CURRENT TREATMENT OF CHRONIC ANAL FISSURE.

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Abstract

This is a prospective study to test the hypothesis that topical isosorbide dinitrate (Isordil) is the best first line of treatment of a chronic anal fissure. This study was done in the outpatient clinic of Sulaimani Teaching Hospital, Sulaimani, Iraq, from the 1st Dec. 2000 through 30th May 2002. There were 65 cases of chronic anal fissure treated with 0.5% Isordil ointment and reviewed at 2, 4, 6 and 12 weeks to assess the symptoms, side-effects, fissure healing and patient acceptance. The age range was 2-65 years with mean age of 31.2 years, and female:male was 1.4:1. At 12 weeks 80% of patients had no fissure. In 20% the treatment was unsuccessful. At 6 months follow-up there was 2.5% recurrence. The prevalence of headache was 46.1% on commencing treatment with 12.3% headache-related noncompliance. The cost of treatment with this new method was 12 ID for 8 weeks while it was 36 ID for the same period of traditional way of treatment. We conclude that medical sphincterotomy with 0.5% Isordil ointment is a feasible, cost-effective method of treatment of chronic anal fissure with high patient acceptance and satisfaction.

Introduction

Anal fissure is a common condition, especially in young adults. It is a longitudinal tear in the distal anoderm caused by hard stool leading to severe pain and some bleeding. Chronic fissures are associated with high intrarectal pressure caused by overactivity of internal anal sphincter. The cause of the overactivity is not known but the high pressure appears to prevents sufficient blood reaching the fissure and inhibits healing. Isosorbide dinitrate is nitric oxide donor which contribute to internal anal sphincter relaxation via a non-adrenergic non-cholinergic pathway and mediating vasodilation. The aims of this prospective study are to elucidate the characteristics of our patients with fissure in ano, the effectiveness of medical sphincterotomy in our locality, to compare these results with traditional treatment, to assess the patients’ satisfaction and evaluate the cost–effectiveness of this method.
Material & Methods
Sixty five consecutive patients who attended Surgical Outpatient Clinic at STH, from Dec. 1st 2000 to May 30th 2002, were included. Chronicity was determined by a history longer than 6 weeks and/or the presence on examination of a sentinel pile or white muscle fibers at the base of the fissure. At presentation, a pain score from 0-10 was established. Zero represented no pain and 10 the worst pain that they experience. Data were collected about age, sex, occupation, smoking, presentation, duration of the illness and physical signs. The patients were started on a course of 0.5% Isordil ointment which was applied digitally peri- and intra-anally twice daily initially for 4 weeks. All patients were reviewed at 2, 4, 6 and 12 weeks. At each review, patients were assessed for the amount of pain at defecation, fissure healing, complications, compliance and the cost of therapy. International classification of function was used for assessment of patient satisfaction. Regarding the cost; t-test was used for the assessment of significance.

Coding          | Qualifying words
----------------|-----------------|
0-4%             | 0 no facilitation
5-24%            | +1 mild facilitation
25-49%           | +2 moderate facilitation
50-95%           | +3 substantial facilitation
96-100%          | +4 complete facilitation

Table I: the positive scale that denotes the extent to which an agent acts as a facilitater.

Results
Patient’s characteristics were as follows:

Age distribution
The age varies between 2-67 years with the mean age of 31.2 years (Figure 1).

Sex distribution
There was 38 female and 27 male with female to male ratio of 1.4:1 (Figure 2).

Occupation
Table II shows the various occupations of patients in this study while table III shows their characteristics.

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular office job</td>
<td>10</td>
<td>9</td>
</tr>
<tr>
<td>Free job</td>
<td>-</td>
<td>17</td>
</tr>
<tr>
<td>House wives/ Worker</td>
<td>26(H)</td>
<td>1(W)</td>
</tr>
<tr>
<td>Pupil/ students</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Children</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

Table II: Occupations of patients.

The mean pain score at presentation was 6 (range 2-8). The mean pain score at 2-weeks follow up was 4 with 13/65 patients (20%) experiencing no pain. At 4 weeks it was 40/65 patients (66.6%), at 6 weeks 50/65 patients (76.9%) and at 12 weeks 52/65 (80%) were pain free.

Healing rate
This is shown below in table IV.

<table>
<thead>
<tr>
<th>time of healing (weeks)</th>
<th>No. of cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>37</td>
<td>56.9</td>
</tr>
<tr>
<td>6</td>
<td>13</td>
<td>76.9</td>
</tr>
<tr>
<td>12</td>
<td>2</td>
<td>80</td>
</tr>
</tbody>
</table>

Table IV

In thirteen patients (20%), treatment with 0.5% Isordil ointment failed. Of these, 10 were not compliant and 3 did not respond.
to treatment. Of the non-compliant patients, 8 stopped treatment because of severe headaches while 2 developed severe annoying peri-anal irritation and itching. At 6 months follow-up, 2 patients who were successfully treated initially developed fissure in ano with a recurrence rate of 2.5%. Thirty out of 65 patients (46.1%) experienced headache on commencing treatment. Eight patients (12.3%) stopped treatment due to severe headache. Fifty-five out of 65 patients (84.8%) were compliant with the treatment.

The cost of a 4-week treatment course with 30 gm.s of 0.5% Isordil ointments was 6 ID while an equivalent course of traditional, locally applied xylocaine-containing ointment would be 18 ID. No cases were submitted to surgery in this study. Table V shows the mean and standard deviations of the methods studied regarding the cost of treatment, where cost 1 is related to the new treatment and cost 2 to the traditional treatment.

<table>
<thead>
<tr>
<th></th>
<th>Cost1</th>
<th>Cost 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Average</td>
<td>7.33846</td>
<td>22.0154</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>1.59371</td>
<td>4.78112</td>
</tr>
</tbody>
</table>

Table V

The computed P-value of the cost was less than 0.05, indicating significant difference in the cost between the two methods of treatment.

**Discussion**

Chronic anal fissure is a common condition\(^1\). It generally occurs during the meridian of life and more common in female\(^5\), which is in agreement with our study as shown in figures 1 and 2. It is uncommon in the elderly because of anal muscular atony\(^5\) which also supported in this study (3% were over 65 years). Two third of the cases in this study were house-wives or males with free jobs while 1/3 of the cases were patients with regular office jobs which might be attributed to the life-style of the former group of patients with regular outdoor work and activities. We expected that smokers are more liable for chronic anal fissure because of the habit of smoking in the toilets, but the majority of patients in this study (61 cases) were non-smokers. We do not know the exact relation or explanation. The presence of pain, constipation and bleeding were more common in this study than elsewhere\(^6\). The majority of the fissures in this study (87.7%) were posterior just like some other studies\(^7\) which is attributed to less blood supply to this site as the terminal branches of the inferior rectal artery are sparsely distributed to the posterior commissure\(^7\) and the increased internal sphincter tone in patients with a fissure reduces ano-dermal blood flow at posterior midline\(^6\). This study shows that 0.5% Isordil ointment applied locally to the lower anal canal is effective in treating 80% of chronic anal fissures which would otherwise require operation\(^9\). In contrast with surgical sphincterotomy, “chemical sphincterotomy” with Isordil is reversible and therefore unlikely to have long-term adverse effects on continence\(^9\). Local application of Isordil ointment reduces the pressure at rest in the anal canal and increase ano-dermal blood circulation leading to healing of chronic anal fissure\(^10\). An initial reduction in pain score at 2 weeks was observed in 20% of cases which increased to 2/3 of the cases at 4 weeks, a figure comparable to other studies\(^9\). The healing rate was 80% at 12 weeks which is higher than what is generally
reported worldwide\(^\text{11}\). We saw minimal differences in the findings at 6 and 12 week follow up and symptom scores were nearly identical. It would appear that compliant patients that respond to treatment do so within 6 weeks or probably not at all. This suggests that failure to respond to topical Isordil at 6 weeks may be an indication for an alternative therapeutic approach. This finding was also observed in other studies\(^\text{11}\). Recurrence of fissure after 6 months follow up was 3.07 % (2 cases), which was less than other reports\(^\text{9,12}\). The incidence of headache was 46% (30/65), but only 8 patients (12%) stopped treatment due to severity of headache, again less than other reports\(^\text{6,9,11}\). In this study 8/65 cases stopped treatment because of complications of the treatment and patients’ acceptance was 88% while the patients’ satisfaction rate was 80% as 20% of the cases were dissatisfied with this treatment which is comparable to other reports\(^\text{9}\). Chronic anal fissure does not usually respond to the traditional locally applied ointments, and for that reason, it was previously treated by surgery\(^\text{13}\). If the traditionally used ointment were used for comparable periods to this new treatment, their cost is still higher as statistical analysis revealed significant difference in the cost of treatment amongst the two methods (the P-value = < 0.05). We conclude that medical sphincterotomy is effective treatment for chronic anal fissure in our locality. It has the advantage over surgical treatment of avoiding long term complications, notably incontinence, and is more cost-effective than the traditional conservative treatment. It also has high patient acceptance and satisfaction.

**Acknowledgement:**

I am greatly thankful for Mr. Nizar A. Ali (M.Sc. Statistics) for his great help. I am very thankful for Miss Awring M. A. from the Secretary of Higher Education for her great help.

<table>
<thead>
<tr>
<th>Presentation</th>
<th>Smoking</th>
<th>Duration of Illness (Weeks)</th>
<th>Site</th>
<th>Duration of Rx (weeks)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Yes</td>
<td>&lt;12</td>
<td>Ant. Post. Both</td>
<td>4</td>
</tr>
<tr>
<td>Const. Bleeding</td>
<td>No</td>
<td>&gt;12</td>
<td>Both</td>
<td>6</td>
</tr>
<tr>
<td>No. of cases</td>
<td>64</td>
<td>43</td>
<td>2</td>
<td>37</td>
</tr>
</tbody>
</table>

Table III shows the patient’s characteristics.

Bas J. Surg, September, 10, 2004
Figure 1 shows the age distribution in this study.

Figure 2 shows the sex distribution in this study.
References: