Outcomes in High Perianal Fistula Repair Using Video-assisted Anal Fistula Treatment Compared With Seton Use: a Randomized Controlled Trial

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Study Protocol:

Patients

Patients of both sexes with age ranging from 15 to 60 years with high perianal fistula will be included in the study. High perianal fistulas will be defined as intersphincteric fistula with more than 50% of internal anal sphincter involvement, transsphincteric fistula with more than 50% of sphincter complex involvement, extrasphincteric fistula, or suprasphincteric fistula. The anatomy of fistulas will be delineated by three-dimensional endoanal ultrasound. Patients with suspected malignancy determined by the presence of a mass on digital rectal examination, history of previous perianal surgery, history of irritable bowel disease determined by medical record, or uncontrolled diabetes will be excluded from the study. After receiving written permission from the ethical review committee, patients fulfilling the inclusion criteria will be admitted through the outpatient department.

Randomization and masking

Patients will be randomly assigned to either repair via VAAFT or traditional seton use via computer-generated random number.

Procedures

Patients assigned to the VAAFT group will receive the following procedure. The external opening of the fistula will be widened with a probe, and a fistulascope will be inserted to delineate the primary and secondary tracts and locate the internal opening. The internal opening will be then stitched with Vicryl™(Polyglactin 910) 2-0 suture through the anal route with the help of a proctoscope. The tract of the fistula will be washed and debrided through scope and it will be coagulated with cautery. For the seton group, Hydrogen peroxide will be injected to the external opening with a 10-cc syringe, and the internal opening will be located by direct visualization of the anal canal via proctoscope. A cannulating probe will be inserted into the external opening and carefully maneuvered through the internal opening. Silk 1/0 suture will be then tied to the tip of the probe, which will be then squeezed out of the external opening. The suture will be then tied around the sphincter and through fistula tract. Later, the seton will be tightened at four week intervals until the suture cut through the sphincter. Intravenous ketorolac 90mg/day and intravenous acetaminophen 3g/day will be used as postoperative anesthesia for both groups.

Outcomes

Postoperative pain will be determined 12 hours after the surgery via the visual analog pain score. Patients will be then monitored via follow-up in the outpatient clinic at two and four weeks, three and six months, and one, two, and three years to determine when a patient could return to work, total healing time, and monitor for any recurrence.

Statistical Analysis Plan:

All the data will be recorded on a predesigned proforma. The data will be analyzed using IBM SPSS Statistics for Windows, Version 21.0 (Armonk, NY: IBM Corp.). The categorical variables like sex, type of fistula, and recurrence will be presented as frequencies and percentages. In contrast, continuous variables like age, duration of surgery, pain score, the time required to return to work, and healing time will be presented as mean standard deviation. Mean pain score, mean duration of surgery, mean time in days to return to work, and mean time of healing will be compared using t-test. Recurrence will be compared using a chi-square test. Differences were considered statistically significant at $p \leq 0{\cdot}05$.