

A Prospective Comparative Randomized Study between Stapled and Conventional Haemorrhoidectomy

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Abstract

Aims & Objectives: In the present study we have compared between recent stapled haemorrhoidectomy and conventional haemorrhoidectomy (Milligan Morgan Technique) for treatment of haemorrhoids in terms of operating time, postoperative pain and bleeding and other complications, hospital stay and time to return to work. **Materials & Methods:** This is a prospective comparative study conducted in the department of general surgery of J.L.N. Medical College, Ajmer, Rajasthan in the duration of November 2015 to December 2017. Sixty (60) patients of age >20 years with symptomatic internal hemorrhoids of 3rd & 4th degree were randomly assigned to either conventional or stapled haemorrhoidectomy (30 in each group). Visual analog scale was used for evaluation of pain. Intra-operative blood loss, procedure time, postoperative pain and other complications like urine retention, bleeding, infection, constipation and recurrence rate were studied. Postoperative hospital stay duration, days required to resume normal bowel habits and normal daily activities and satisfaction with treatment. Follow up was done at 1 week, 1 month and 3 month. Data collected and analyzed. **Results:** Intra-operative blood loss (70.33 v/s 30.33 ml, p value <0.01), duration of surgery (32.8 v/s 27.1 minutes, p value <0.01), postoperative pain (p value <0.01) and hospital stay (2.2 v/s 1.0 days, p value <0.001) were less in stapled haemorrhoidectomy. Earlier normal bowel habits (3.6 v/s 2.2 days, p value <0.01) and earlier resumption of normal personal activities (5.6 v/s 4.2 days value <0.001) and better patient satisfaction

(53.33% v/s 93.33%, p value < 0.001) were associated with stapled haemorrhoidectomy. Results regarding post operative complications like bleeding, urinary retention, infection and constipation were no statistical difference found (p value >0.05). **Conclusion:** Stapled haemorrhoidectomy procedure is superior to conventional haemorrhoidectomy in terms of intra operative blood loss, operative time, post-operative pain, first defecation, early resumption of activity, hospital stay and patient's satisfaction. Regarding anal stenosis and recurrence rate long term follow-up is necessary.

Keywords: Anal Stenosis; Haemorrhoids; Post Operative Complications; Recurrence; Urinary Retention.

Introduction

Haemorrhoids are cushions of sub mucosal tissue containing venules, arterioles, and smooth-muscle fibers that are located in the anal canal. Three haemorrhoidal cushions are found in the left lateral, right anterior and right posterior positions. Haemorrhoids are thought to function as part of the continence mechanism and aid in complete closure of the anal canal at rest. Because haemorrhoids are a normal part of anorectal anatomy, treatment is only indicated if they become symptomatic. Excessive straining, increased abdominal pressure, and hard stools increase venous engorgement of the haemorrhoidal plexus and cause prolapse of haemorrhoidal tissue. Rectal bleeding, thrombosis, and symptomatic haemorrhoidal prolapse may result [1]. Haemorrhoids present above the dentate line are classified as internal haemorrhoids. Haemorrhoids occurring below the dentate line are classified as external hemorrhoids. External haemorrhoids are in sensitive anal canal skin and are painful, while internal

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haemorrhoids are in insensitive anal canal mucosa and are painless (unless complicated).

Internal haemorrhoids are classified by their degree of prolapse, which helps determine management: [2]

First degree: Bleeding with no prolapse

Second degree: Prolapse with spontaneous reduction with bleeding, seepage

Third degree: Prolapse requiring digital reduction with bleeding, seepage

Fourth degree: Prolapse that cannot be reduced and strangulated

In early cases haemorrhoidal disease can be treated by dietary modifications, topical medications. In late haemorrhoidal disease surgical procedures are necessary to provide satisfactory, long term relief. Stapled haemorrhoidectomy, as developed by Dr. Antonio Longo with use of a circular stapler, has emerged as a possible alternative to open haemorrhoidectomy. Unlike excision haemorrhoidectomy, stapled haemorrhoidectomy does not aim to excise redundant haemorrhoidal tissue. Instead, stapled haemorrhoidectomy removes a short circumferential segment of rectal mucosa proximal to the dentate line using a circular stapler. This effectively ligates the venules feeding the haemorrhoidal plexus and fixes redundant mucosa higher in the anal canal [3].

In this study we are going to compare stapled haemorrhoidectomy with conventional haemorrhoidectomy in terms of outcome variables.

Aims & Objectives

Comparison between stapled haemorrhoidectomy and conventional haemorrhoidectomy.

1. To compare procedural time.
2. To compare post operative complications.
3. To compare duration of hospital stay.
4. To compare postoperative duration for resumption of normal bowel habits.
5. To compare the time period to return to daily routine activities after surgery.

Materials & Methods

Place of Study: Department of General Surgery, J.L.N.M.C. & Hospital, Ajmer.

Source of Data

The participants for this study are patients with grade III and IV haemorrhoids reporting to outpatient Department of general surgery, J.L.N.M.C. & Hospital, Ajmer.

Duration of Study

November 2015 to December 2017. (Two Years)

Methodology

A total number of 60 patients between the age group of 20 and 70 years who were diagnosed to have Grade III and IV Haemorrhoids, evaluated by Proctoscopy/ Colonoscopy and treated in Surgical Department were included in the study, after obtaining the approval from the Institutional Ethics Committee (IEC). They were divided into two groups and randomly selected for procedure by simple random technique through opaque sealed envelope technique.

Group A: The patients undergoing conventional (open) haemorrhoidectomy. (30 Patients) [CONV]

Group B: The patients undergoing stapled haemorrhoidectomy. (30 Patients) [STAP]

After explaining the diagnosis to the patient and attenders, they were consented for surgery. Pre-anesthetic assessment and relevant investigation were done. Pre-operative Investigations conducted were complete blood counts, blood grouping, random blood sugar, serum creatinine, chest X-ray, bleeding time and clotting time, Anti-HIV and HBs AG.

After relevant investigations and pre anesthetic evaluation, the patients were subjected for either open haemorrhoidectomy or stapled haemorrhoidectomy. Thirty patients underwent conventional haemorrhoidectomy and thirty patients underwent stapled haemorrhoidectomy.

Pain was assessed using a visual analog scale (VAS) in which 0 corresponds to "no pain" and 10 to "maximum pain". The aim was to keep the pain down to a VAS score of less than 3 at all times.

Post operative pain therapy consisted of intravenous diclofenac aqueous 12 hourly for the 1st post operative day, followed by oral NSAIDs in the form of diclofenac 50mg 8th hourly was given for the next 5 post operative days in both the groups. Additional analgesia was supplemented on patient's request.

- Post operative care was given and patient will be discharged on basis of his/her general condition.
- Patients were in regular follow up for 3 months (at 1 week, at 1 month and at 3 months) in surgery OPD or by taking their contact numbers.

Inclusion Criteria

1. Age more than 20 years
2. Internal haemorrhoids (Third & fourth degree)

Exclusion Criteria

1. First & Second degree haemorrhoids

2. Haemorrhoids with complications
3. Previous rectal surgery
4. Secondary haemorrhoids.
5. Haemorrhoids with associated other local pathology including sentinel piles, eczema, fissures & fistula.

Statistical Analysis

Data were recorded on a predesigned Performa and managed on excel spread sheet. Comparative analysis between two groups were done based on, Independent sample 't' test or students 't' test using a SPSS version 20 (IBM Corporation Chicago.)

Results

A total of 60 cases were included in the study out of which 30 undergone conventional haemorrhoidectomy (CONV) and 30 undergone stapled haemorrhoidectomy (STAP). Gender ratio for both the group was same (26:4). Mean age in CONV group was 42.6 years and in STAP group, it was 45.0 years. Mann Whitney test for comparison of mean shows there was no statistical difference of age between two groups (p value >0.05).

Mean duration of procedure time was higher in CONV group of subjects (32.8 minutes) than STAP group of subjects (27.1 minutes). The difference of procedure time was statistically significant (p-value <0.001) [Table 1].

Post-operative pain was assessed by VAS system. The data was analyzed by Mann Whitney U test. Pain perception was significantly higher on post-operative day 0 (41.1 v/s 19.9), 1 (41.1 v/s 19.9) and 2 (45.2 v/s 15.8) in CONV group of subjects as compared to STAP group of subjects (p value <0.001). On post-operative day 7 (34.2 v/s 26.8), statistical difference of pain perception between two groups was less. (p value <0.05) [Figure 1].

Out of 30 subjects undergone CONV surgery 33.3% had post-operative urine retention, 16.6% had bleeding, 3.3% had infection and 10% had constipation, while out of 30 subjects undergone STAP surgery 16.6% had post-operative urine retention, 6.6% had recurrence of symptoms and 1% had constipation. There was no statistical difference of post operative complication between two groups (p value >0.05) [Table 2].

Mean duration of hospital stay in CONV group was 2.2±0.5 days and in STAP group it was 1.0±0.1 day. It was significantly higher in CONV group of subjects than STAP group of subjects. (p value <0.0001) [Figure 2] Average days to resume normal bowel

Table 1: Comparison of procedure time between 2 groups

	Procedure time in minutes (mean ±SD)	p value
Conventional haemorrhoidectomy	32.8 ± 2.5	< 0.001
Stapled haemorrhoidectomy	27.1 ± 2.5	

Table 2: Comparison of post-operative complication between two groups

	Number of Subjects Having Post Operative Complication				
	Post OP urine retention	post op bleeding	post op infection	recurrence of symptom	Constipation
Conventional haemorrhoidectomy	10 (33.3%)	5 (16.6%)	1 (3.3%)	1 (3.3%)	3 (10%)
Stapled haemorrhoidectomy	5 (16.6%)	0	0	2 (6.6%)	1 (3.3%)
p-value	0.233	0.052	1 .000	0.492	0.612

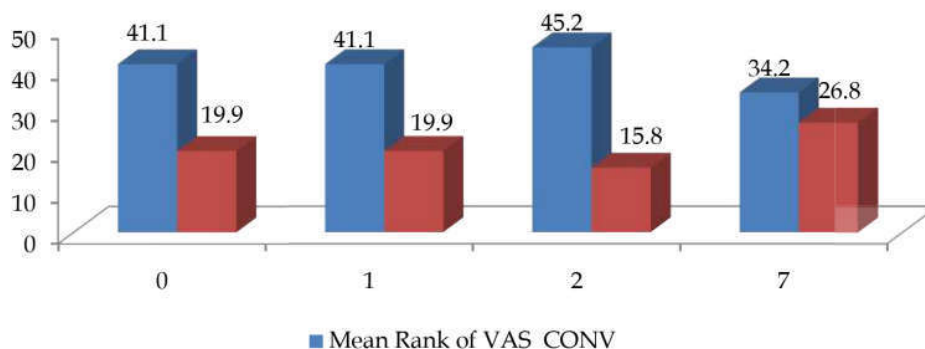


Fig. 1: Comparison of post-operative pain assessed by VAS between two groups

habits in CONV group were 3.6±0.7 days as compared to 2.2±0.6 days in STAP group. The difference was statistically significant (p value <0.001) [Figure 3] Average days to resume normal daily activities in CONV group were 5.6 days as compared to 4.2 days in STAP group. The difference was statistically significant (p-value<0.001) [Table 3].

Sixteen of thirty patients in CONV group were satisfied i.e. 53.33%. twenty eight of thirty patients in STAP group were satisfied i.e. 93.33%. By Fisher Exact Test p value is 0.00176 i.e. <0.01 hence significant. Therefore the difference in level of satisfaction between the two groups was statistically significant [Figure 4].

Table 3: Comparison of days required to resume normal daily activities

Group	Days to resume normal daily activities (mean ±SD)	p value
Conventional haemorrhoidectomy	5.6 ± 0.7	< 0.001
Stapled haemorrhoidectomy	4.2 ± 0.6	

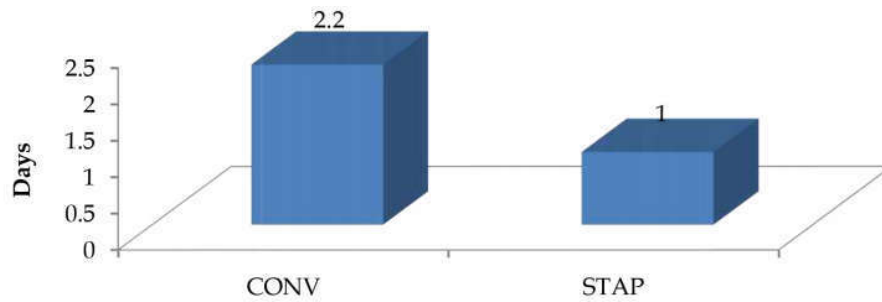


Fig. 2: Comparison of hospital stay between 2 groups

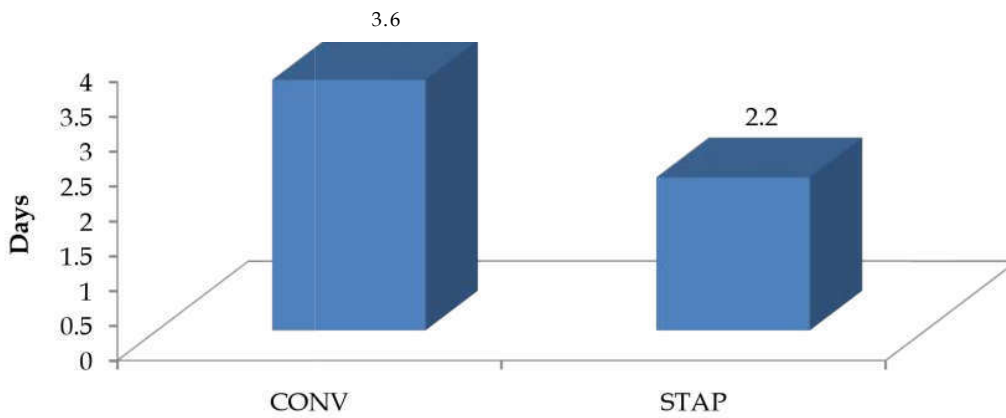


Fig. 3: Comparison of days required to resume normal bowel habits

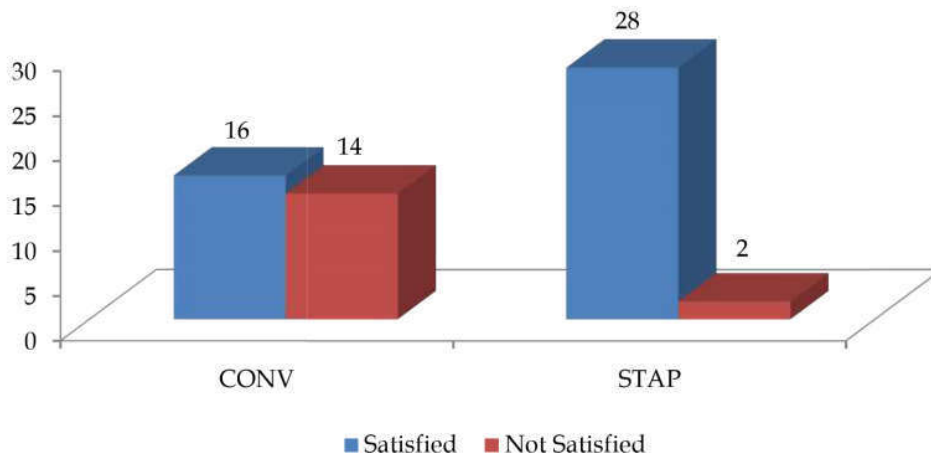


Fig. 4: Satisfaction with treatment: patient's evaluation

Table 4: Comparisons of various studies

Parameters	H.Aggarwal, R.Bansod 2007[9]	Stolfi VM 2008 [6]	Gouda M. Ellabban 2010 [7]	P.Krishana Kishore 2016 [8]	Srikanth Kulkarni et al 2016 [16]	Present study 2017	
No. of Patients per group	25	MMH:100(76) SH:100 (95)	15	50	50	30	
Procedure time (min.)	MMH:50 SH:37.5	MMH:28.41 SH:28.30	MMH:38 SH:35	MMH:36.4 SH:28.7		MMH:32.8 SH:27.1	
Post op. pain (mean VAS)	Less in SH (p<0.0001)	First two days same, (p=0.9) day 3 to day 8: MMH:4.71 SH:3.60 (p<0.002)	MMH:7 SH:2.5 (p<0.0001)		MMH:5.14 SH:3.24 (p<0.0001)	MMH:41.1 SH:19.9 (p<0.0001)	
Post Op. complications	U.Retention		MMH: 0% SH: 3.1%	MMH: 6.7% SH: 6.7%	Less in SH	MMH: 4% SH: 8%	MMH:33.3% SH: 16.6%
	Bleeding	MMH: mod to sev.48% Mild: 4% SH:mild: 92% Mod.: 8 %	Less in SH	MMH: 26% SH: 20%	MMH: more SH: Nil	MMH: 2% SH: 2%	MMH:16.6% SH: 0.1%
	Infection	MMH:20% SH: 8%	Less in SH				MMH:3.3% SH:0.1%
	Constipation						MMH: 10% SH: 3.3%
Hospital Stay post op (In days)	MMH:11.5 SH: 1.5	MMH: 1 SH: up to 4	MMH:2.8 SH: 1.09	MMH: 4.6 SH: 3	MMH:2.32 SH: 1.72	MMH:2.2 SH: 1.0	
Day to resume Normal bowel Habit			p=0.72 not significant			MMH:3.6 SH: 2.2	
Day to resume Normal daily activity	MMH: 25 SH: 3	MMH: 18+ 9 SH: 17+ 11	MMH: 31 SH: 18 p=0.0005	Earlier in SH	MMH: 4.64 SH: 3.49	MMH: 5.6 SH: 4.2	
Recurrence	Almost similar	MMH: 2.6% SH: 7.4%	MMH: 13.3 SH: 6.7	Marginally higher in SH		MMH: 3.3 SH: 6.6	
Other long term complication		Anal stricture MMH: 2.6% SH: 2.1%	Anal stenosis MMH: 6.7% SH: 0%	Anal Stenosis Higher in MMH			
Satisfaction with treatment		Almost same	MMH: 93.3% SH: 93.3%			MMH: 53.3% SH: 93.3%	
Follow up period	6 months	34.8+15.6 months	3 months	2 months extended to 30 months	3 months	3 months	

MMH: Milligan Morgan Haemorrhoidectomy SH: Stapled haemorrhoidectomy

Discussion

Haemorrhoidal disease is one of the common surgical problems encountered in surgical practice. Patients tend to avoid hospital visits for fear of social stigma hence late presentation is common in many cases. Most of the patients affected by haemorrhoidal disease complain of bleeding in the stool. Other

symptoms are prolapse, mucous discharge and pain during prolapsed. After proper history and proctologic examination, patients are categorized into grades (Grade 1-4). The vast majority of patients of grade 1 and 2 can be conveniently and adequately treated in a conservative manner by high fiber diet, proper toilet habits, anal cleaning after passing stool and topical medication.

Surgery is offered when conservative treatment and/or minor ambulatory procedures (i.e. rubber band ligation, sclerotherapy or photocoagulation) have failed. Surgical treatments are conventional technique (open and closed haemorrhoidectomy) and newer technique (Longo Stapled Haemorrhoidectomy). Conventional haemorrhoidectomy is gold standard technique used for many decades. Stapler haemorrhoidectomy is being used widely now a days and various studies have been performed to compare it with gold standard conventional technique.

In this study we tried to compare the stapled haemorrhoidectomy with conventional technique.

Age and Sex Distribution

From a total of 60 patients, 30 underwent stapled haemorrhoidectomy; among those 26 were male and 4 were female. (M:F-26:4). The remaining 30 patients were operated with conventional haemorrhoidectomy (M: F-26:4). Mean age in conventional group was 42.6 years and in STAP group, it was 45.0 years.

Procedure Time

Procedure time in stapled haemorrhoidectomy is significantly less (27.1 minutes) than conventional (32.8 minutes) with $p < 0.001$. Results of study of Shalaby R et al. [5], Vito Maria Stolfi [6], Gouda M. Ellabban [7], P. Krishna Kishore [8] are also similar to our study.

Post Operative Complications

Urinary retention, constipation, bleeding and wound infection were more common in conventional group whereas stapled haemorrhoidectomy was more associated with recurrence of symptoms but the difference was not statistically significant. H. Aggarwal (2007) in a study found the similar results as stapled haemorrhoidectomy showed higher incidence of anal fissure compared with Milligan Morgan Haemorrhoidectomy (6.3% v/s 0%; $p = 0.025$) but no differences in urinary retention, anal stricture, urgency or anal hemorrhage [9].

Palimento D et al. [10] in a study on 76 patients concluded that haemorrhoidectomy with a circular staple device is easy to perform and achieves better results than the Milligan-Morgan technique in terms of postoperative pain and recovery. Tjandra JJ et al. [11] concluded that although there was increase in the recurrence of haemorrhoids at one year or more after stapled procedure, the overall incidence of recurrent haemorrhoidal symptoms was similar. The overall complication rate did not differ significantly from that of conventional procedure. Compared with conventional surgery, stapled haemorrhoidectomy has less postoperative bleeding, wound complication, constipation, and pruritis. [Table 4]

Shalaby R et al. [5] concluded that use of a circular stapler in the treatment of haemorrhoidal disease was safe, and was associated with fewer complications than conventional haemorrhoidectomy.

Post Operative Pain

Our study shows that Stapled haemorrhoidectomy is associated with less post operative pain than conventional technique. That helps in early discharge from the hospital and early resumption of normal daily activities. Shalaby R et al. [5], Pavlidis T et al. [12], E. GAnio et al. [13], Palimento D et al. [10], Tjandra JJ et al. [11], Correa-Rovelo JM et al. [14], Wilson MS et al. [15], H. Aggarwal [9], Vito Maria Stolfi [6], Gouda M. Ellabban [7], Srikanth Kulkarni et al. [16] also noticed less post operative pain in patients treated with stapled haemorrhoidectomy than conventional technique.

Hospital Stay

In present study mean duration of hospital stay in conventional group was 2.2 days and in STAP group it was 1 day. It was significantly higher in conventional group than STAP group (p -value < 0.0001). Stapled haemorrhoidectomy results in better utilization of health resources, less chances of hospital acquired infections and reduced healthcare costs. Studies did by Shalaby R et al. [5] Pavlidis T' et al. [12] and E. GAnio et al. [13], H. Aggarwal [9], Gouda M. Ellabban [7], P. Krishna Kishore [8], Srikanth Kulkarni et al. [16] also support this analysis.

Early Resumption of Bowel Habit and Normal Daily Activity

As results show that patients undergoing stapled haemorrhoidectomy resumed early bowel habit (2.2 days) and daily activity (4.2 days) then conventional (3.6 and 5.6 days respectively), stapled haemorrhoidectomy is more cost effective and time effective than conventional. It also decreases loss in social, economic and professional performance of the patient.

Studies of Shalaby R et al. [5], E. GAnio et al. [13], Palimento D et al. [10], Tjandra JJ et al. [11], Correa-Rovelo JM et al. [14], Wilson MS et al. [15] H. Aggarwal [9], Gouda M. Ellabban [7], P. Krishna Kishore [8], Srikanth Kulkarni et al. [16] and also showed early recovery and resumption of daily activity in stapled haemorrhoidectomy than conventional technique.

Satisfaction with Treatment- Patients Evaluation

As regards patient's evaluation and satisfaction with treatment, more than 93.33% patients were satisfied in STAP group as compared to only 53.33% in CONV group.

Shalaby reports that 92% patients in stapled group

as against 80% in conventional open group were satisfied with the procedure. [5]

Ommer et al. (2011), in a study, described that patients undergone SH achieved a high level of patient satisfaction and symptom control, with a low rate of reoperation for recurrent haemorrhoidal symptoms. Out of total 257 patients, 195.

Patients (87.1%) were satisfied or very satisfied with the operation outcome; 19 patients (8.5%) were moderately satisfied; and 10 (4.5%) were not satisfied. [17].

The factor of cost was not evaluated in the study since the hospital stay as well as stapling instrument was totally free in J.L.N. Hospital, Ajmer.

Thus we can say that Stapler haemorrhoidectomy is better technique than conventional in terms of short operative time, less post operative pain, short hospital stay, early resumption of bowel habits, daily activity and better satisfaction with treatment. However, there is no difference between both methods in terms of post operative other complications.

Conclusion

Stapled haemorrhoidectomy (SH) is more effective than conventional technique in terms of decreased operative time, less post operative pain, short hospital stay, early resumption of bowel habits and normal daily activity and better patient satisfaction with treatment. Stapled haemorrhoidectomy group had less postoperative complications but there was no statistical difference of post operative complication between two groups.

Limitations

1. Small sample size
2. Short follow-up

Conflict of interest

Anil kumar sharma declare no conflict of interest
Satyaveer singh declare no conflict of interest
Rekha porwal declare no conflict of interest
Amit singh declare no conflict of interest
Mukesh kumar declare no conflict of interest
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