

Early Outcomes of Stapled Haemorrhoidopexy for 3RD Degree Haemorrhoids in Diabetic Patient

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Abstract

Original Research Article

Background: Stapled haemorrhoidopexy is a newer modality representing a paradigm change in the treatment of haemorrhoids with better short-term outcomes, shorter operating times and less post-operative pain. Though short-term effects of stapled haemorrhoidopexy are well documented in general haemorrhoid patients, but till date, no study focused the outcome of diabetic patients. **Aim of the Study:** The aim of the study was to determine the short-term outcome of stapled haemorrhoidopexy in diabetic patients. **Methods:** This prospective observational study was conducted at the Department of Surgery in BIRDEM General Hospital, for one year of period following approval of this protocol. A total of 30 patients with diabetes mellitus and 3rd degree haemorrhoid was enrolled in this study. Written informed consent was ensured from each of the participants. A detailed history and thorough clinical examination were carried out in each patient. All patient underwent stapled haemorrhoidopexy. Follow up was taken at 24 hours of operation, 14th POD, after 1 month, after 3 months and after 6 months. All information was recorded in separate case record form. After collection of all the required data, analysis was done by SPSS 23.0. **Results:** Mean age of the study participants was 45.53±3.91 (SD) years with a majority in 40-49 years of age. About 70% of the study population were male and 30% were female. Post-operative mean VAS score was 1.83±1.05 (SD) after 24 hours of operation and 0.60±0.89 after 2 weeks. About 66.7% patients experienced single episode of per-rectal bleeding after 24 hours of surgery, 20.7% had 2 episodes and 6.7% had 3 episodes. Mean hospital stay duration was 1.17±0.46 (SD) days. Average usual daily resumption of all patients was 6.90±2.37 (SD) days. **Conclusion:** The average age of the studied patients was 45 years with clear male predominance. short operative time, less post-operative pain, quicker return from hospital and early return to their normal activity was observed along with minimum early post-operative complications.

Keywords: Stapled haemorrhoidopexy, Paradigm change, Post-operative pain, Diabetic patients, 3rd degree haemorrhoid.

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INTRODUCTION

The haemorrhoidal disease is one of the most common anorectal conditions. Globally the prevalence of haemorrhoids ranges from 50-85% of the total population [1]. These patients are often doubled burdened with co-morbidities such as diabetes compared to the general population. Additionally, obesity and constipation are substantial risk factors for haemorrhoids found commonly in diabetic people, making them prone to haemorrhoidal diseases [2, 3]. The exact prevalence of diabetic patients suffering from

haemorrhoidal diseases is yet to explore. Generally, the treatment approach to haemorrhoids depends on the extent of anal prolapse. Patients with III and IV degrees haemorrhoids usually require surgery. Conventional surgical options include excisional haemorrhoidectomy such as banding, open and closed haemorrhoidectomy [4-6]. Excisional haemorrhoidectomy is considered the gold standard; however, it is associated with significant post-operative pain leading to an increased hospital stay and delay in return to normal activity [7]. Hence, novel surgical procedures such as the haemorrhoidal artery

ligation operation (HALO) and Stapled haemorrhoidopexy (SH) have been increasingly used in recent years [8]. Stapled haemorrhoidopexy is a non-excisional surgical method that repositions the prolapsed haemorrhoid tissue through a circular resection of the inner layers of the anal canal [9]. Analysis of early outcome of SH in the general population is found to be a safe procedure, requires less analgesic dose, takes reduced operative time, causes less intraoperative bleeding and less post-operative pain resulting in shorter hospital stay [10, 11]. Compared to conventional surgery, the short-term outcomes result in favour SH more [11, 12]. Nonetheless, the negative effect of stapled haemorrhoidopexy ranges from 2-56%, which commonly includes bleeding, pain, urinary retention, and early faecal urgency, thrombosed external haemorrhoids. Some are specific to stapled haemorrhoidopexy, which provides for the failure of the stapling gun, urosepsis, and pelvic sepsis [13]. Despite the minor complications, SH has been an effective treatment for haemorrhoids leading to better patient acceptance and higher compliance in the general population [14]. When co-morbidity such as diabetes are present in haemorrhoidal patients, its treatment requires customization and multidisciplinary approach. The benefit to risk ratio should be kept in mind in choosing the treatment options in such vulnerable cases [15]. Since diabetic patients generally fall into a high-risk group for surgeries due to hyperglycemia disturbs many body functions, including wound healing and body response to surgical trauma. They require careful preoperative evaluation, risk assessment, and optimal surgical technique [16, 17]. However, despite the possible frequent incidence of haemorrhoids in diabetic patients, there is a lack of data on the standard treatment of haemorrhoids in diabetic patients. Given that SH is shown better outcome in normal individuals, it might be useful in vulnerable diabetic control. Hence, the present study aimed to find early post-operative results of stapled haemorrhoidopexy for Grade-III haemorrhoids in diabetic patients.

OBJECTIVES OF THE STUDY

General Objective:

To evaluate the early outcome of stapled haemorrhoidopexy for 3rd degree haemorrhoids in diabetic patient

Specific Objective:

- To evaluate short operative time
- To evaluate the minimum post-operative complications
- To evaluate the resumption of usual daily activity
- To assess the level of satisfaction of the study population

METHODOLOGY

This was a prospective observational study, conducted in the Department of General Surgery of

BIRDEM General Hospital and Dhaka Medical College and Hospital, BSMMU from April 2020 to March 2021. A total of 30 clinically diagnosed diabetic patients with 3rd degree haemorrhoids of both sexes was recruited as study population. Purposive sampling was done in this study.

Inclusion Criteria:

- Diabetic patient with 3rd degree haemorrhoids.
- Age adult.
- Sex- both sexes.

Exclusion Criteria:

- Rectal prolapse.
- Rectocele.
- Bleeding disorder.
- Portal hypertension with rectal varices.
- Inflammatory Bowel Disease.

Data Collection Procedure:

This prospective observational study was carried out in BIRDEM General hospital, Dhaka Medical College Hospital and Bangabandhu Sheikh Mujib Medical University (BSMMU). According to inclusion and exclusion criteria, 30 clinically diagnosed diabetic patients with 3rd degree haemorrhoids were included in this study. After selecting the subject with written consent, clinical history, presenting complaints and other related evidence were taken. Thorough clinical examination was performed according to the pre-designed study performa. Digital Rectal Examination (DRE) and proctoscopy +/- sigmoidoscopy were done to detect the grade of haemorrhoids. Colonoscopy was done to exclude any malignancy and other pathology to exclude the diagnostic dilemma to select appropriate cases for the study. Senior Consultant/Consultant did the surgical procedure (Stapled Haemorrhoidopexy). This procedure excised a strip of mucosa and submucosa (together with the vessels travelling within them) circumferentially well above the dentate line. The activation of the gun simultaneously repaired the cut mucosa and submucosa by stapling the edges together. All the findings were recorded according to the design study performa. Postoperatively the patients were taken care by stiz bath, antibiotic prophylaxis, analgesics and a standard rehabilitation programme. Follow up was taken at 24 hours, 14th POD, after 1 month and after 3 months. After 6 months, review was taken through a mobile telephone conversation. On follow up, patients were asked to rate the control of their symptoms, degree of continence to flatus and faeces, duration to return to normal activities and any other problems they had. The outcome measures were post-operative pain, analgesia requirement, operative time, hospital stay, time to return to normal activity, continence, patient satisfaction and complications. Data were collected in a pre-designed data collection sheet, including particulars of the patients, history and relevant investigations.

Data Processing and Analysis:

After meticulous checking and rechecking all data were recorded into computer. Continuous variables were expressed as mean ± SD. Categorical variables was expressed as frequency & percentage. All analysis was done using the SPSS 22.0 (Statistical Package for Social Science) package for windows.

Ethical Clearance:

Ethical clearance for this study was taken Ethical Review Committee of BIRDEM General hospital, Dhaka Medical College and Hospital and Bangabandhu Sheikh Mujib Medical University (BSMMU).

RESULTS

This prospective observational study was conducted in BIRDEM General Hospital, BSMMU and Dhaka Medical College and Hospital, Bangladesh. After careful history taking, examination and appropriate investigations fulfilling inclusion and exclusion criteria, total 30 clinically diagnosed cases of 3rd degree haemorrhoids with diabetes mellitus who underwent stapled haemorrhoidopexy in study places during study period, irrespective of their age, sex, race and ethnic group were included in this study. The main aim of the study was to evaluate the early outcome of stapled haemorrhoidopexy for 3rd degree haemorrhoids in diabetic patients.

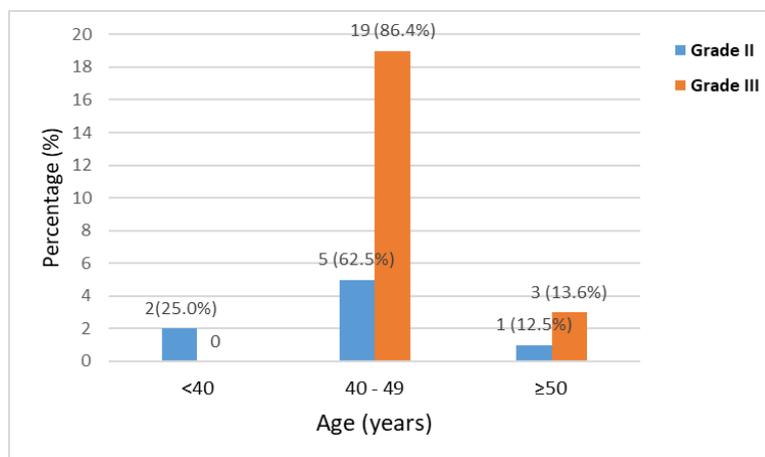


Figure I: Age distribution of patients according to ASA grading (N=30)

Mean age of all patient was 45.53±3.91 years (37- 55 year) with majority belonged to 40-49 years of age (80%). Physical status of maximum patients was graded as ASA grade III (73.3%) and rest 26.7% were ASA grade II. Among ASA grade II, 2(25.0%) were <40 years, 5(62.5%) were 40 - 49 years and 1(12.5) was ≥50 years old. Among ASA grade III, 19(96.4%) were 40 - 49 years and 3(13.6) were ≥50 years old.

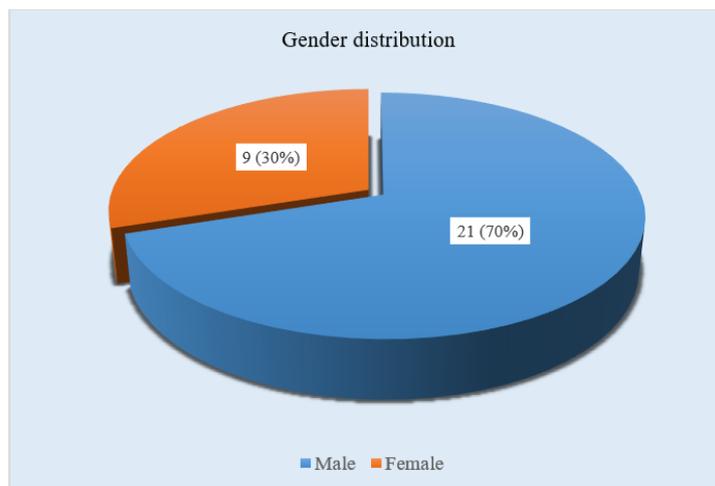


Figure II: Gender distribution of patients (N=30)

Figure showed majority of the patients were male (70%) with a male: female ratio 2.33:1.

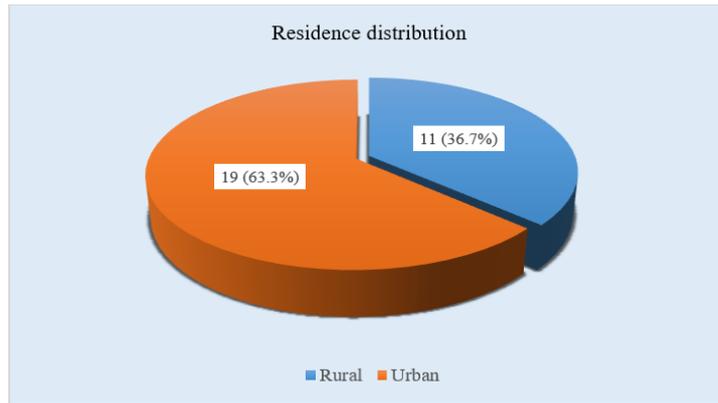


Figure III: Residence distribution of patients (N=30)

Figure III showed most of the patients were hailed from urban residence (63.3%).

Table 1: Distribution of study subjects according to clinical manifestations (N=30)

Clinical manifestations*	Frequency (n)	Percentage (%)
Per-rectal bleeding	30	100
Prolapse (manually reduced)	30	100
Mucous discharge	10	33.33

*multiple response

Table 1 showed all of the study patients had per-rectal bleeding and prolapse (manually reduced). Besides, 10 patients (33.33%) had mucous discharge.

Table 2: Diabetes status of study subjects (N=30)

DM status	Frequency (n)	Percentage (%)
Controlled (HbA1C <6.50%)	20	66.7
Uncontrolled (HbA1C ≥6.50%)	10	33.3
Duration of DM (in years)		
Mean ±SD (Range)	3.73±2.49 (1-10)	
Median	3	

Average duration of DM of all patients was 3.73±2.49 years (1-10), wherein maximum (66.7%) patients had well controlled DM as HbA1C <6.50%.

Table 3: Operation duration and VAS score after 24 hours and 2 weeks of surgery of the study subjects (N=30)

	Mean ±SD	Median	Minimum	Maximum
Operation duration (minute)	35.53±2.52	35	30	40
VAS score				
After 24 hours	1.83±1.05	1	0	4
After 2 weeks	0.60±0.89	0	0	3

Table 3 showed average duration of operation of all patients was 35.53±2.52 minutes (30-40). Mean VAS score after 24 hours and 2 weeks of surgery was 1.83±1.05 and 0.60±0.89, respectively.

Table 4: Per-rectal bleeding status after 24 hours of surgery (N=30)

Per-rectal bleeding after 24 hours	Frequency (n)	Percentage (%)
Episode		
1	20	66.7
2	8	26.7
3	2	6.7
3+	0	0
Volume		
Scanty	28	93.3
Moderate	2	6.7
Profuse	0	0

Table 4 showed maximum patients had single episode of per-rectal bleeding (66.7%) after 24 hours of

surgery. Besides, majority patients had scanty amount of per-rectal bleeding (93.3%).

Table 5: Hospital length and usual daily resumption of study patients (N=30)

	Mean ±SD	Median	Minimum	Maximum
Hospital stays (days)	1.17±0.46	1	1	3
Usual daily resumption (days)	6.90±2.37		5	14

Table 5 showed the mean duration of hospital stay was 1.17±0.46 days (1-3). Average usual daily resumption of all patients was 6.90±2.37 days (5-14).

Table 6: Assessment of study patients after 2 weeks, 1 month and 3 months (N=30)

Outcome	2 weeks N=30 n (%)	1 month N=30 n (%)	3 months N=30 n (%)
Per-rectal bleeding	0(0)	0(0)	0(0)
Infection	2(6.7)	0(0)	0(0)
Urinary incontinence	0(0)	0(0)	0(0)
Liquid stool incontinence	0(0)	0(0)	0(0)
Anal fissure	2(6.7)	2(6.7)	2(6.7)

Table 6 showed at 1st follow up assessment after 2 weeks, only 2 patients (6.7%) had infection. No one had per-rectal bleeding, urinary incontinence or liquid stool incontinence. Besides, none had experienced any of these complications after 1 and 3

months of follow up. However, anal fissure was seen in 2 patients after 2 weeks and persists after two consecutive follow-up assessments after 1 and 3 months.

Table 7: Assessment of study patients after 6 months (N=30)

	Frequency (n)	Percentage (%)
Incomplete evacuation	1	3.33
Something comes out during daefecation	1	3.33

Table 7 showed after 6 month's follow-up assessment through mobile telephone conversation,

only one case (3.33%) of recurrence of haemorrhoid and 1 case of anal stenosis was found.

Table 8: Satisfaction level among study patients (N=30)

	Frequency (n)	Percentage (%)
Excellent	8	26.7
Very good	12	40.0
Good	8	26.7
Not satisfactory	2	6.7

Table 8 showed maximum patients had very good or excellent level of satisfaction (66.7%) whereas only 2 patients were not satisfied (6.7%).

investigations fulfilling inclusion and exclusion criteria (rectal prolapse, rectocele, bleeding disorder, portal hypertension with rectal varices and inflammatory bowel disease). Physical status of maximum patients was graded as ASA grade III (73.3%) and rest 29.7% were ASA grade II. Average duration of DM of all patients was 3.73±2.49 years (1-10), wherein maximum (66.7%) patients had well controlled DM as HbA1C <6.50%. Average age of all patient was 45.53±3.91 (37-55) years with majority belonged to 40-49 years of age (80%). Male gender (70%) was explicitly predominant with a male: female ratio 2.33:1. Previous studies also found male predominance with a mean age ranging from 38-49.8 years of age among haemorrhoid patients [18-22]. For men, haemorrhoids are more likely to occur as a result of heavy lifting or engaging in strenuous activities. Besides, women commonly

DISCUSSION

Stapled haemorrhoidopexy (SH) is newly developed method for the surgical management of haemorrhoids, as an alternative to conventional haemorrhoidectomy. This study was conducted with an aim to evaluate the early outcome of stapled haemorrhoidopexy for 3rd degree haemorrhoids in diabetic patients. Total 30 clinically diagnosed cases of 3rd degree haemorrhoids with diabetes mellitus who underwent stapled haemorrhoidopexy in study places during study period, irrespective of their age, sex, race and ethnic group were included in this study, after careful history taking, examination and appropriate

develop haemorrhoids during pregnancy as a result of hormonal changes and the pressure exerted by the growing uterus. In my research project, average duration of operation of all patients was 35.53 ± 2.52 minutes (30-40). VAS score analysis showed that stapled haemorrhoidopexy had less post-operative pain after 24 hours, with a mean of 1.83 ± 1.05 (0-4). Besides, patients were experienced less hospital stays (1.17 ± 0.46 days, range: 1-3) and earlier usual daily resumption (6.90 ± 2.37 days, range: 5- 14). Several systematic reviews also found lesser operation time and post-operative pain, faster functional recovery with shorter time off work and earlier return to normal activities, compared to conventional haemorrhoidectomy [23-26]. According to this study findings, Lomanto *et al.*, [21] observed that pain score (VAS) after 24 hours ranged from 2 to 4 and the average length of hospital stay was 2.3 days. Bove *et al.*, [27] also found that the mean length of the operation was 25 minutes (range: 15 to 45 minutes) with a mean hospital stay 2.1 days (range: 1 to 12 days). However, a direct consequence of shorter hospital stays and earlier return to routine activities might be due to reduced post-operative pain among stapled haemorrhoidopexy patients. In addition, shorter post-operative stay and an earlier return to work balance the relatively higher cost of the stapler device. At 1st follow up assessment after 2 weeks, only 2 patients (6.7%) had infection. No one had per-rectal bleeding, urinary incontinence or liquid stool incontinence. Besides, none had experienced any of these complications after 1 and 3 months of follow up. However, anal fissure was seen in 2 patients after 2 weeks and persists after two consecutive follow-up assessments after 1 and 3 months. After 6 month's follow-up assessment through mobile telephone conversation, only one case (3.33%) of somethings comes out during defecation and 1 case (3.33%) of incomplete evacuation of stool was found. In studies in the literature, the rate of anal stenosis in stapled haemorrhoidopexy was reported around 2% [28-30] and recurrence rates were reported as 1-10% [22,27]. Maximum patients had very good or excellent level of satisfaction (66.7%) whereas only 2 patients were not satisfied (6.7%). treatment of haemorrhoids with a circular stapler appears to be safe, effective and rapid, bringing few post- operative complications. According to this study findings, Lomanto *et al.*, [21] also found that 95.7% patients were fully satisfied with stapled haemorrhoidopexy. Besides, several other studies assessed patient satisfaction during follow-up using different measurements, found that stapled haemorrhoidopexy perceived a higher level of patient satisfaction than those undergoing conventional procedures [31-33]. The reasons behind very good or excellent level of satisfaction are mainly because shorter operative time, lesser post-operative pain, quicker return from hospital and early return to their normal activity, as well as fewer early post-operative complications.

Limitation

- All samples were collected from three hospitals.
- Sample size was not representative to generalized the findings.
- There was no comparison group.

CONCLUSION AND RECOMMENDATION

The average age of the studied patients was 45 years with clear male predominance. short operative time, less post-operative pain, quicker return from hospital and early return to their normal activity was observed along with minimum early post-operative complications. However, further study with appropriate design with large sample size is recommended.

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