

Stapled hemorrhoidopexy and long term outcomes - a single center experience of 3130 cases at healing hands clinic, India

Abstract

Introduction: Stapled Hemorrhoidopexy (SH) is relatively less painful surgery and treatment of choice for grade III and IV internal hemorrhoids. The current study reveals the long term effectiveness of modified Longo technique in 3130 patients treated at a single center.

Methods: All the patients with complaints of hemorrhoids visited Healing Hands Clinic, Pune during study period were evaluated. Patients diagnosed with grade III and grade IV were operated with modified Longo technique Stapled Hemorrhoidopexy. Follow up was done after 15days, 1month, 3months&12months. Telephonic follow up was done in patients who were not available. The minimum follow up period was 1years and maximum 7years. The data evaluated for pre-operative and post-operative symptoms improvements, resumption to normal activity, treatment satisfaction and recurrence rate and quality of life.

Results: The mean surgery time and hospitalization duration were 20minutes and 18hours respectively. Post-operatively mild pain was reported by 57.53% (n=1801) patients, by 19.14% (n=599) on day15, 4.89% (n=153) at 3Months and no patient had pain at the end of 1year. Patient's satisfaction on Day3, 57.82% (n=1810) patient were very satisfied, 33.04% (n= 1034) were moderately satisfied and 9.14 % (n=286) were not satisfied with the treatment. The immediate complications (all mild) included urinary retention (5.69%, n=178), difficult defecation (11.69%, n=366), anal fissure (3.83% (n=120), post-operative bleeding 1.05%, (n=33), and anal stenosis 0.93 % (n=29). All patients returned to normal work / activities in an average of 5days. There was significant improvement in overall perception of World Health Organization-Quality of life and social, physical, psychological domains after surgery. The recurrence rate at 1year was 0.23%.

Conclusion: Modified Longo Technique of Stapled hemorrhoidopexy is associated with low complications rate, minimal post-operative pain and negligible recurrence rate.

Keywords: stapled hemorrhiodopexy, hemorrhoids, circular stapler, recurrence, stricture, stenosis, per rectal bleeding

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Introduction

Hemorrhoids are one of the commonly reported anorectal disorders and a worldwide problem. It has prevalence rate of 4.4% in the United States.¹ However; no epidemiological data is available for India, but considered to be higher in Indian population. Most of the patients who turned up late to the hospitals, presented with advanced disease (Grade III or IV). The treatment options for hemorrhoids are conservative (medical), nonsurgical (office based) and surgical treatments. A surgical option would be considered in patients with grade III & grade IV hemorrhoids and concomitant anorectal pathology.²

The conventional surgical techniques such as Milligan-Morgan's open hemorrhoidectomy and Ferguson's closed hemorrhoidectomy were preferred choice for the surgery in these patients and were considered to be "gold standard" till the evolution of stapled hemorrhoidopexy (SH), using a transonic circular stapling instrument, introduced by Dr. Antonio Longo in 1990s.³ SH is also known as procedure for prolapsed hemorrhoids (PPH). The early clinical experience showed better clinical outcome with SH compared to conventional hemorrhoidectomy.⁴⁻⁸ Subsequently published various randomized controlled clinical studies and systematic reviews have again compared the SH with conventional hemorrhoidectomy to

evaluate the short term and long term safety and effectiveness of the procedure.⁹⁻¹⁶

The technique developed by Dr. Antonio Longo is globally accepted and widely used even in India. The literature published before have reported it as patient friendly, minimally invasive and superior as compared to conventional hemorrhoidectomy. Although the recurrence rate and cost remained major drawbacks of the technique. The modification to Longo technique is a small effort by author to overcome this clinical drawback. The present descriptive study was conducted with objectives to study the clinical outcomes of the modified Longo technique of Stapled hemorrhoidopexy and to evaluate its effectiveness in long term.

Methodology

The study was conducted at Healing Hands Clinic, Pune, India from January 2009 to April 2016, wherein patients presented to us with complaints of either 3rd or 4th degree hemorrhoids were screened. Patients diagnosed and operated for grade III and IV hemorrhoids and who have completed all follow up visits were included. Patients who had not completed all follow up visits were excluded. Patients with anal stricture, fecal incontinence, proctitis, rectal sigmoid growth

were not included in the study. Total of 3130 patients underwent Stapled hemorrhoidopexy procedure as specified by Longo.³ At our center we follow procedure which is slightly modified by the author.

Procedure

The procedure was performed under spinal anesthesia wherein the patient was in supine lithotomy position. Intraoperative sigmoidoscopy was done in all patients before starting surgery. Steps in standardized procedure were followed. The Hemorrhoid Circular Stapler (PPH-03) manufactured by Ethicon Endo-surgery was used in all patients. Anal canal was thoroughly observed for pathology other than hemorrhoids. Then sphincter was progressively dilated digitally, to facilitate insertion of anoscope. The circular Anac Dilator (CAD) of the scope was sutured to the perianal skin with vicryl sutures to retain it in position (Figure 1 & 2). The purse string suture anoscope was inserted through the circular anoscope and the purse string suture placed approximately 1cm above the apex of hemorrhoids using a 2/0 polypropylene suture incorporating only the mucosa and sub mucosa (Figure 3). This is a modification to Longo technique done by the author.



Figure 1 Grade 3 Hemorrhoid prolapse.



Figure 2 Fixation of Circular Anal Dilator.

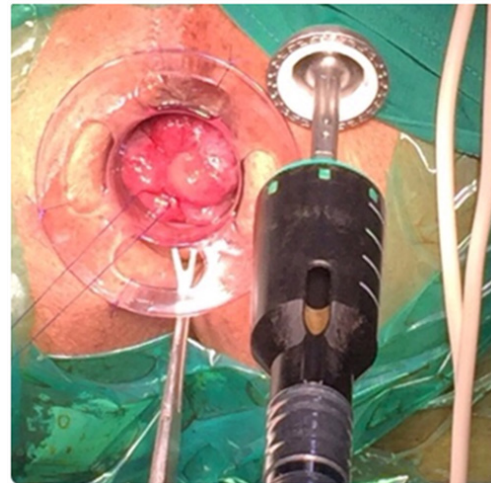


Figure 3 Tighting of purse string.

Then purse string suture anoscope was removed and PPH-03 inserted (Figure 4), with the head of the stapler fully opened. After that, purse string suture was tightened and tied around the anvil of the stapler (Figure 5). The suture threaded was passed through each of the side channels on the stapler head, and the tails of the purse string suture brought out from either side of the head of the stapler. Once the tails of the suture were brought through the side channels of the stapler head, gentle traction was applied to the suture and the stapler advanced into the anal canal such that the 4cm mark on the head of the stapler was at the level of the anal verge. The stapler head was tightened after confirmation that adequate tissue is included and in females, vaginal wall is free. When fully closed (up to the red mark), stapler was fired. After firing, the stapler was held in position for 30sec and then withdrawn after partial untwisting (3/4th of the circle) and the doughnut examined (Figure 6) for completeness. Then anoscope was inserted back into the anus and staple line was inspected for bleeding (Figure 7). If bleeding was present, it was addressed by over sewing that aspect of the staple line with an absorbable, 3/0 polyglactin, suture. Mucopexy was done in all cases of internal mucosal prolapsed. In post operative care, antibiotics and antacids were prescribed for five days and analgesics for 10days. Figure 8 shows healing of wound after Stapled hemorrhoidopexy surgery.

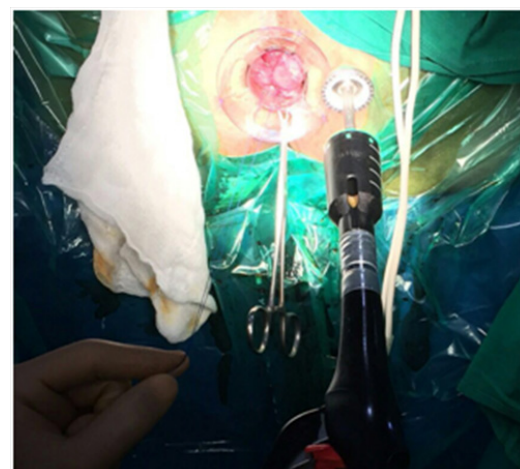


Figure 4 Introduction of PPH 03 device.



Figure 5 Tighting of PPH 03 device.



Figure 6 Circular Donut.

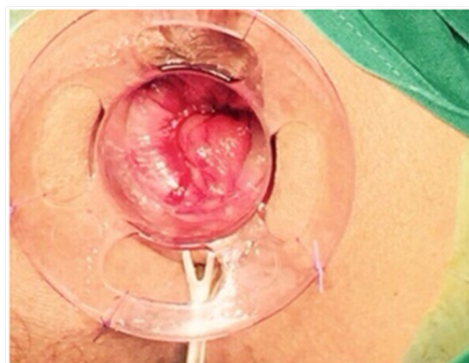


Figure 7 Staple line.

Follow Up- All the patients were advised follow up after 15days; 1month, 6months and 12months. During follow up visits patients were assessed for complications and asked to fill up a pretested semi structured questionnaire. At the end of one year follow up visit, screening proctoscopy was performed to assess the recurrence or prolapsed. The patients who couldn't come for follow up were assessed telephonically. After 24months patients were followed up at regular intervals over telephone and were asked about recurrence of symptoms and overall satisfaction .The minimum follow up period is

2years while maximum is seven years. The information collected was about the background data, grade, previous treatment and continence and defecator symptoms before and after surgery, recurrence of symptoms. Outcomes assessed in terms of time required for procedure, duration of hospital stay, post-operative pain and urinary retention, major postoperative hemorrhage, return to normal activity and overall improvement of symptoms and satisfaction.



Figure 8 After Stapled hemorrhoidopexy surgery (Stapler surgery).

Assessment of pain is done by using Visual Analogue Scale (a score of 4 or more indicates severe pain).The resumption to normal routine activities was assessed by using the Katz Index of Independence in Activities of Daily Living.¹⁷ Six basic activities like bathing, dressing, toileting, transferring, feeding and continence were considered to evaluate the adequacy of performance. A complete independence is indicated by score 6, score 4 is moderate independence while score 2 or less indicates severe functional impairment.¹⁷ Patient's overall satisfaction was assessed by using Liker's scale at the end of one year. Patient quality of life was assessed by WHO-QOL and evaluated pre operatively, immediately after SH procedure and at 1Month follow up visit.

Analysis

Data was managed by using SPSS version 21.0 for Windows and Descriptive analysis of demographic data, clinical parameters, postoperative complications, and WHO-QOL questionnaire scores was performed. Wilcox on signed rank test was used for comparing scores of various domains of WHO-QOL questionnaire. Quantitative variables were summarized by mean and other data represent in percentage. $P < 0.05$ was considered as statistically significant.

Results

A total of 3130 patients with hemorrhoids grade III and IV (symptomatic with bleeding per rectum) underwent Stapled hemorrhoidopexy procedure. All have completed follow up for one year .Only 326 (10.42 %) patients were not available for telephonic follow up. Out of 3130 patients 2389 (76.33%) were male and 741 (23.67 %) were female. As per the age distribution 27.03% (n=846) patients were in age group 18 to 45 years while most of the patients 72.97% were above 45 years (n=2284). However, the youngest patient operated was of 16years and the oldest was 91years. 17.98% (n=563) patients had grade IV hemorrhoid out of which 63 (2.01%) had thromboses hemorrhoids, 82.02% (n=2567) had grade III hemorrhoids (Table 1). Prolapse (87.98%, n=2754) was the most commonly reported complaints, followed by bleeding in 77.47%

(n=2425), burning or itching sensation in 68.49% (n=2144), hard stool 38.27% (n=1198), pain 25.11% (n=786) and straining while defecation in 20.3% (n=635). Associated co-morbidities such as fistula 4.34% (n=136), Fissure 12.72% (n=398), skin tag 6.03% (n=189) and internal mucosal prolapse 75.46% (n=2362) were also present. Hence, additional procedures such as fistulectomy, sphincterotomy, Trans anal rectal Mucopexy, and skin tag excision were performed along with stapled hemorrhoidopexy. In patients with thromboses hemorrhoids (2.01%), at the end of stapled hemorrhoidopexy the thrombus was excised making an incision on thrombus.

The mean surgery time and hospitalization duration was 20minutes and 18hours respectively. Katz index of independence score of 6 is achieved by 56.19% (n=1759) on second post-operative day, 36.51% (n=1143) achieved it by day5 while 7.28% (n=228) patients achieved it in 7 to 10days. On the day of surgery, postoperatively, 57.82% (n=1810) patients had mild pain, 34.50% (n=1080) patients had moderate pain and 3.83% (n=120) patients had severe pain. Most of the patients 69.00%, (n=2160) were relieved of pain by the end of Day 15. Only 4.89% (n=153) patients reported mild pain at 3 Months and none patient had pain at the end of 1year (Table 2). During the follow up period, difficulty in defecation 11.69 % (n=366) was most commonly reported clinical complaints by the patients, followed by

urinary retention 5.68% (n=178) and anal fissure 3.83% (n=120). No major bleeding or anatomic disruption was reported. Majority of patients, 64.21% (n=2010), have no clinical complaints post SH procedure. Only 1.05 % (n=33) patients reported post-operative bleeding out of which 21 were managed with medicine while 12 patients needed evaluation under anesthesia. Staple line stenosis was seen in 0.5% (n=15) patients between five to six weeks, all were male patients. It was managed by four quadrant stricture pasty. Persistent pain during defecation, mild and dull in nature was seen in 44 (1.41%) patients at the end of one year. Total 7 cases (0.23%) have reported a recurrence of hemorrhoids at the end of one year follow up visit. Increased frequency of loosing stools (urgency) was seen in 46% (n=1439) patients during first 2weeks which was reduced to 18% in one month and 9% at the end of 3 months and persisted in 127 patients (4.08%) at the end of one year. Patient quality of life was assessed by WHO-QOL questionnaire on three parameters - physical, social and psychological. There was significant improvement in overall perception of social, physical and psychological domains (Table 3). On Liker's scale, at the end of Day3, 59.90% (n=1875) patient were very satisfied, 28.75 % (n=900) were moderately satisfied and 11.34% (n=355) were not satisfied with the treatment. The percentage of patients, who were very satisfied, increased to 79.84% (n=2499) at the end of Day15.

Table 1 Background characteristics of study subjects

Characteristics	Total number of patients n = 3130
Age (yrs)	16 Yrs Minimum, 91yrs Maximum
Male	2389 (76.33%)
Female	741 (23.67 %)
Grades of Hemorrhoids	
Grade III	2567 (82.02 %)
Grade IV	563 (17.98 %)
Associated Co-morbidities* (*Multiple Responses)	
Internal mucosal prolapse	2362 (75.46%)
Fissure	398 (12.72%)
Skin tags	189 (6.03%)
Fistula	136 (4.35%)
Thrombosed Hemorrhoids	63 (2.01%)
Surgery Details	
Mean surgery time	20 min
Mean hospitalization duration	18 hours

Table 2 Post-operatively pain assessment by severity

Duration	Day I		Day 15		Month 1		Month 3		End of the Year	
	N	%	N	%	N	%	N	%	N	%
Mild Pain	1810	57.75%	600	19.16%	390	12.46%	150	0.47%	0	0.0%
Moderate Pain	1080	34.50 %	240	7.66%	0	0.0%	0	0.0%	0	0.0%
Severe Pain	120	4.89%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
No Pain	0	0.0%	2160	69.00%	2610	83.38%	2981	95.23%	3130	100.0%

Table 3 Patients quality of life assessed by WHO-QO

WHO-QOL (Mean)	Pre operatively	Post operatively	Wilcoxon Rank Test p	Month 1	Wilcoxon rank Test p
Physical	58.22	76.00	0.01	98.29	0.005
Social	69.30	70.82	0.10	70.91	0.05
Psychological	70.14	78.44	0.05	95.20	0.01
Overall	70.42	80.31	0.05	92.98	0.02

Discussion

Hemorrhoids are known to be a commonest anorectal disease since ancient times. Many of the treatments are proposed in ayurvedic literature and widely practiced. In India, this condition is associated with social taboos and stigma hence the exact prevalence is not known. Patients usually neglect the disease and hesitate to seek treatment for it. This leads to progression of the disease because of this grade III and IV hemorrhoids are more common in India. The disease is also under reported and neglected by general physicians due to social problems, taboos and fear associated with proctoscopy. Patients usually seek surgical treatment after repeated failure of all other non surgical treatments. Conventional surgical hemorrhoidectomy is considered to be the most promising treatment for both internal and external hemorrhoids. This treatment found to be effective but the post-operative pain, recurrence rate were the major drawbacks.

The procedure developed by Longo in 1998, have been adopted globally due to its distinct advantages over conventional surgical procedure for hemorrhoids. Since then, number of randomized controlled clinical trials, systematic reviews and meta-analysis have been published. As mentioned earlier, the early clinical trials have shown the safety and effectiveness of the SH procedure. The clinical effectiveness have been proved by showing minimal post-operative pain, shorter hospital stay, early to resume the work, shorter operative time, and acceptable safety profile.¹⁰⁻¹⁶ Many of the studies¹⁸⁻²² reported the average length of operation time was around 25 minutes, highlighting the saving time as compared to conventional surgeries. Additionally, SH procedure also resulted in shorter hospital stay, early recovery, and time to resume normal activities. The other studies also have reported shorter hospital stay post SH procedure.¹⁸⁻²² Our case series also showed similar findings.

PPH multicenter study trial demonstrated that stapled hemorrhoidopexy offers the benefits of less post operative pain, less analgesic requirements, and less pain at bowel movement, while providing similar control of symptoms and less frequent need for additional anorectal treatments at 1-year follow-up.²³ Other studies observed reduced post-operative pain^{19,25} and also, in systematic reviews and meta-analyses relief of post-operative pain was observed after SH procedure.^{10,11,13} Similarly, we have observed 96 % pain relief at 1 year follow up.

The complication rate reported in this study varies from 1% to 15% and lesser as compared to other studies (6-32%).^{20,24-29} Post operative bleeding leading to interventions is reported 6-8 % in these studies as compared to 1.05% in our study. We have seen only 7 cases (0.23%) of recurrence of prolapse, which is in contrast to other studies where it was shown that SH procedure carries higher incidences of recurrence compared to conventional procedures.⁹⁻¹³ Internal mucosal prolapse is the most commonly seen co morbid condition in Grade III and IV hemorrhoids because of internal mucosal prolapse hemorrhoids are developed. The modification in Longo technique helps in treating this internal mucosal prolapse in better way hence the recurrence rate is low. Stapled hemorrhoidopexy is gaining popularity and has been widely practiced in India. It still lacks universal acceptance and popularity predominantly due to its cost.³⁰ In our case series we have not considered the cost of treatment. The clinical success of SH procedure is dependent on the surgeon's skill set, adhering the technical principals of circular staples and right patient selection. Learnt through the years, we could able to implement the right protocol for better patient clinical outcome. The modification in standard Longo technique helps in reducing post operative bleeding

and recurrence rate which can promise the cost effectiveness of the treatment.

Conclusion

We have presented a long term clinical outcome data of 3130 patients. In spite of the limitations of a case series, here we can conclude that negligible recurrence rate on long term follow up, exceptionally less post-operative bleeding, minimally invasive with faster recovery or return to work makes SH as procedure of choice for grade III and IV prolapsed hemorrhoids. Authors modification in original surgical technique as projected by A Longo is the key to long term success. Mucopexy and taking the purse string just above the apex of hemorrhoids significantly decreases the recurrence rate from 10 to 15% (as reported by studies conducted previously with small sample size and short follow up) to less than 1% and post-operative bleeding from 8-10% to less than 1%. Post-operative frequency (46%) during the first four to six weeks is a major challenge though it is also common with traditional open hemorrhoidectomy but to a lesser extent. The author is currently working on surgical technique which may show promising results.

Limitations and recommendations

Being observational study this case series has many limitations. Being a single center, hospital based study, results cannot be generalized. As the follow up period was too long there are chances of recall bias. The cost effectiveness of the procedure is not considered here. We recommend that as this relatively less painful procedure should be performed by trained surgeons. As its success depends upon surgeon's skills and technical knowledge, we recommend that training in this regard should be given to the colorectal surgeons.

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Conflicts of interest

Author declares there are no conflicts of interest.

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