NON SURGICAL TREATMENT OF FIRST DEGREE HEMORRHOIDS: TABLET DAFLON VERSUS INJECTION SCLEROTHERAPY

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ABSTRACT

Objective: To compare the therapeutic efficacy of tablet Daflon and injection Sclerotherapy in treatment of first degree hemorrhoids.

Design: Randomized control trial.

Place and Duration of Study: Outpatient department of Surgery, Combined Military Hospital (CMH) Rawalpindi from March 2008 to September 2009.

Patients and Methods: Sixty patients of first degree hemorrhoids with chief complaint of bleeding per rectum were randomized into two groups (30 patients in each group). Severity of bleeding per rectum was assessed by symptom score card. Bleeding episodes of more than five per week was considered as severe, three to five episodes as moderate while less than three per week was considered as mild. Patients in group A were started with tab Daflon 500 mg twice daily for four weeks[1]. Patients in group B were subjected to single peri-haemorrhoidal injection with 5% Almond oil in phenol. Patients were reviewed after four weeks and the outcome measure was reduction in episodes of bleeding per rectum.

Results: In group A, at presentation 24 patients had mild bleeding, 5 patients had moderate bleeding and 1 patient had severe bleeding. In group B 23 patients had mild bleeding, 5 patients had moderate bleeding and 2 patients had severe bleeding ($p \geq 0.05$). At 4 Weeks, 22 (73.3%) patients in Group A and 24 (80%) patients in group B achieved symptomatic relief from bleeding ($p \leq 0.05$). 6 (20%) patients in group A had mild bleeding at 4 weeks and 1 (3.3%) patient had moderate bleeding. No patient in group A had severe bleeding at 4 weeks. In group B 5 (16.7%) patients had mild bleeding at 4 weeks, 1 (3.3%) patient had moderate bleeding and 1 patient had severe bleeding ($p \leq 0.05$).

Conclusion: Tab daflon is a suitable alternative and effective non invasive treatment in controlling bleeding in first degree hemorrhoids when compared to injection sclerotherapy.

Keywords: Hemorrhoids, Sclerotherapy, Tablet daflon.

INTRODUCTION

Hemorrhoids are defined as a mass of dilated veins in the anorectum involving the venous plexus of the area. Haemorrhoidal disease is a common anorectal condition affecting 4% of the adult population[2]. Clinically they present as bleeding per rectum, mucous discharge, prolapse or painful defecation[3]. Hemorrhoids may be classified according to the degree of prolapse. First degree hemorrhoids bleed but do not prolapse. Second degree hemorrhoids prolapse on straining but reduce spontaneously. Third degree hemorrhoids prolapse on straining and require manual reduction. While fourth degree hemorrhoids are prolapsed or incarcerated[4].

There are many treatment options available depending on the degree of the haemorrhoidal disorder. Nevertheless, the best treatment is prevention; by avoiding constipation, intake of high fibre diet and administration of bulk laxatives. Local symptoms can be alleviated by some soothing creams and suppositories, but long term benefit is not often achieved[5]. A wide

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array of treatment modalities is available for first and second degree hemorrhoids like rubber band ligation, injection sclerotherapy (using 5% phenol in almond oil), photocoagulation and cryotherapy[6]. Although, there is consensus on the treatment for third and fourth degree hemorrhoids i.e. haemorrhoidectomy, there is a persistent confusion regarding the treatment options in first and second degree hemorrhoids[7].

Injections sclerotherapy is well suited treatment for first and second degree hemorrhoids. It can be carried on outdoor basis and no special after treatment is required. However, injection sclerotherapy is not flawless and has certain disadvantages. It is an operator skill dependent procedure, may cause bleeding and ulceration. While impotence and prostatitis are also known complications if injected at wrong site[8].

Daflon is a flavonoid vasoprotector venotonic agent whose active component is micronized flavonidic fraction that contains 90% diosmin and 10% hesperidin[9]. Bensandein in 1997 introduced Daflon in France. It is a phlebotrophic agent that increases the duration of contraction of veins, decreases production of prostaglandins responsible for inflammatory process and increase lymphatic drainage. Side effects include mild gastrointestinal discomforts[10].

In our clinical setup, surgeons come across patients with symptomatic internal hemorrhoids on daily basis. They mostly turn up with second or third degree hemorrhoids but there also are a considerable proportion of patients who present with first degree. In these first degree patients Daflon and sclerotherapy are useful. Tab Daflon avoids a surgical procedure and is free from serious complications. Purpose of our study was to compare the therapeutic efficacy of Daflon and injection sclerotherapy in terms of reduction in bleeding per rectum.

MATERIAL AND METHODS

Study was carried out in the outpatient department of General Surgery, Combined Military Hospital Rawalpindi, from March 2008 to September 2009. A total of 60 consecutive patients were included in the study keeping p=4% and using formula $n=z^2\ pq/\ e^2$, keeping error at 5% for a 95% confidence interval study. After taking informed written consent patients were randomly assigned into two groups of 30 each. All clinically diagnosed cases of first degree hemorrhoids according to Goligher's classification and above 18 years of age of both sexes was included in the study. Severity of bleeding was labelled as mild, moderate and severe on the basis of episodes of bleeding per week. Bleeding episodes of less than three was considered mild, between three to five moderate and more than five severe. Known patients of Inflammatory Bowel disease, chronic liver disease and patients with bleeding disorders, pregnant and lactating ladies, patients with previous history of haemorrhoidal surgery second degree, third degree, inflamed/thrombosed /bleeding hemorrhoids and those having colorectal carcinoma were not included in the study.

After detailed history and examination, diagnosis was objectively confirmed by anoproctoscopy. The severity of bleeding was assessed at the time of presentation by number of bleeding episodes per rectum per week and recorded, 30 patients were started with tab Daflon 500 mg twice daily. This group of patients was named as group A 30 patients were subjected to a single perihaemorrhoidal injection of 5% phenol in almond oil about 3-5 cc. This group was named as group B.

In group B (n=30), patients were briefed about the procedure and placed in left lateral position. No bowel preparation was done, 5% phenol in almond oil was taken in a disposable syringe with 20 gauge spinal needle and a well lubricated proctoscope was inserted gently into the rectum. Obturator was removed and

proctoscope slowly withdrawn till the pedicle of the haemorrhoid to be injected became visible. Needle of the syringe was inserted into the sub mucosal plane of the pedicle above the dentate line. Suction with the needle was done to rule out any possibility of intravascular injection. After confirmation of proper placement of needle in sub mucosal plane, 3-5 ml of the solution was injected into each pile in a single setting. No more than 2 hemorrhoids were injected at a time. All patients were treated on an outpatient basis. They were assessed after 04 weeks for severity of bleed and other symptoms.

The data analysis was done using SPSS 11. Mean and standard deviation were calculated for qualitative variable i.e, age. Frequency and percentage were calculated for qualitative variables i.e., gender and severity of bleeding per rectum. Chi square test was applied as a test of significance to compare the therapeutic efficacy of tab Daflon and injection sclerotherapy in terms of mild, moderate and severe bleeding per rectum and $p < 0.05$ was considered significant.

RESULTS

A total of 60 consecutive patients were randomly assigned into two groups of 30 each. In group A mean age was 45.07 ± 13.56 yrs the range being 23-65. In Group B mean age was 37.9 ± 12.81yrs the range being 21-69 years. There were 2 females in group A and 4 in group B ($p \geq 0.05$). Comparison of grouped variables like duration of symptoms, bleeding per rectum and number of hemorrhoids didn't show any statistically significant difference between the two groups ($p \geq 0.05$) (Table 1).

In group A, at presentation 24 patients had mild bleeding, 5 patients had moderate bleeding and 1 patient had severe bleeding. In group B 23 patients had mild bleeding, 5 patients had moderate bleeding and 2 patients had severe bleeding ($p \geq 0.05$).

Table-1: Frequency and percentage of grouped variables for hemorrhoids.

Grouped variable	Value	Group		*p*-value
		'A' (n=30)	'B' (n=30)	
Bleeding PR as presenting complaint	Bleeding PR	26 (86.6%)	27 (90.0%)	(>0.05)
Duration	< 6 Months	20 (66.7%)	16 (53.3%)	(>0.05)
	6-12 Months	7 (23.2%)	10 (33.3%)	
	> 12 Months	3 (10.0%)	4 (13.3%)	
No of hemorrhoids	One	16 (53.3%)	12 (40.0%)	(>0.05)
	Two	11 (36.7%)	14 (46.7%)	
	Three	3(10%)	4 (13.3%)	
	Yes	2(6.7%)	3 (10%)	

Note: Percentage is within group. 'A' → Tab Daflon , 'B' → Injection sclerotherapy

At 04 weeks 22 (73.3%) patients in group A and 24 (80%) patients in group 'B' achieved symptomatic relief from bleeding ($p \leq 0.05$)[6]. (20%) patients in group A had mild bleeding at 04 weeks and 1 (3.3%) patient had moderate bleeding. No patient in group A had severe bleeding at 04 weeks. In group B 5 (16.7%) patients had mild bleeding at 04 weeks, 1 (3.3%) patient had moderate bleeding and 1patients had severe bleeding ($p \leq 0.05$).

DISCUSSION

Hemorrhoids are one of the most common complaints affecting in (various forms) almost up to 50% of people over the age of fifty[11]. Studies into the aetiology and incidence of hemorrhoids in Pakistan are lacking, but they are believed to be due to an underlying genetic predisposition. Toilet habits, chronic constipation and a westernized diet are believed to be common contributing factors.

The symptoms include bleeding, prolapsing tissue, fullness after defecation and pain.

Bleeding can mimic or mask the diagnosis of cancer and must be thoroughly evaluated. In most cases however swift, simple, and effective treatment can be given in an outpatient clinic or a health centre[12]. The key point in understanding the feasibility of outpatient treatment is that there are no sensory nerve fibres above the dentate (pectinate) line in the anus, which is at the squamomucosal junction. Internal hemorrhoids arise above this line, so they can be treated without an anaesthetic. External hemorrhoids develop below the dentate line and are exquisitely sensitive.

The treatment options available for internal hemorrhoids include Injection Sclerotherapy, Infrared Coagulation, radiofrequency coagulation, direct current coagulation, rubber band ligation, cryosurgery, scalpel surgery and laser surgery[13]. But the choice of treatment depends upon the degree of haemorrhoid. Though majority of the surgeons consider surgery to be the mainstay of treatment for second and third degree hemorrhoids but there is difference of opinion on treatment of first degree hemorrhoids.

Daflon mainly acts as an anti inflammatory drug. It causes contraction of dilated venous plexus and local lymphatics[14]. It also acts by decreasing the synthesis of PGE 2 and Thromboxane B 2 thus reducing the capillary hyperpermiability and fragility. It is generally used in treatment of acute bleeding hemorrhoids and in patients with venous insufficiency. It has also been advocated for use in first degree hemorrhoids[6].

Injection sclerotherapy is an older method of treating hemorrhoids non-surgically. It is very effective and a less tedious procedure but is not free from complications which can be serious sometimes. Rare complications reported were liver abscess[15], life threatening retroperitoneal sepsis[16], and necrotizing fasciitis of the perineal region[17]. Phenol induced chemical hepatitis from injection sclerotherapy has been reported by Suppiah[18]. In a survey conducted by Al-Ghnaniem and his colleagues in UK, among the complications associated with injection sclerotherapy, 82% were urological[19]. Despite all these associated complications, injection sclerotherapy, because of its ease of use and effectiveness, is the widely used nonsurgical method of treating hemorrhoids. Fortunately, in our study none of such complication occurred.

Our study encompassed a population from various walks of life. The findings demonstrate a significant decrease in bleeding symptoms after a two-week course of treatment. We found that injection sclerotherapy and tablet Daflon to be equally effective in treating first degree hemorrhoids. Previous reports have confirmed the efficacy of oral diosmin (Daflon; Les Laboratories Servier, Orleans, France), in the treatment of first degree hemorrhoids[6,8]. In our study the side effects were trivial and were averted by taking the tablets after meals. Advantage is lack of Daflon interaction with anticoagulant drugs such as warfarin. This study included a patient who had Behcet's disease and was on warfarin; his haemorrhoidal symptoms were controlled with a month's course of Daflon, which averted surgery with all its attendant risks.

In a study carried out at the Department of Surgery, Liaquat University Hospital Jamshoro/Hyderabad and Sindh Employees Social Security Institute (SESSI) Hospital Kotri concluded that diosmin improves haemorrhoidal symptoms significantly for sufficient time so patients should initially be treated with diosmin[8]. A study conducted at Sir Ganga Ram Hospital Lahore, concluded that in the present day, both Injection sclerotherapy and Daflon can be recommended for the treatment of 1st and 2nd degree hemorrhoids as the results were almost equivocal[6]. Though the Injection sclerotherapy is operator dependant and may be associated with complications while Daflon is more safe to use and can achieve equally good results provided there is patient compliance, as it has to be taken over long period and is still considered expensive for use among our average population.

As the long-term effect of Daflon treatment was not addressed in this study, it would be sensible to have long-term follow-up for patients in this study to see if symptoms recurred and how long after the initial treatment, and the percentage of the study patients who eventually come to surgery.

CONCLUSION

This study highlights the value of Daflon in treating haemorrhoidal symptoms in patients attending the surgical clinic. Tablet Daflon is a suitable alternative and effective non invasive treatment in controlling bleeding in first degree hemorrhoids when compared to injection sclerotherapy.

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