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ORIGINAL ARTICLE

Role of local antibiotics in the treatment of acute anal fissure.

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ABSTRACT… Objective: To assess the role of topical antibiotic (mertronidazole) in the treatment of acute anal fissure. **Study Design:** Randomized Control Trial. **Setting:** General Surgery Outpatient Department of Aziz Fatima Hospital. **Period:** January 2020 and March 2021. **Material & Method:** In this study, patients were divided into two groups randomly. Patients in Group 1 were given only 0.2% GTN ointment and those in Group 2 were given 0.2% GTN ointment and metronidazole cream. All patients' VAS scores for pain and healing of fissure by examining the peri anal area, as well as any adverse effects of the drugs, were recorded and statistically compared. Patients demographic characteristics, such as age and gender, were recorded. All patients were physically examined at the end of weeks 2, 4, and 6 of treatment. All statistical data analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 23.0. Descriptive statistics were used for comparisons. t test, and chi-square test were used to assess independent samples. A p-value <0.05 was accepted as statistically significant. **Results:** There were 46 (92%) female and 4 (08%) male patients in Group 1 and 48 (96%) female and 2 (24%) male patients in Group 2. The mean ages of the patients were 35.4 ± 3.7 years in Group 1 and 37.8 ± 4.2 years in Group 2. The mean VAS scores of the patients at the time of presentation to the hospital (pretreatment) were 7.2 ± 1.2 in Group 1 and 7.4 ± 0.9 in Group 2 ($p=0.058$). The mean VAS scores of the patients at the end of week 2 were 4.6 ± 0.8 in Group 1 and 4.2 ± 0.9 in Group 2 ($p=0.058$). The mean VAS scores of the patients at the end of week 4 were $3.2\pm$O.7 in Group 1 and 2.4 ± 0.8 in Group 2 ($p=0.00004$). The mean VAS scores of the patients at the end of week 6 were $2.36+0.65$ in Group 1 and 1.86 ± 0.48 in Group 2 ($p<0.00054$). In Group 1, 6(12%) patients had recovery at week 4 and 26 (32%) patients at week 6 with no recovery seen in 18(36%) patients. In Group 2, 9 (18%) patients had recovery at week 2 and 33(66%) patients at week 4 with no recovery seen in 8(16%) patients. There was a statistically significant difference between these data ($p=0.022$). **Conclusion:** We have observed that topical metronidazole along with other traditional management is an fruitful, easy-to-use, safe, rapid and secure option that helps in further reducing pain associated with anal fissure and increasing the healing rate. It is also effective in preventing the anal fissure to become chronic.

Key words: Acute Anal Fissure, Lateral Internal Sphincterotomy (LIS), Visual Analogue Scale (VAS).

INTRODUCTION

Anal fissure is one of the very common pathologies of the peri anal area that is frequently encountered in surgical practice.[1] It is a longitudinal tear of anal mucosa that is lined with stratified squamous epithelial tissue, distal to the dentate line and its usual position is in posterior midline (6 o clock) and anterior midline (12 o clock). Yet the exact cause of its pathogenesis is not clearly defined, the most probable factors responsible for the pathophysiology of anal fissure are its anatomical position and its structure such as tight anal sphincter. Other factors include internal anal sphincter spasm, compromised blood supply, certain infections and localized trauma due to passage of hard faecal matter, chronic constipation or diarrhoea.[2] Though there are certain drugs (nitroglycerin or diltiazem gels and botulinum injection locally) which are now being used in management of this disease, still almost 40% of patients would still need surgery for cure of their disease. Lateral internal sphincterotomy (LIS) is the most commonly done procedure for treatment of anal fissure and is considered as gold standard as it is safe and because it is believed to be safe, associated with fewer complications and it is easy to perform.

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However, certain studies relieve that LIS is associated with anal incontinence in 14% of the cases. That is the reason that the role of conservative management cannot be underestimated.[3] The American Society of Colon and Rectal Surgeons (ASCRS) favors conservative management of anal fissure with stool softeners, diet rich in fibers and sitz bath as the first line of treatment.[4] The main disadvantage of LIS is the possible complication of faecal incontinence or incontinence to flatus. That is why it is important to use alternative pharmacological means (chemical sphincterotomy) in the management of acute anal fissures.[5] It is identified that different types of microorganisms are found in base of acute anal fissure. Anaerobic organisms are present in almost half of cases of anal fissure.

We postulated that microbial colonization of anal fissures results in its delayed healing and aimed to determine whether reducing the bacterial load with topical antibacterial medicines helps in accelerating the healing of anal fissure.[6]

MATERIAL & METHODS

This was a randomized control trial conducted on 100 consecutive patients who presented to the general surgery outpatient department of Aziz Fatima Hospital between January 2020 and March 2021 and were diagnosed with acute anal fissure. Patients were divided into two groups of 50 patients each randomly by choosing a color-coded card in envelopes. Patients received the medication from an assistant staff nurse who noted the color of the cards. The researcher was blinded to the medicine administered to each patient. Patients in Group 1 were given only 0.2% GTN ointment and those in Group 2 were given 0.2% GTN ointment and metronidazole cream. The chief complaints of the patients at presentation were painful defecation, bleeding per rectum, constipation, diarrhea, and peri anal itching. The diagnosis of acute anal fissure was made based completely on clinical examination. The study included patients aged between 18 and 60 years who had their symptoms for less than 6 weeks, whose tears were confined to the epithelium, and who had pain in the anal region together with tear in the posterior or anterior anoderm without any external skin tags. Patients with fistula in ano, perianal abscess, associated inflammatory bowel disease, and receiving oral immunosuppressive drugs or steroids; with a history of hemorrhoids or hemorrhoidectomy; with a co morbid disease, such as ischemic heart disease, hypertension, chronic obstructive pulmonary disease, and diabetes mellitus and who were pregnant were excluded from the study. All patients underwent detailed medical history and physical examination before treatment was started. All patients were advised to locally apply a pea-sized amount of each drug I to their anal margin 3 times per day for 6 weeks. A diet rich in fiber was recommended to patients. Stool softeners were prescribed and patients were advised to take sitz bath three times a day.

Patients demographic data, such as age and gender, were inquired. All patients were physically examined at the end 2nd, 4th, and 6th weeks of treatment. Visual Analogue Scale (VAS) was used to record the pain during defecation. If the patient's symptoms were settled and there was complete epithelization of their anal mucosa with absence of tear and no redness or inflammation of the surrounding skin, it was considered as clinically healed fissure. The VAS score was used to measure pain. The VAS was divided into 10 equal parts, where 0 represented no pain and 10 represented unbearable pain. VAS scores of every patient for pain and healing of fissure by inspection of perianal area, as well as side effects of the drugs, were recorded and statistically compared.

The study protocol was approved by the local ethics committee (DME/843-20). Written informed consent was obtained from all patients. All statistical data analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 23.0. Descriptive statistics were used for comparisons. t test, and chi-square test were used to assess independent samples. A p-value <0.05 was accepted as statistically significant.

RESULTS

There were 46 (92%) female and 4 (08%) male

patients in Group 1 and 48 (96%) female and 2 (24%) male patients in Group 2. The mean ages of the patients were 35.4±3.7 years in Group 1 and 37.8±4.2 years in Group 2. Most common complaint of the patients was painful daefecation, followed by constipation and bleeding per rectum.

Table-I shows the frequencies and percentages of presenting symptoms of patients in both the groups. Table-II shows the mean duration of symptoms of patients. All patients completed their course without any adverse affects.

Symptoms	Group 1 (n=50)	Group 2 (n=50)
Pain during defecation	50 (100)	50 (100)
Bleeding	38 (76)	41(82)
Constipation	40 (80)	38(76)
Diarrhea	3(6)	1(2)
Itching	22 (44)	20 (40)

Table-I. Frequencies and percentages of symptoms

Duration of Symptoms	Group 1 Mean	Group II Mean
Pain during defecation (days)	17.68 +7.99	20.12+8.69
Bleeding (days)	10.73+4.60	12.95+6.06
Constipation (days)	21.47+6.77	21.07+6.67
Diarrhea (days)	12.33+5.11	7+0
Itching (days)	12.72+ 4.75	13.2+6.28

Table-II. Mean duration of symptoms of patients.

The mean VAS scores of the patients at the time of presentation to the hospital (pretreatment) were 7.2±1.2 in Group 1 and 7.4±0.9 in Group 2 (p=0.058). The mean VAS scores of the patients at the end of week 2 were 4.6±0.8 in Group 1 and 4.2±0.9 in Group 2 (p=0.058). The mean VAS scores of the patients at the end of week 4 were 3.2±O.7 in Group 1 and 2.4±0.8 in Group 2 (p=0.00004). The mean VAS scores of the patients at the end of week 6 were 2.36+0.65 in Group 1 and 1.86±0.48 in Group 2 (p<0.00054).

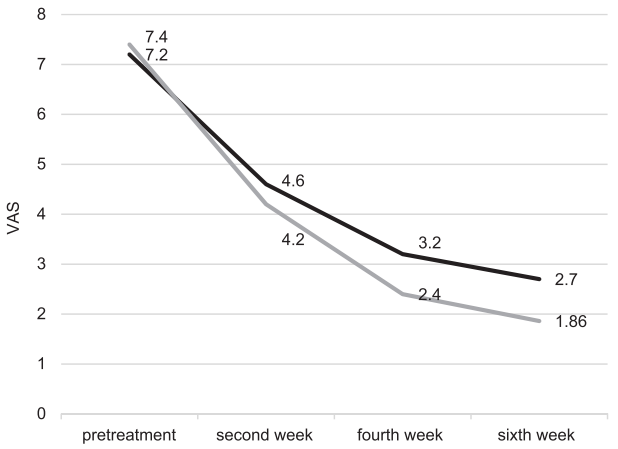

Figure-1. Pain score pretreatment, after 2nd, 4th and 6th week of treatment

In Group 1, 6(12%) patients had recovery at 4th week and 26 (32%) patients at 6th week with no recovery seen in 18(36%) patients. In Group 2, 9 (18%) patients had recovery at 4th week and 33(66%) patients at week 6th week with no recovery seen in 8(16%) patients. There was a statistically significant difference between these data (p=0.022).

DISCUSSION

Acute anal fissure is very common disease and it is associated with great discomfort and equally affects both women and men.

Most probably, the reason behind increased no of female patients in our study is that the surgeon who did peri anal examination and who treated the patient was a female. In our society, there are social and cultural limitations for female patients and they feel embarrassed to get examination of peri anal area by male surgeon. And usual attitude of people is towards conservative management. That's why most of females prefer female surgeon. The most common age of presentation in patients with anal fissure is 20-40 years. We observed that mostly patients were in 30 to 40 years of age which co relates with findings of other studies.[3]

The typical symptoms at presentation in acute anal fissure are painful defecation and bleeding per rectum. Pain is usually sharp and aggravated during defecation. Bleeding may or may not be present with painful defecation. Rectal bleeding

is bright red in color and usually occurs in small quantity. The chief complaints of our patients were pain during and after defecation, per rectal bleeding, and constipation. These data is compatible with those in the literature.[7] In the present study, we observed that combination of local metronidazole and 0.2 % nitroglycerine ointment for acute anal fissure resulted in a significant relief of symptoms especially pain score after 2 weeks of treatment. The tear occurring at the anal mucosa causes spasm of the internal sphincter and increases resting pressures of the anal canal, leading to increased pain and decrease blood flow leading to relative ischemia. As a result, pain, spasm, and ischemia altogether converts the tear into a wound that is difficult to heal, leading to chronic anal fissure.[8]

A previous study showed that 40%–60% healing occurs with the use of local 0.2% GTN ointment in patients with acute anal fissure.[9] Our results were similar to these except that the healing rate was 64% in the group where 0.2% GTN ointment was used alone. Taking into consideration that almost half of patients have not recovered after the use of this treatment, it is important to eliminate other factors that are responsible for pathophysiology of the disease.[10] We think that one of these important factors is local inflammatory process and infection because of the regional microorganisms and bacteria that may be present in stools. According to one study, infection present in this area contributes to the etiology of this acute anal fissure.[11] Grekova et al. stated that those patients who had anaerobic bacteria in their swab test and subsequently treated with topical metronidazole, their symptoms settled early and 95.6% had healing of their wound. These results are compatible with our study.[12]

CONCLUSION

Anal fissure has been managed both conservatively as well as surgically, an ideal treatment for acute anal fissure is still under consideration. We have observed that topical metronidazole along with other traditional management is an fruitful, easy-to-use, safe, rapid and secure option that helps in further reducing pain associated with anal fissure and increasing the healing rate. It is also effective in preventing the anal fissure to become chronic. it also save the patients from undergoing surgery that somehow is associated with complications. Local studies are not available regarding this aspect of the management. Further work is needed to reach some consensus.

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2	Khurram Saqib	Data analysis.	