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Review Article

Stapled Haemorrhoidopexy in India– Worthy of Its Cost?

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Abstract: Hemorrhoids are one of the commonest anorectal disorders, being treated commonly by conventional hemorrhoidectomy. Stapled haemorrhoidopexy is usually reserved for 3rd and 4th degree haemorrhoids and sometimes for 2nd degree haemorrhoids as well. In Indian scenario, the disease continues to be neglected by the patients as well as clinicians and often the patients obtain proper treatment after considerable suffering. Although it has been widely practiced in India for more than a decade; it still lacks universal acceptance and popularity predominantly due to its cost. Forty nine patients remaining undergo stapled haemorrhoidopexy. Adverse outcomes were assessed at each of the follow up visits (15 days, 1 month, 6 months and 12 months) in the form of a questionnaire concerned recurrence of symptoms, symptoms related to continence and defecatory disorders. The post-operatively pain was assessed using Visual Analogue Scale and the time taken for resumption of activities of daily living using (ADLs) which was evaluated using the Katz Index of Independence in Activities of Daily Living. For patient satisfaction, Quality of life (QOL) assessment was done by WHO Quality of Life-BREF (WHOQOL-BREF) questionnaire. It was also asked whether they found the procedure to be cost effective or not and would the patients recommend this procedure to others. The median score for overall perception of QOL which was 50 (IOR 45-55) pre-operatively increased to 85 (IOR 80-85) one year after surgery for these patients. Similarly the score for overall perception of health was 50 (IOR 50-55) pre-operatively, which increased to 80 (IOR 80-85) one year after surgery thereby proving that quality of life had been improved a lot. Regarding cost, thirty five (71.4%) patients rated the procedure as costly though 44 (89.8%) patients accepted it cost effective and 44(89.8%) out of 49 reported that they would like to recommend it to others.
Keywords: Hemorrhoids **,** Stapled Haemorrhoidopexy, cost of treatment.

INTRODUCTION

Hemorrhoids are one of the commonest anorectal disorders. They are engorged blood vessels (cushions of specialized sub mucosal tissue which assist the continence mechanism) covered by the lining of the anal canal that may slide down, prolapse, enlarge and bleed [1]. Conventional hemorrhoidectomy is the commonly applied surgical approach which basically originated in 1888 when Fredrick Salmon expanded the previously conventional surgical procedure of ligation into surgical excision and ligation [2]. Till late 1990s, surgical haemorrhoidectomy was the treatment of choice when a newer technique known as stapled haemorrhoidopexy was introduced.

Stapled Hemorrhoidopexy (SH) was first described by an Italian surgeon, Dr. Antonio Longo in late 1990's and since then has been widely adopted worldwide [3]. This utilizes stapled gun is inserted per anum to hold back the internal haemorrhoids and a circumferential strip of mucosa from the proximal anal canal is excised to reduce the degree of prolapse resulting in no external wound. Stapled haemorrhoidopexy is usually reserved for 3rd and 4th degree haemorrhoids. It may be sometimes used to treat 2nd degree haemorrhoids as well [1]. In Indian scenario, the disease continues to be neglected by the patients as well as clinicians and often the patients obtain proper treatment after considerable suffering.

Since its inception in 1998 Stapled Heomrroidopexy, there have been many studies regarding efficacy, duration of surgery, post-operative pain or time to return to normal activity and nearly all of them substantiate the superiority of this technique over the conventional 'open' hemorrhoidectomy [4-7]. Although stapled technique has been widely practiced in India for over more than a decade; it still lacks universal acceptance and popularity predominantly due to its cost. The aim of this study was to evaluate the clinical outcomes after stapled haemorrhoidopexy and assessment of its patient friendly nature and reasonability in our context.

MATERIAL AND METHODS

The study was conducted at Department of Surgical Gastroenterology, RML Institute of Medical Sciences, Lucknow, India from January 2013 to April 2016, wherein a total of 61 patients presented to us with complaints of either 3rd or 4th degree hemorrhoid (grade 3 piles are the ones which re-prolapse repeatedly after digital reduction and grade 4 piles are prolapsed irreducible piles). Two patients with acute thrombosed piles and 1 patient with previous hemorrhoidectomy were excluded. Anal strictures (2 patients), fecal incontinence (2 patients) and medical conditions that made the patient unfit for elective surgery (3 patients) were also excluded. Rest of the 51 patients who underwent stapled haemorrhoidopexy were recruited as study participants after informed consent. The data included information regarding age, gender, grade of haemorrhoidal disease, previous treatment, local symptoms, continence and defecatory disorders.

Forty nine patients remaining after exclusion were operated. All operations were performed under regional anesthesia, with the patient in the supine lithotomy position. A standardized procedure was followed for performing the surgery. After a gentle per rectal examination and gentle anal dilation the external device (transparent anoscope) was fixed to the cutaneous margin. This facilitates reduction of the prolapsed piles. A transparent retractor was used to insert a 2/0 propylene purse string suture, taking submucosal bites of the lower rectum, at least 2 cm above the dentate line. The detachable anvil (head) was inserted beyond the purse-string suture and firmly tied over the stem of the anvil. The distal end of the stapler was attached to the anvil and gradually the screw tightened incorporating the prolapsing hemorrhoidal tissue in the cup of the stapler. After examination that adequate tissue is incorporated and vaginal wall in females is free the stapler was fired and removed with the doughnut. Hemostasis along the staple line was then examined and if required diathermy or a 3-0 vicryl suture was used in case of a staple line bleeds.

Outcomes in terms of early post-operative pain, early post-operative urinary retention, major post-operative hemorrhage, return to normal activity and overall improvement of symptoms with satisfaction vis a vis cost incurred specific to the procedure were assessed for which a semi structured and pretested follow up questionnaire was made to be filled by each patient during each of the follow up visits (15 days, 1 month, 6 months and 12 months) and they were examined to assess for reported complications. The items contained in the questionnaire concerned recurrence of symptoms, symptoms related to continence and defecatory disorders, their assessment of pain post-operatively (using Visual Analogue Scale wherein a score of 4 or more indicates severe pain) and the time taken for resumption of activities of daily living using (ADLs) which was evaluated using the Katz Index of Independence in Activities of Daily Living [8]. The Index ranks adequacy of performance in the six functions of bathing, dressing, toileting, transferring, continence, and feeding. Patients are scored Yes/No for independence in each of the six functions. A score of 6 indicates full function, 4 indicates moderate impairment, and 2 or less indicates severe functional impairment.[8] For patient satisfaction, Quality of life (QOL) assessment was done by WHO Quality of Life-BREF (WHOQOL-BREF) questionnaire [9]. It consists of 24 items, covering four domains: physical condition, psychological condition, social relationships, and environmental issues. Besides these domains, two additional questions were used: "How would you rate your QOL?" and "How satisfied are you with your health?" The final questionnaire, thus, contained 26 items. Each item used a 5-point Likert scale. For example: 5 = very satisfied, 4 = satisfied, 3 = neither satisfied nor dissatisfied, 2 = dissatisfied, and 1 = very dissatisfied. The high scores indicate a better QOL. For comparing the domain scores before and after SH, the WHOQOL-BREF scores were converted into scores from 0 to 100, with a lowest score of zero and a highest score of 100 for each domain and for two additional questions [9]. This was done by taking median value of scores of items in each domain and multiplying it by 20. The patients were asked to complete WHOQOL-BREF questionnaire before and one year after the surgery. Regarding the cost incurred of the instrument for surgery, they were asked whether they found the procedure to be cost effective or not. Apart from relief from symptoms, it was also asked whether they would recommend this procedure to others.

RESULTS

Of the 51 patients included in the study 39 had 3rd degree and 13 had 4th degree hemorrohoids. 70% (35) were males and 30 % were female patients.

Data was analyzed for 49 patients who could be followed regularly. Two patients could not be contacted after 1 year. Of the 49, 37 (75.5%) were males and 12 (24.5%) were females. Only 14(28.6%) patients were of age less than or equal to 45 years, rest were of more than 45 years. The presenting complaints and grade of haemorrhoidal disease have been shown in Table 1. Forty five (91.8%) patients had symptoms lasting for more than 5 years and only 1 patient had symptoms lasting for 2 years. Twelve patients had received banding or sclerotherapy as initial treatment for bleeding. Nine patients had a history of blood transfusions for anaemia related to the blood loss from hemorrhoids. The mean age of the patients was 50.5 years. None of the patients was given indwelling Foleys' catheter.

Two (4%) of the patients had post-operative bleed which was minor and did not require any blood transfusion. One patient had underlying chronic liver disease and the other was on ecospirin after cardiac bypass surgery. Only 1(2%) patient had urinary retention which was defined as inability to pass urine after 12 hours of surgery and required per urethral catheterization. He was aged 65 with underlying benign prostratic hypertrophy and required to be discharged on per urethral catheter. This was removed after medication and bladder training exercises after 7 days. Two patients had persistent pain requiring intravenous analgesics for 48 hours, both aged 34 and 42 male patients, had grade 4 hemorrhoids. Apart from 4 patients all the patients were discharged within 24 hours of the procedure.

Those with minor bleeding and post-operative pain were discharged after 48 hours. Forty four patients had achieved Katz index of independence score of 6 by second post-operative days, 4 patients achieved it after 5 days and 1 patient (with urinary retention) achieved it after 7 days (Table 2).

During the follow up after 2 weeks, those with minor bleeding continued to suffer from it but on further follow ups, i.e. at 1 month, the bleeding disappeared in one patient and in other, it disappeared after one and a half months. At 2 weeks follow up, one patient presented with anal stenosis (Table 3).

During rest of the follow up visits till 12 months, no recurrent bleeding, urinary tract infection, fissure, pain, thrombosis, fecal urgency, fecal incontinence or any other complication was reported.

As far as patient satisfaction is concerned, the median score for overall perception of QOL which was 50 (IOR 45-55) pre-operatively increased to 85 (IOR 80-85) one year after surgery for these patients. Similarly the score for overall perception of health was 50 (IOR 50-55) pre-operatively, which increased to 80 (IOR 80-85) one year after surgery thereby proving that quality of life had been improved a lot. On applying Wilcoxon signed rank test, the differences in both these pre-operative and post-operative scores were found to be significant ($p < 0.05$).

Regarding cost, thirty five (71.4%) patients rated the procedure as costly. When asked about cost effectiveness, 44 (89.8%) patients said that it is cost effective. When asked whether they would recommend this procedure to others, 44 out of 49 answered yes.

Table 1: Bio-profile and presenting complaints of patients

	Males (n=37)	Females (n=12)
Age group		
18-45	10	4
>45	27	8
Grade of Haemorrhoidal disease		
Grade III	29	11
Grade IV	7	1
Presenting symptoms		
Pre op prolapse (%)	28	2
Pre op bleeding (%)	33	9
Pre op pain (%)	30	9
Pre op leak (%)	5	0
Continence disorders	2	0
Defecatory disorders	2	1

Table 2: Immediate post operative complications

Post op complications (Immediately)	No. of patients
Bleeding	2
Post operative severe pain	2
Urinary retention	1
Thrombosis	0
Anastomotic dehiscence	0
Fissure	0
Perineal Haematoma	0

Table 3: Post operative complications after 2 weeks

Post op complications (After 2 weeks)	No. of patients
Recurrence	0
Severe pain	0
Anal Stenosis	1
Fissure	0
Minor Bleeding	2 (continued)
Thrombosis	0
Fecal Urgency	0
Fecal Incontinence	0

DISCUSSION

Hemorrhoids are cushions of vascular tissue in the anus and are one of the most common anal disorders. The etiology includes associated constipation, diarrhea, prolonged straining, pregnancy, heredity, erect posture, increased intraabdominal pressure with obstruction of venous return, aging, and internal sphincter abnormalities. The patients usually complain of bright red bleeding per rectum, anal pain, anal masses and protrusion, poor perianal hygiene [10].

Hemorrhoidal disease is common and symptomatic hemorrhoids affect >1 million individuals in the western world per year [11]. Such estimates for India are not available. The problem in India is worse because of social stigma and taboo attached to this disease which leads to under-reporting and thus many a times, delay in treatment seeking. Also, the fear of proctoscopy, especially in elderly, results in not seeking treatment for the disease. All this leads to more number of grade III and grade IV haemorrhoids because of advancement of disease due to delay in treatment.

There exists a wide plethora of non-surgical treatments for haemorrhoids, like sclerotherapy and rubber band ligation, which are mostly tried before taking a patient for surgery. Failing these treatments, the patient is considered for surgery. In truth, the patient has already had suffered a lot till the decision of surgery is made.

Two types of surgeries are there, conventional haemorrhoidectomy and stapled haemorrhoidopexy. Conventional surgical hemorrhoidectomy involves excision of the hemorrhoidal cushions as described by Milligan-Morgan (open) and Ferguson (closed) hemorrhoidectomy, has been there since long back. In 1998, Italian surgeon Antonio Longo described the ‘‘procedure for prolapse and hemorrhoids’’ (PPH) [3] which is today referred to as stapled hemorrhoidopexy. This procedure combines the favorable aspects of both fixative and excisional techniques. It corrects the anatomic and physiologic abnormalities of symptomatic, prolapsing hemorrhoids without leaving painful external wounds. The stapled hemorrhoidopexy makes use of the theory of fixation by returning the vascular cushions to their anatomic location high in the anal canal. The crucial characteristic of this procedure is the absence of any perceived perianal wounds, which therefore should be less painful than conventional hemorrhoidectomy. There is adequate evidence to support that PPH causes less postoperative pain than conventional excisional hemorrhoidectomy while achieving equivalent postoperative results [4-7].

In the present study, all the stapled haemorrhoidopexies were done under a single surgeon, thereby making the procedure and the operative technique consistent reducing bias introduced by different operating surgeons and increasing reliability.

The high patient satisfaction in terms of improvement in QOL scores, relief of symptoms as well as very less post operative complications in the present study further strengthens the fact that this procedure is definitely advisable to patients with grade III and grade IV haemorrhoidal disease.

Systemic review of over 14,000 cases of stapler haemorrhoidectomy has shown early and late complications ranging from 3-81%, with 5 mortality11. The immediate post operative complication, i.e. bleeding was found in 4% of cases which is similar to that found in other studies [12,13]. Urinary retention occurred in one patient (2%) in the present study and two patients (4.3%) complained of severe pain post operatively which is in conformity with other studies [11-13].

The complications after two weeks in the present study were found to be none except one case of anal stenosis and are similar with other studies [11]. The studies mention one or more complications like recurrence of hemorrhoids in 2.3% of patients after 1 week, severe pain (1.7%), stenosis (0.8%), fissure (0.6%), bleeding (0.5%), skin tag (0.5%), thrombosis

(0.4%), papillary hypertrophy (0.3%) fecal urgency (0.2%), problem related to staple line (0.2%), gas flatus and fecal incontinence (0.2%), intramural abscess, partial dehiscence, mucosal septum and intussusception (each <0.1%). Jongen J *et al* [14] in their study found the reintervention rates of 6.4% for complications at one month following the surgery in a retrospective study. The above mentioned complications were not encountered in our study and the re intervention rate was zero.

Most distressing symptoms for the patients presenting with haemorrhoids was pain and prolapse. Many of the patients in the study wanted to have an operation because prolapse of haemorrhoids was causing pain and discomfort. The concept of surgery (conventional hemorrhoidectomy) to relieve pain, causing more pain was not very attractive to most patients. Patients preferred stapled haemorrhoidopexy more as opposed to surgical haemorrhoidectomy as it claims to gives less pain in the post-operative period. The present study highlights that stapled haemorrhoidopexy is a very good choice for treatment of Grade III and Grade IV haemorrhoids. Also, it has a very high patient satisfaction rate. When asked regarding SH, 71% of the patients said that they found it expensive but when it was asked whether they would go for this operation in future or recommend this to others, 90% of them said yes. Therefore, we can conclude that this operation is cost effective as compared to the conventional haemorrhoidectomy in our scenario.

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