EFFICACY OF ALOE VERA CREAM VERSUS TRANSCUTANOUS ELECTRICAL NERVE STIMULATION ON POST – HEMORRHOIDECTOMY PAIN

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ABSTRACT

Background: Post - haemorrhoidectomy pain a major dilemma facing either patients or doctors and a little research work have been done to done to eliminate or decrease this agonizing pain.

Aims & Objective: The purpose of this study was to determine the best treatment modality to decrease Post - haemorrhoidectomy pain either by natural pharmacological agent (aloe vera cram) or non-inexpensive, non-invasive physiotherapeutic modality Transcutaneous electrical nerve stimulation (TENS) as measured by visual analogue score (VAS) or post-operative analgesic consumption.

Material and Methods: Thirty female patients ranging in age from 18 to 40 years and who had done open haemorrhoidectomy were classified into 3 equal groups 10 of each, Group (1): received aloe vera cream in addition to analgesic drugs , Group (2): received TENS application over acupuncture points in the hand in addition to analgesic drugs. And Group (3): served as control group and receive only analgesic drugs. Measurements of knee extension range of motion were conducted before treatment, post 5 days of treatment, and after 8 days of treatment.

Results: The one way analysis of variance was used to compare VAS and postoperative analgesic consumption which revealed that both treatment groups (aloe vera and TENS) had significant (P< 0.05) decrease in VAS post-operative analgesic consumption either at 1st and 2nd week postoperatively. But aloe vera cream had highly significant (P< 0.001) decrease in VAS post-operative analgesic consumption either at 1st and 2nd week postoperatively when compared with TENS group.

Conclusion: The results of this study suggest that aloe vera cream is more effective than TENS alone to decease post-haemorrhoidectomy pain.

KEY-WORDS: Pain; Post – Haemorrhoidectomy; Aloe Vera; TENS

Introduction

Haemorrhoids is a common disease worldwide and causes symptoms in 4.4% of the population.[1] Among several modalities studied for the treatment of haemorrhoids, surgical resection seems effective in eradicating the symptoms about which patients complain.[2] However, agonizing postoperative pain and thus the need of hospitalization for pain relief remains the major drawback for a patient undergoing haemorrhoidectomy.[3] Several interventions, for example, transdermal delivery of fentanyl, intraoperative use of Toradol® (Syntex Laboratories, Palo Alto, CA), and use of a subcutaneous morphine pump, have been used to relieve postoperative pain after haemorrhoidectomy.[3–6] Nevertheless, the results are unsatisfactory.

Although, diet bowel regulation, or elastic ligation will alleviate most symptoms of internal haemorrhoids, occasionally, an excisional haemorrhoidectomy will be necessary. The excision of haemorrhoids should be limited to large third and fourth degree haemorrhoids that cannot treated on an outpatient basis, mixed haemorrhoids, acutely thrombosed, incarcerated haemorrhoids with severe pain and impending gangrene.[7] Numerous approaches have been used for the surgical removal of haemorrhoids. Closed haemorrhoidectomy involves resection of Haemorrhoidal tissue and closure of the wound with absorbable suture.
Although, pain is not actually a complication of surgery, it is nonetheless the single most important reason why patients avoid haemorrhoidectomy.[10] A great deal of emphasis has been applied to the management of this pain, not only because of the pain itself, but because of the role it plays in urinary symptoms. Pain and fluid overload are the primary factors that cause urinary retention, which is the most complication after haemorrhoidectomy. If pain medication is inadequate, the patient cannot relax the sphincter mechanism sufficiently to urinate. Different options have been employed for analgesia after haemorrhoidectomy such as narcotics, injection of Tradol (Ketorolac tromethamine) into the anal sphincter at the time of operation, application of transdermal Fentanyl.[15] Attempts to reduce this pain have been continued. Even postoperative oral or topical Metronidazole is used.[9–11]

Transcutaneous electrical nerve stimulation (TENS) is peripheral stimulation via electrodes applied to the skin used as a medical procedure for health care and pain control.[12] Several lines of evidence suggest a similar effect in TENS and electroacupuncture.[13] Moreover, TENS has been shown to relax the lower oesophageal sphincter in patients with achalasia and to relax the sphincter of Oddi in patients with biliary dyskinesia.[14,15] Because of present management methods for post-haemorrhoidectomy pain remain unsatisfactory; the effect of TENS for pain relief on patients undergoing haemorrhoidectomy is worth investigation.

Aloe Vera (family: Liliaceae) has been used in traditional medicine for a long time. Aloe Vera gel, obtained by breaking or slicing its leaf (the principle part of the plant), is used in herbal medicine. Aloe vera contains many important nutrients including amino acids, B group vitamins, polysaccharides, and other nutrients that support general health. It also has many pharmacological properties including antioxidant, wound healing, antibacterial, analgesic, antifungal, antiviral, and immunomodulating effects.[16–18]

Realizing the importance of reducing pain after haemorrhoidectomy, we examined the effects of Aloe vera cream vs. TENS in reducing postoperative pain after open haemorrhoidectomy.

### Materials and Methods

#### Patients

Sixty consecutive patients with symptomatic haemorrhoids, Grade III to IV, were eligible for surgical resection of the haemorrhoids (open haemorrhoidectomy). Patients with chronic liver insufficiency (serum bilirubin > 2.0 mg/dl), massive ascites, chronic renal insufficiency (serum creatinine > 1.5 mg/dl), pregnancy, involvement of colorectal cancer, history of bleeding, long-term analgesic intake, cardiac arrhythmia, and pacemaker implantation were excluded from the study. Under regulations of Om El Masryine General Hospital, Cairo, Egypt, patients who given informed consent were prospectively assigned to three groups as described below. Surgical procedures, including one to three wedge resection(s) of the haemorrhoids, were standardized and performed by a single surgical team. Perioperative prescriptions for haemorrhoidectomy included preoperative sedation (diazepam, 10 mg intramuscularly), intraoperative perineal anaesthesia with 30 ml of a mixture of 0.25% Marcaine™ (bupivacaine, Winthrop Pharmaceuticals, New York, NY), with units of epinephrine at 1:200,000 and two ampules of Wydase™ (hyaluronidase; Wyerst-Ayther Laboratories, Philadelphia, PA). After the operation, patient-controlled analgesia (PCA) was administered by an ambulatory infusion pump (model 5800, Pharmacia Deltec, Inc., St. Paul, MN) administering morphine intravenously. A bolus dose of 2 mg of morphine sulphate was given, followed by patient controlled bolus doses of 0.5 mg every six hours. The PCA ambulatory infusion pump was programmed to administer bolus doses with a lockout feature to prevent overdosing. This dose was not enough for adequate pain relief, so that it was feasible to evaluate the usefulness of postoperative TENS and Aloe vera cream.

#### Preparation of Aloe Vera Cream

Liquid white paraffin (2 g), sterile alcohol (7.5 g), cetyl alcohol (7.5 g), solid white paraffin (3 g), and propylene paraben (0.015 g) were mixed and heated to the boiling point as the oil phase. Aloe vera powder (0.5 g) mixed with 70 mL deionized water was added to a mixture of propylene glycol.
(7 g), sodium lauryl sulfate (3 g), and methylparaben (0.025 g). The mixture was heated as the aqueous phase. These two separate phases were mixed continuously while being cooled. Thus, after cooling, the uniform cream that was produced was placed in an aluminum package similar to a placebo tube, weighing 50 g. The cream contained Aloe vera gel powder 0.5%. Placebo creams were prepared according to similar protocol without aloe powder. Our experimental research and formulations were carried out under sterile conditions. The final creams were tested for any probable contamination microbes, which were not detected during the applications.[19]

**Study Procedure**

In this study, 30 patients were randomized into three groups. Aloe Vera group; 10 patients applied Aloe Vera cream (3 g of aloe cream to the wounds outside) immediately after surgery and 12 hours after haemorrhoidectomy. Patients were discharged from the hospital 24 hours after surgery. Patients were instructed to apply the cream with the tip of the index finger to the wounds three times daily. This treatment was continued on the surgery site 3 times a day up to 28 days postoperatively.[19]

**Transcutaneous Electrical Nerve Stimulation (TENS) group:** consisted of 10 patients who received TENS from a pocket stimulator (Han Acutens, WQ1002F, Beijing, China) was given two times per day. The stimulation was pulse-waved with frequency alternating between 2 and 100 Hz, 300 μ sec pulse duration and 30 - minute stimulation duration. The intensity was adjusted until rhythmic flexion of thumb and index finger was obtained without producing pain, usually at 20 to 30 mA. Two electrodes, were applied to the skin areas on the dorsal web between the first and the second metacarpal bones (Hegu, Large Intestine meridian, 4th ampoint, negative electrode) and on the radial side 3 cm proximal to the wrist crease (Lieque, Lung meridan, 7th ampoint, positive electrode) of the same hand as shown in figure (1). Patients were discharged from the hospital 24 hours after surgery. Patients were instructed to apply TENS two times daily and continued up to 28 days postoperatively.[20]

Control group consisted of 10 patients who applied the same quantity of placebo cream in a similar fashion. In addition to sham TENS application

All patients were supplied with the same analgesic drugs as needed. The patients were followed up after discharge from the hospital. Postoperative pain was evaluated by using a visual analog scale (VAS)[21], which was scored as 0 (no pain) to 10 (very severe pain). Pain score were obtained immediately postoperatively and at days 14 and 28. On the same time the amount of analgesic requirements[22] was recorded in the two treatment groups and the control group.

**Statistical Analysis**

Data were analyzed using the ANOVA test and MANOVA, as appropriate, to compare patients' demographics, pain score, and analgesic drug use. P<0.05 was considered a significant difference. Statistical analysis performed using SPSS software (version 12, SPSS Inc., Chicago, IL).

**Results**

Thirty five patients enrolled into the study that all of them were female, 2 patients in the aloe vera group due to severe headache and three patients from the control group due to loss of follow up were excluded. At the end, thirty patients, 10 for each group entered the study. As shown in table 1, mean of age and grades of haemorrhoid in treatment groups and control group show no significant differences.

Post- haemorrhoidectomy pain was measured by visual analogue scale as stated earlier in the
material and method section have been reduced significantly either at 1st and 2nd week postoperatively in both treatment groups ( aloe vera group and TENS group) when compared with control group. More over aloe vera group showed a highly significant difference (p<0.05) when compared with TENS group either at 1st or 2nd week as shown in table 2.

An indirect measure of Post-haemorrhoidectomy pain is the measurement of Non-narcotic Analgesic Consumption. As shown in table 3 there was a significant decrease in Analgesic Consumption in both treatment groups when compared to control group(p<0.05), more over there was a significant decrease in Analgesic Consumption in aloe vera group when compared with TENS group.

**Table-1: Prevalence of Confounding Variable in both Treatment Groups and Control Group**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Groups</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± SD)</td>
<td>Aloe</td>
<td>TENS</td>
</tr>
<tr>
<td>Haemorrhoid Gr. III</td>
<td>34.1 ± 0.7</td>
<td>35.0 ± 0.5</td>
</tr>
<tr>
<td>Haemorrhoid Gr. IV</td>
<td>6</td>
<td>7</td>
</tr>
</tbody>
</table>

*p value > 0.05: Not significant

**Table-2: Postoperative Pain Scores in Aloe vera, TENS and Control Groups**

<table>
<thead>
<tr>
<th>Time</th>
<th>Groups</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Aloe</td>
<td>Control</td>
</tr>
<tr>
<td>Immediately postoperative</td>
<td>8.10±0.7</td>
<td>8.50±0.5</td>
</tr>
<tr>
<td>At the end of 1st week</td>
<td>2.70±0.6</td>
<td>6.10±0.7</td>
</tr>
<tr>
<td>At the end of 2nd week</td>
<td>1.00±0.3</td>
<td>3.70±0.9</td>
</tr>
</tbody>
</table>

X: Comparison between Aloe Group vs. Control Group; Y: Comparison between TENS Group vs. Control Group; Z: Comparison between TENS Group vs. Aloe Group; P value: >0.05 – Not Significant, <0.01 – Significant, <0.001 – Highly Significant

**Table-3: Post-haemorrhoidectomy Nonnarcotic Analgesic Consumption in Aloe, TENS and Control Groups during 2 Weeks after Discharge from Hospital**

<table>
<thead>
<tr>
<th>Time</th>
<th>Groups</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Aloe</td>
<td>Control</td>
</tr>
<tr>
<td>At the end of 2nd week</td>
<td>50.0</td>
<td>1500.0</td>
</tr>
</tbody>
</table>

X: Comparison between Aloe Group vs. Control Group; Y: Comparison between TENS Group vs. Control Group; Z: Comparison between TENS Group vs. Aloe Group; P value: >0.05 – Not Significant, <0.01 – Significant, <0.001 – Highly Significant

**Discussion**

The pain after haemorrhoidectomy has always been a major concern for both surgeons and the patients.[23] It is associated with hypertonia of internal sphincter[24], and the traditional therapy of lateral sphincterotomy has been effective in muscle relaxation and thus pain relief.[25] but it was found to be associated with fecal incontinence (up to 8-30%).[26,27] That why, the aim of the current study is to determine the best Medical alternatives by either using natural pharmacological agents like aloe vera or simple non-invasive inexpensive physiotherapeutic modality such as TENS.

Earlier studies[19,20] have proved that either TENS or Aloe vera was effective in reducing the post-haemorrhoidectomy pain but no studies have been made to detect what is the superior treatment modality. In our current study all confounding variable such as age, sex, degree of haemorrhoid and technique of haemorrhoidectomy was controlled and there was no significant difference between both treatment groups and control group.

Our current study revealed that there was no significant difference (p>0.05) between both treatment groups and control group on the amount of pain experienced post-haemorrhoidectomy measured by VAS which mean that any reduction will be due to the application of either TENS or aloe vera cream.

The current study revealed that aloe vera cream was highly effective in reducing post-haemorrhoidectomy pain either at the end of 1st or 2nd week (p<0.05) when compared with the control group. This results goes hand in hand with the result of Eshghi et al[19] who studied the effect of aloe vera cream on the reduction of pain and enhancement of wound healing on forty nine patients undergoing haemorrhoidectomy and found that Application of Aloe vera cream on the surgical site is effective in reducing postoperative pain both on resting and during defecation, healing time, and analgesic requirements in the patients compared with the placebo group.

Similarly TENS application on acupuncture point was effective in reducing post-haemorrhoidectomy pain either at the end of 1st or 2nd week (p<0.05) when compared with the control group. This results goes hand in hand with
the result of Chiu et all[20] who studied the effect of application of TENS on acupuncture point on reducing post-haemorrhoidectomy pain and found that, TENS is effective for pain relief in patients receiving haemorrhoidectomy. Its efficacy and safety could assist outpatient pain management after haemorrhoidectomy.

On the other hand, our study revealed that aloe vera cream was more superior than TENS application on acupuncture point (p<0.05) and this results was documented by a significant reduction in the analgesic consumption in aloe vera group when compared with either TENS or control group. The superior efficacy might be due to the ability of aloe vera cream in enhancing wound healing, decreasing inflammation and edema[18] which are considered as a primal factors in post-haemorrhoidectomy pain.

**Conclusion**

The result of the current study have showed that aloe vera cream is more superior to TENS application in reducing post- haemorrhoidectomy pain and decreasing analgesic consumption.

**ACKNOWLEDGEMENT**

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