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Original research

Randomized clinical trial of transcutaneous electrical posterior tibial nerve stimulation *versus* lateral internal sphincterotomy for treatment of chronic anal fissure

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HIGHLIGHTS

- The objective was to evaluate the efficacy of TENS in treatment of chronic anal fissure in comparison with LIS.
- 75% of patients in TENS group had clinical improvement one month following the procedure.
- All patients in LIS group had clinical improvement one month following the procedure.
- Recurrence of anal fissure after one year was reported in 2.7% and 40.7% of patients in LIS and TENS groups respectively.
- LIS remains the gold standard for treating chronic anal fissure.

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ABSTRACT

Objectives: The objective of this study was to evaluate the efficacy of transcutaneous electrical posterior tibial nerve stimulation in treatment of patients with chronic anal fissure and to compare it with the conventional lateral internal sphincterotomy.

Patients and methods: Consecutive patients with chronic anal fissure were randomly allocated into two treatment groups: transcutaneous electrical posterior tibial nerve stimulation group and lateral internal sphincterotomy group. The primary outcome measures were number of patients with clinical improvement and healed fissure. Secondary outcome measures were complications, VAS pain scores, Wexner's constipation and Peascatori anal incontinence scores, anorectal manometry, and quality of life index.

Results: Seventy-three patients were randomized into two groups of 36 patients who were subjected to transcutaneous electrical nerve stimulation and 37 patients who underwent lateral internal sphincterotomy. All (100%) patients in lateral internal sphincterotomy group had clinical improvement at one month following the procedure in contrast to 27 (75%) patients in transcutaneous electrical nerve stimulation group. Recurrence of anal fissure after one year was reported in one (2.7%) and 11 (40.7%) patients in lateral internal sphincterotomy and transcutaneous electrical nerve stimulation groups respectively. Resting anal pressure and functional anal canal length were significantly reduced after lateral internal sphincterotomy.

Conclusion: Transcutaneous electrical posterior tibial nerve stimulation for treatment of chronic anal fissure is a novel, non-invasive procedure and has no complications. However, given the higher rate of clinical improvement and fissure healing and the lower rate of fissure recurrence, lateral internal sphincterotomy remains the gold standard for treating chronic anal fissure.

1. Introduction

A chronic anal fissure (CAF) is a non-healing tear in the distal

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anal mucosa below the dentate line [1]. It is estimated that 10% of visits to colorectal units are for anal fissure with both sexes affected equally [2]. The initial hypothesis for the development of anal fissure is anal canal trauma by passage of hard stool or bouts of diarrhea [3]. Fissures persisting for longer than four weeks are generally defined as chronic [4]. This chronicity is explained by two factors. The first factor is the presence of persistently high basal internal sphincter tone [3]. The second factor is the presence of ischaemia in the distal anal canal due to deficiency of arterioles in the posterior anal commissure of the anal canal which is present in 85% of individuals. This area is usually only supplied by end vessels and is then more susceptible to ischaemia [1].

Lateral internal sphincterotomy (LIS) is the gold standard against which all treatments are compared with a healing rate over 92% [4]. However, the most serious complication of this procedure is anal incontinence. The overall incontinence rates (early and late incontinence) range from 3.3% to 16%, with incontinence rates beyond two months at 3%–8% [5–8]. Another issue is the recurrence of the fissure following surgical treatment with a range of 1%–8% [9].

To overcome these problems, continued efforts are being tried to find less invasive treatments modalities for anal fissure that is as effective as surgical therapy with lower morbidity. Pharmacological treatments have been investigated but the results are still inferior to those for lateral sphincterotomy [4]. Sacral nerve stimulation has been recently tried for management of CAF with promising results [10,11]. However, the technique described is invasive with the need for surgically implantable expensive stimulator electrodes. Transcutaneous electrical nerve stimulation of posterior tibial nerve has been proved to be of acceptable results in treatment of fecal incontinence [12,13] and urinary incontinence [14].

The aim of this study was to evaluate the efficacy of posterior tibial nerve stimulation (PTN) by transcutaneous electrical nerve stimulation (TENS) and to compare it with the conventional LIS.

2. Patients and methods

This prospective randomized study was conducted at Surgery and Rheumatology and Rehabilitation Departments of Mansoura University Hospitals from July, 2012 to July, 2013. Consecutive symptomatic adults affected by CAF were enrolled in the study. The diagnosis was based on the following clinical criteria [1]: evidence of posterior circumscribed ulcer with presence of indurated edges, visible internal sphincter fibers at the base of the fissure, a sentinel polyp at the distal end of the fissure or a fibroepitheliomatous polyp at the apex; and [2] symptoms (postdefecatory and/or nocturnal pain, bleeding) persistently present for over 2 months that had failed to resolve. Exclusion criteria included [1]: patients younger than 18 years [2]; patients with laterally located or painless fissures [3]; concurrent fistula or significant hemorrhoidal disease [4]; inflammatory bowel disease [5]; diabetes mellitus [6]; pregnancy [7]; neurological disease [8]; spinal cord lesions [9], use of cardiac pacemaker [10]; previous anal surgery or previous episiotomy. Males and females were considered for inclusion. This study was approved by Mansoura Faculty of Medicine ethical committee and registered at the clinical trials registry of the National Institute of Health (NCT02395809). All patients provided written informed consent for inclusion in the study after explanation of the nature of anal fissure and possible treatment.

Patients were randomly assigned to two treatment groups, either transcutaneous posterior tibial nerve stimulation group (TENS group) or subcutaneous lateral internal sphincterotomy group (LIS group). Randomization was performed by a nurse not involved in the study using sealed envelope method.

All patients were subjected to pretreatment evaluation including careful history taking including Visual Analogue Score for pain and Wexner's constipation score [14] clinical examination and anorectal manometry. Anorectal manometry was performed using a standard low compliance water perfusion system and eight-channel catheters with pressure transducer connected to 5.5 mm manometric probe with spirally located ports at 0.5-cm interval, which measures the pressure along the length of the anal canal. The protocol of performance is stationed pull-through technique with recording the functional length of the anal canal (FACL), mean maximum resting pressure (MRAP), and the mean maximum squeeze pressure (MSAP). Pressures were recorded using a computerized recording device (Sandhill Bioview program, USA) which included menu-driven software to aid with data acquisition. Data were analyzed with the use of a complied software package that automatically produced numeric reports and graphs.

2.1. Transcutaneous electrical posterior tibial nerve stimulation group (TENS group)

Transcutaneous electrical posterior tibial nerve stimulation was applied through a stimulating TENS unit (Endomed 182, Enraf Nonius, Holland). The technique of TENS application was similar to that reported by Queralto et al. [12] Stimulation was done on the PTN route using a self-adhesive surface stimulation electrode without an implanted needle electrode. The negative contact electrode was placed on the ankle skin behind the medial malleolus, and the positive electrode, 10 cm above the negative electrode. The adequate position of the electrode was determined by visualization of rhythmic flexion of toes during stimulation. The intensity level selected was determined based on the intensity immediately under the threshold motor contraction and varied from 15 to 30 mA. A 200-μs, 10-Hz current was applied for 20 min three times per week for 4 weeks in the outpatient clinic.

2.2. Lateral internal sphincterotomy group (LIS group)

Under local anesthesia, adequately lubricated anal retractor was positioned and intersphincteric groove was identified. A blade knife (No 11) was inserted between internal and external sphincter. The tip of the blade was angled medially pointing just above the dentate line and IS was divided. When the knife was felt beneath the intact mucosa, it was withdrawn. Digital pressure was applied to ensure haemostasis.

The primary outcome measure was number of patients with clinical improvement and healed anal fissure. Secondary outcome measures were procedures complications, VAS score for pain, constipation score, anal incontinence score, anorectal manometry, patient's satisfaction and quality of life index.

Patients were reexamined at the end of TENS sessions (one month) while LIS group patients were reexamined postoperatively on days 1 and 7 and after one month. Thereafter all patients were followed up every 3 months for a year starting at 3rd postoperative month. They were asked to attend immediately if they develop symptoms. The parameters investigated were assessed by investigators who were blinded to the patient's study group. Fissure healing was defined as mucosal healing with complete epitheliliazation. Pain was assessed before treatment and one month after treatment using visual analogue scale (VAS) scores that ranged from 0 (no pain) to 10 (worst pain). Constipation was assessed using Wexner's constipation score [15]. Anal incontinence was assessed using Peascatori grading system for anal incontinence [16]. Postoperative patient's satisfactions were assessed on visual analogue scale (VAS). Quality of life was assessed with the GI Quality of Life Index (GIQLI) developed by Eypasch and coworkers [17], a validated tool for measuring quality of life in patients with