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RESEARCH ARTICLE

A COMPARATIVE INTERVENTIONAL STUDY OF DOPPLER GUIDED HAEMORRHOIDAL ARTERY LIGATION WITH MUCOPEXY VS OPEN HAEMORRHOIDECTOMY IN THE MANAGEMENT OF GRADE II AND GRADE III HAEMORRHOIDS

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ABSTRACT

The study was aimed at studying the comparisonbetween Doppler guided haemorrhoidal artery ligation with mucopexy vs open haemorrhoidectomy in the management of grade ii and grade iii haemorrhoids. This study was conducted in the Department of General surgery, ESI-PGIMSR, over a period of 17months. One hundred patients diagnosed with grade II and III haemorrhoids were enrolled in the study. They were randomized in to two groups A and B. Group A undergone Doppler Guided Haemorrhoidal Artery Ligation and Group B Open haemorrhoidectomy. The mean age in group A was 38.82±9.08 and in group B was 38.80±8.89 (P=0.28). In group A, there were 17 males and 33 females and in group B, 18 males and 32 females (P = 0.83). The most common symptom in both groups was per-rectal bleeding with prolapsed haemorrhoids, followed by bleeding alone. In group A, 26 patients had grade II (52%) and 24 patients had grade III (48%) haemorrhoids and in group B, 32 patients had grade II (64%) and 18 patients had grade III (36%) haemorrhoids, so there was no statistical significance between the two groups (P=0.22). During the surgery and the early postoperative period complications were monitored in both the groups with regard to intra operative bleeding, postoperative pain, and urine retention, day of discharge and work resume time. The per-operative bleeding was monitored for both groups. In group A, 10 patients had intraoperative bleeding and ceased conservatively and in group B, 30 patients had bleeding that was controlled with simple ligature or cautery (P<0.001). The present study concludes that: The Doppler Guided Haemorrhoidal Artery Ligation and Mucopexy in comparison with Open Haemorrhoidectomy in the management of Grade II and III haemorrhoids has Low rate of immediate post-operative complications and Faster recovery with early return to work.

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INTRODUCTION

The word 'haemorrhoides' is a Greek word, 'haem'-blood, 'rhoos'- flowing, meaning flowing of blood. The word 'piles' comes from Latin word denoting a pill or ball. To be accurate, to be called as 'piles' when patient complains of swelling and called as 'haemorrhoids' when patient complains of bleeding. There has been long search for the best method of treatment for haemorrhoids (Keighley and Williams, 2008). A wide variety of techniques, are currently available for the surgical management of haemorrhoids. Under these circumstances, factors like associated morbidity, postoperative pain and complication, hospital stay and work resume time should be taken into consideration in choosing a method of treatment.

Aim of the study: The aim of the study is to compare Doppler Guided Haemorrhoidal Artery Ligation with mucopexy and Open Haemorrhoidectomy in the management of grade II and grade III haemorrhoids with regard to Postoperative pain as a primary objective. Intra operative bleeding, Postoperative retention of urine, Day of discharge, Time of return to work, as secondary objectives.

MATERIALS AND METHODS

The study was conducted as a clinical trial at ESIC medical college and PGIMSR, Chennai -78, during the period between November2014 to March 2016. The Patients diagnosed to have haemorrhoids attending the Surgery Outpatient Department (OPD) of ESIC Medical College and Hospital. Diagnosis was based on history, clinical examination and Proctoscopy. The inclusion criteria were Patients in the age group of 20 to 65 years, Patients with Grade II and Grade III haemorrhoids with bleeding per rectum and both genders. Patients with the following associated conditions were excluded from the study: Associated anal pathology – Fistula in ano, Fissure in ano, Associated bleeding disorder, Recurrent Hemorrhoids and

Pregnant women. With the above mentioned selection and exclusion criteria, the appropriate Sample was drawn from the population. In this comparative Interventional trial- Parallel Study Design involving two groups, Sample size was calculated to be 100, with 50 patients in each group. Total 100 patients with haemorrhoids attending Surgical Out Patient Department were enrolled in the study. Odd numbered patients starting 1,3,5,…99 were assigned to group A, who received treatment of Doppler Guided Haemorrhoidal Artery Ligation with mucopexyand the remaining even numbered patients starting from 2,4,6,…100 were assigned to group B who underwent Open haemorrhoidectomy. After diagnosing, patients were assigned to undergo Doppler Guided Haemorrhoidal Artery Ligation with Mucopexy or Open Haemorrhoidectomy in a 1:1 ratio by alternate allocation, odd numbered patients named as GROUP A underwent Doppler Guided Haemorrhoidal Artery Ligation with Mucopexy and even numbered patients named as GROUP B underwent Open Haemorrhoidectomy procedure after taking informed consent. Patients in two groups underwent clinical examination, per rectal digital examination, proctoscopy examination, Ultrasonography (USG) Abdomen and Sigmoidoscopy, Preoperative anaesthetic assessment was done in all the patients. Patients in both the groups had same preoperative preparation. In both the group surgery was performed under spinal anaesthesia in lithotomy position. In present study Doppler guided haemorrhoidal artery ligation with mucopexy was compared with open haemorrhoidectomy in terms of Postoperative pain, Intra operative bleeding, Postoperative retention of urine, Day of discharge, Return to work (work resume time). Every patient was supplied with a pain score chart. They were instructed to mark the level of the pain daily. These charts were graded from 0 to 10 and marked at one end- 0 (no pain) and at the other end -10 (worst pain). 1-3(mild pain), 4-7 (moderate pain), 8-10 (severe pain). Work resume time was defined as the time required by the patients for symptomatic pain relief and to resume Daily routine work. It was calculated in weeks. All the patients were assessed during postoperative period. They were followed up for 2 months. The subjects underwent clinical examination including a digital rectal and proctoscopy examination. The post-operative parameters after discharge of patients were assessed by the questionnaire filled by patient at the time of follow-up.

DISCUSSION

The analysis of this study, between the two groups was done and the results were compared with the literature for establishing its significance. Starting from the primary objective of Postoperative pain to the secondary objectives of Intra- operative bleeding, Post-operative urinary retention, Day of discharge and Work resume time were discussed in a detailed manner. One hundred patients diagnosed with grade II and III haemorrhoids were enrolled in the study. They were randomized in to two groups A and B. Group A undergone Doppler Guided Haemorrhoidal Artery Ligation and Group B Open haemorrhoidectomy. The mean age in group A was 38.82±9.08 and in group B was 38.80±8.89 (P=0.28). In group A, there were 17 males and 33 females and in group B, 18 males and 32 females (P = 0.83). The most common symptom in both groups was per-rectal bleeding with prolapsed haemorrhoids, followed by bleeding alone. In group A, 26 patients had grade II (52%) and 24 patients had grade III (48%) haemorrhoids and in group B, 32 patients had grade II (64%) and 18 patients had grade III (36%) haemorrhoids, so there was no statistical significance between the two groups (P=0.22). During the surgery and the early postoperative period complications were monitored in both the groups with regard to intra operative bleeding, postoperative pain, and urine retention, day of discharge and work resume time. The per-operative bleeding was monitored for both groups. In group A, 10 patients had intraoperative bleeding and ceased conservatively and in group B, 30 patients had bleeding that was controlled with simple ligature or cautery (P<0.001). The Visual analogue scale (VAS) was used for postoperative pain assessment (0 to 10). The mean score in group A was 1.82±0.64 and group B was 4.26±2.86 (P=0.0001). According to the Visual analogue scale (VAS), we divided patients into four groups: no pain, mild pain, moderate pain and severe pain. The urinary retention during immediate postoperative period on the day of surgery was monitored. In group A, 3 patients had urinary retention (6%) and in group B, 13 patients had urinary retention (26%) with P value of 0.01. The day of discharge after the surgery denotes the number of hospitalization days necessary for immediate postoperative care. In group A, the mean day of discharge was 1.8±0.75 days and that of in group B was 2.5±0.95 (P=0.0001) with 95% confidence interval of -1.121 to -0.439. Among the two groups 62% (n=31) of patients in the group A resumed their work and normal activities by the end of first week and 72% (n=36) of the patients in the group B resumed their work at the end of second and third week. The statistical significance on comparing the two groups is p value of < 0.001. The study population was followed up for a period of two months. The pain and bleeding history during the follow up period was obtained from the population. At the end of first month, in Group A 14% (n=7) patients had history of pain and 16% (n=8) patients had residual bleeding with p value of less than 0.005. Whereas in Group B 56% (n=28) of patients had pain and 44% (n=22) patients had residual bleeding. In the present study, the 20% of the patients treated with Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) had intra operative bleeding. In various other studies the incidence of intra operative bleeding (Ratto *et al.,* 2010; Greenberg *et al.,* 2006; Infantino *et al.,* 2010; Shabahang *et al.,* 2013; Gupta and Kalaskar, 2008) was ranging from 1% to 11%. as 4% in Gupta PJ et al, 1.2% in Ratto *et al.* (2010) 11% in Greenberg R et al, 1% in Shabahang *et al.* (2010) and 2.6% Infantino *et al.* (2010). In present study the incidence of intra operative bleeding complication was higher when compared to other studies, but is significantly low comparing with Open Haemorrhoidectomy.

In the present study the immediate postoperative pain (Ratto *et al.,* 2010; Giordano *et al.,* 2009; Dal Monte *et al.,* 2007; Greenberg *et al.,* 2006; Infantino *et al.,* 2010; Festen *et al.,* 2009; Jeong *et al.,* 2011; Shabahang *et al.,* 2013; Hoyuela *et al.,* 2016) measured by Visual Analogue Score (VAS) on the day of surgery in Group A patients was 1.82. When compared with the previous similar studies in the literature, mean VAS score of the patients undergone Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) was ranging from 1.32 to 3.10. The average pain score of the studies were Festen S et al (3.1±0.1), Dal Monte *et al.* (2007) (1.32), Jeong *et al.,* (2011) (2.4±3.0), Greenberg *et al.,* (2006) (1.4±2.1), Shabahang *et al.,* (2013) (1.0±0.6), Infantino *et al.* (2010) (2.0±0.5) and Hoyuela *et al.,* (2016) (1.7). The mean Visual Analogue Score (VAS) among the group A in present study and other studies shows, No pain or Mild pain during the day of surgery among the patients who underwent Doppler Guided Haemorrhoidal Artery Ligation (DGHAL).The retention of

urine[57,62] is one of the early complications of the haemorrhoidal surgeries. In the present study 6% of patients in group A had retention of urine and the same is compared with other studies, Gupta *et al.,* (2008) (9%) and Infantino *et al.* (2010) (6.2%). The incidence of the retention of urine among the patients in Group A is comparable with the other studies and significantly low when compared to the patients in Group B who underwent Open Haemorrhoidectomy. The day of discharge (Giordano *et al.,* 2009; Greenberg *et al.,* 2006; Jeong *et al.,* 2011; Noguerales *et al.,* 2015) denotes the length of postoperative hospitalization. The mean day of discharge of the patients in group A is 1.8±0.7 days and that of group B is 2.58±0.95 days. In various studies where patients underwent Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) showed significant reduction in hospitalization days, e.g. Bursics *et al.* (2004) (19.4±41.8 hours), Jeong *et al.* (2011) (1.6±1.1 days), Gupta *et al.* (2008) (12±4 hrs), Noguerales *et al.* (2015) (0.4±0.3 days), Hoyuela C et al [11hrs (3-25)], one day in Greenberg R et al and Shabahang *et al.* (2013). The duration of hospitalization in present study is comparable with the other studies, whereas is significantly less compared to Open Haemorrhoidectomy. Work resume time correlates directly with the relief of pain and symptoms. Among the two groups, 62% (n=31) of patients in the group A resumed to their work and normal activities by the end of first week (1.0±0.6 weeks) and 72% (n=36) of the patients in the group B resumed their work at the end of second and third week. The work resume time (Giordano *et al.,* 2009; Infantino *et al.,* 2010; Hoyuela *et al.,* 2016) of the patients undergone Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) when compared the other studies i.e. Bursics A et al (3.0±5.5 days), Jeong *et al.* (2012) (2.3±2.0 weeks), Greenberg R et al (1.0±0.7 weeks) and Hoyuela C et al (3 weeks) shows early recovery and early resuming to normal activities.

Nowadays, surgical treatments of diseases have become minimally invasive and cause less physiologic stress on patients; so new modalities such as the Stapled Haemorrhoidopexy and Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) is gaining much more acceptance universally. We performed this study to compare the new technique, Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) with the Milligan-Morgan open excisional haemorrhoidectomy. Patient selection, demographic characteristics, symptomatology, and type of anaesthesia had no effect on present results because correct randomization was done, which was confirmed by statistical analysis. In present study, comparison of both the procedures with regard to intra operative bleeding, postoperative pain, post-operative urine retention, day of discharge and time period to resume normal activities was done systematically. According to literature search, there was only one study by Attila Bursics *et al.* (2004) which was structurally similar to present study. In present study, when comparing Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) and Open Haemorrhoidectomy groups, we observed less postoperative pain, similar hospital stay, less need for analgesics and equal complication rates. After 2 month follow up we did not find any complications such as anal stenosis, incontinence or vacuation problems. Results of this study are comparable with Attila Bursics *et al.* (2004) in a systemic review by Giordano *et al.,* (2009), they evaluated all studies on the Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) technique, but did not find a leading study and all studies were limited to case series by pioneer surgeons. Finally, after reviewing all of those series, they concluded that this new modality seemed to be beneficial in the treatment of grade II and III haemorrhoids. Two other studies, Greenberg *et al.* (2006) and Abdeldaim *et al.* (2007) have confirmed these results. In another study Charua Guindic *et al.* (2004), the results of Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) alone proved to be satisfactory. Some studies added other modalities such as recto anal repair adjunct to Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) with similar results to Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) alone. Khafagy *et al.* (2009) compared Milligan-Morgan Haemorrhoidectomy, Stapled Haemorrhoidectomy, and Doppler Guided Haemorrhoidal Artery Ligation (DGHAL) and concluded that the two last techniques have the same outcome as Milligan-Morgan Haemorrhoidectomy, with more patient satisfaction.

Conclusion

The present study concludes that: The Doppler Guided Haemorrhoidal Artery Ligation and Mucopexy in comparison with Open Haemorrhoidectomy in the management of Grade II and III haemorrhoids has –

1. Less per-operative bleeding.
2. Significantly less post-operative pain.
3. Low rate of immediate post-operative complications and
4. Faster recovery with early return to work.

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