

Study Protocol

Version 3

1 September 2018

Title:

A prospective double-blinded randomized controlled trial: assessment of immediate post-operative pain for FiLAV versus LIFT in the treatment of trans-sphincteric anal fistulas (LASERLIFT)

Design

A prospective, double-blinded, single credentialed colorectal surgeon, randomised controlled trial.

Settings

University Malaya Medical Centre, a tertiary teaching hospital.

Patients

Patients with high transsphincteric anal fistulas from January 2018 to December 2020

Intervention

Laser versus ligation of the fistula tract (LIFT) treatment

Primary Outcome Measure

Pain scores at rest and movement, at 6 and 24 hours post operatively will be measured using the visual analogue scale (VAS)

Secondary Outcome Measures

1. Operative time was measured in minutes at 0-, 3- and 6-months post-surgery
2. Continence assessed using Wexner at 0-, 3- and 6-months post-surgery
3. Quality of life assessed using SF-36 questionnaire at 0, 3 and 6 months post-surgery

Study Participants

Written informed consent was obtained from all patients all patients with high transphincteric anal fistulas were recruited into this trial.

Inclusion Criteria:

1. 18 – 75years
2. Able to give consent
3. Complex transphincteric fistulas; high transphincteric fistula, involving >30% of the external anal sphincter; Multiple fistulas; Anterior fistulas; Recurrent fistulas; Fistulas with seton

Exclusion Criteria:

1. Active perianal sepsis requiring drainage
2. Fistulas of non-cryptoglandular origin
3. - Crohn's, TB, malignancy
4. Expected lifespan <6 months
5. Pregnant women
6. Patient's with more than 1 definitive surgery done for the fistula before
7. Patient's with human immunodeficiency virus infection
8. Patient's with pre-existing chronic pain disorders
9. Patient's with Non-steroidal Anti-inflammatory Drug (NSAIDS) / Paracetamol allergies

All patients' will be recruited from the surgical outpatient clinic at UMMC, where thorough history and clinical examination will be performed. Next patient will undergo an endo-anal ultrasound (EAUS - 2052 probe, GE healthcare BK Medical) by an experienced operator which then confirms the presence of a high transphincteric fistula and/or other branching tracts as per Park's fistula classification. An MRI would only performed if the EAUS was inconclusive. Baseline assessment of quality of life (QOL) using the SF36 questionnaire and continence using Wexner's scale will be done at the start upon recruitment. Patients will randomised into the laser or ligation arm using block randomisation via the Sealed Envelope program (<https://www.sealedenvelope.com>). Double blinding was achieved as patients and the data collector were blinded to the interventions.

Study Intervention And Post-Intervention Care

The laser procedure will be performed according to the technique described by Wilhelm et al. The internal and external opening will first be identified and the tract debrided. Upon activation a laser fibre (10Watt, 600nm, fibreglass length 1800nm, emitting a wavelength of 1470 nm, ENDOTEQ Medical Laser Germany GmbH) will release thermal energy of maximum 100 Joules homogeneously into the tract while being withdrawn at the speed of 1mm/s. The internal orifice was then closed with an interrupted absorbable stitch. For cases which required a core out, the external opening then left open to heal by secondary intention.

The LIFT procedure would be performed as first described by Rojanasakul et al 2007. The internal and external opening was first identified. A curvilinear incision made at the intersphincteric plane after identification of the internal and external opening. Dissection was then performed up until where the tract was encountered where it was then ligated as close as possible to the internal opening and a portion of the tract excised. The external opening was then curetted and tissue sent for histopathology studies. The skin then closed loosely with an interrupted absorbable suture.

Standardised analgesia (PO Celecoxib 40mg and PO Paracetamol 1g) will be served at exactly 6 hours post operatively. Pain scores was assessed by a blinded healthcare professional using the visual analogue scale (VAS) at 6 hours and 24 hours post operatively, at rest and on movement.

Upon discharge, patients would be given oral antibiotics, PO celecoxib 40mg BD and PO paracetamol 1g QID for a week duration. All patients were reviewed at one week post-op for a wound assessment, and an official surgical consult at 1 month and 6 months post operatively.

Each surgical consult involved a history taking, clinical examination, QOL and continence assessment. Should there be any suspicion of a recurrence before 6 months they will be subjected to an EAUS. An MRI will be performed if the EAUS is inconclusive.

Study Definitions And Outcome Measures

Successful fistula healing is defined as complete wound healing and closure of all the external openings in combination with the cessation of outflow from the external openings at 6 months post operatively. Surgical failure was defined as failure of the fistula to close with persistence of discharge at 6 months post operatively. This encompassed the spectrum of wound infection, recurrence and technical failure.

Sample Size Justification

As there were no prior studies with the primary outcome on pain score prior to trial commencement, we proceeded to calculate the sample size based on the score obtained from a local audit. Then using the G-power software, to achieve an alpha error of 5%, confidence interval of 95%, power of 0.9 and a large effect size, 28 fistulas were required per arm.

Statistical Analysis

Analysis would be performed using SPSS Statistics for Mac (version 23 Inc., Chicago, IL, USA) with an intention-to-treat basis. Continuous variables will be presented as median and range or mean and standard deviation. Differences between groups can be compared using chi-square analysis or the Fisher exact test when data is categorical. While continuous variables can be compared using the student t-test or Mann-whitney based on normality of data distribution. We will consider data to be statistical significance if $p < 0.05$.

