limitation of the present study.

The majority of the operations performed in the present study were fistulotomy with or without marsupialization (90.0%). For SAF, a primary fistulotomy with marsupialization of the wound is the best option. Marsupialization leads to faster wound healing (1, 2). Fistulotomy is not feasible if a part of the fistula tract is obliterated. We have combined fistulotomy with fistulectomy with the advantage to tackle fistulae with obliterated EO, IO, or parts of the tract. Conventionally, anorectal surgery is performed under RA or GA. However, several studies have found LA to be a safe and effective technique for anorectal surgery with early recovery, reduced postoperative complications, and shorter hospital stay (18-20). Different local anesthetic techniques for perianal block have been described for anorectal surgery (4, 5, 21-29). In patients with SAF, the disease process is localized to a limited

sector along the fistula tract; hence, local infiltration covering the EO, fistula tract, and IO is sufficient to allow a painless surgical procedure (Figure 1). Surgery for SAF, being a procedure of short duration, is eminently suitable for LACS.

It is a common practice to use midazolam/diazepam and other adjuvant drugs with local anesthesia for their beneficial effects of sedation, amnesia, and analgesia (22, 26, 30, 31). No narcotic or short-acting anesthetic was used with midazolam in the present study. In 100 patients undergoing surgery for benign anorectal disorders, Saranga et al. administered 2 mg midazolam and 15-30 mg pentazocine intravenously before local anesthetic infiltration to make the surgical procedure painless (31). In their study, 3% of patients required conversion to GA. In the present study, acetaminophen, diclofenac sodium, and midazolam were used to supplement LA. Two patients, who were found to have blind sinus tracts during the first operation, required a second operation under SA for persistent discharge from the wound.

The median (IQR) pain score during surgery was 0 (0-1) on the NRS. Only 3.3% and 10% of patients required additional medication during the intraoperative and postoperative periods, respectively. Park et al., in a study of 13 fistulotomy cases under LA, observed mean VAS pain scores of 2.1 and 2.6 during the intraoperative and postoperative periods, respectively (6). Noori observed a mean VAS pain score of 2.2 during the operation and 2.8 on the first postoperative day in a study of 45 low fistulectomy cases under LA (5). These studies confirm that LA provides adequate analgesia for a fistulotomy/ fistulectomy. The use of adjuvant medications along with LA accounted for low pain scores in our patients. Numerous side effects have been reported following anorectal surgeries performed under conventional anesthesia (GA/RA) (31-33). Postoperative nausea and vomiting, fever, wound bleeding, anal incontinence, and urinary retention were not observed in any of our patients. Surgery under LA results in less postoperative urinary retention as compared to surgery under SA (5, 19).

Several measures/component constructs have been described to assess the acceptability of healthcare interventions (34). In the present study, the acceptability of the procedure was assessed with two parameters: the patients' satisfaction score on a VAS and their willingness to undergo fistula surgery under LACS again if required. The median (IQR) VAS score for patient satisfaction regarding the surgery under LACS was 10 (9-10). In addition, all patients expressed their willingness to undergo fistula surgery under LACS again if required in the future. A high satisfaction level for anorectal surgery under LA has been reported by several other authors (5, 6, 32, 35). Most patients (83-85%) have expressed their willingness to undergo surgery under LA again if necessary (4, 5). LACS seems to

be the ideal anesthetic technique for daycare anal procedures (4, 5, 29, 31, 32). In our study, 38.3% of patients underwent daycare surgery while 61.7% of patients were admitted one day prior to surgery as per their convenience.

In conclusion, the set of clinical criteria based on physical findings was found to be highly accurate in diagnosing SAF. The use of these criteria will restrict the need for specialized imaging for anal fistulae that fail to fulfill the criteria. The present study also affirms the feasibility of surgery for SAF under LACS. The procedure scores a high degree of patients' acceptance and surgeons' satisfaction. The procedure has the advantage of a short hospital stay and can be carried out as a daycare procedure, if convenient to the patient. LACS may fast track surgery for SAF in a busy hospital and may relieve pressure from the main operation list, which can be utilized better for major operations under GA/RA.

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