

## Can Yoga Improve the Outcome of Surgery for Haemorrhoids? A Prospective Randomized Controlled Study.

**Brij B. Agarwal, Shruti Sharma, Manish K. Gupta, Rathindra Sarangi, Krishan C. Mahajan\***

*Department of General Surgery, Sir Ganga Ram Hospital, New Delhi, India*

*\*Advisor, Ganga Ram Institute of Postgraduate Medical Education & Research (GRIPMER), India*

**Abstract:** Procedure for Prolapse and Hemorrhoids (PPH) for symptomatic hemorrhoids has become popular. Benefits of PPH are theoretically premised upon physiological restoration of anatomical cushions. Outcomes of PPH can be further improved by addressing symptoms like postoperative pain. Cyclical mechanical stretch, as in Yoga is known to be beneficial in tissue repair. This study was undertaken to assess the impact of yoga exercises on the outcomes of PPH. From December 2005 to November 2007, one hundred consecutive candidates for PPH were prospectively randomized and an informed consent was taken for day care surgery. Postoperative pain, difficult defecation, Perianal burning / pruritus/irritation, incontinence, Perianal soiling, rectal urgency and retention of urine were the end points. Squamous anal mucosa seen in resected donuts was the exclusion criteria. Fewer patients had postoperative pain, difficult defecation, Perianal irritation and perianal swelling in the yoga exercises group as compared to the control group. The improvement was uniformly significant ( $p$  value  $<0.05$  for all). Urinary retention ( $n=2$ ) & post-operative bleed ( $n=2$ ) were seen only in those operated under regional anesthesia. Both these complications occurred independent of each other & in both the groups. Yoga exercises can be easily offered to patients for PPH with improved outcomes.

### INTRODUCTION

Hemorrhoids, a feature of normal human anatomy sometimes become symptomatic<sup>1</sup>. Stapled hemorrhoidopexy is also known as procedure for prolapse and hemorrhoids (PPH). It has been accepted as a safe<sup>2</sup>, effective and day care procedure<sup>3</sup>.

There is evidence in favor of PPH for operating time, length of hospital stay, pain, discharge and patient satisfaction<sup>4</sup>. Other outcome measures such as persistence of prolapse, urinary retention, difficult or painful defecation and incontinence do not appear to be improved compared to traditional surgery<sup>2,4</sup>. Preventing fragmentation of Parks ligament<sup>5</sup> or rupture of Treitz muscle by avoiding straining at defecation<sup>1</sup> can help in reducing symptoms. Painful defecation is a result of sphincter spasm<sup>5</sup>. PPH is sometimes a cause of pain<sup>6</sup>. Pain remains an important tool in evaluation of PPH outcome<sup>5</sup>. Joint clinical practice guidelines by American College of Physicians and American Pain Society have recommended incorporation of non-pharmacotherapy like Yoga in acute and chronic pain<sup>7</sup>. Brief mechanical stretches (10 minutes) have demonstrated favorable response to tissue trauma by moderating the effects of transforming growth factor  $\beta$ -1<sup>8</sup>. Cyclical mechanical stretch augments the biosynthetic effect of transforming growth factor  $\beta$ -1<sup>9</sup>. These stretch mediated changes improve the contractility of connective tissue fundamentally thought to be non-contractile<sup>10</sup>. This has been supported by an increase in Matrix-Metalloproteinase-2 activity in injured tissue undergoing remodeling<sup>11</sup>. Yoga exercise (YE) (involving cyclical stretch) aimed at the tissues around anorectum may help repair of soft tissue injured during surgery. This study was undertaken to evaluate the impact of YE on the outcome of PPH.

### PATIENTS AND METHODS

This prospective study was conducted at a tertiary level teaching hospital. The same surgeon operated upon all patients. The operating surgeon was also a qualified yoga proponent (trained in Yoga at a National Institute >20 years back).

Consecutive patients with symptomatic second, third and fourth degree hemorrhoids agreeing to PPH were enrolled during December

2005 – November 2007. Patients with concomitant anal disease (abscess, fistula, inflammatory bowel disease) and patients with abnormal coagulation profile were excluded. All the preoperative data was recorded in a standard case sheet. Patients were explained about PPH and an informed consent obtained. Routine hematology, biochemistry and pre-anesthesia check were done. An ultrasound for significant post void residual urine (PVR) was done in patients above 45 years of age. In case of significant PVR Tamsulosin 0.4 mg at bedtime was started.

An independent team of a medical student and a doctor (AID) randomized the patients into YE or non-YE groups. One hundred pre-sealed envelopes of the two options were shuffled like a deck of cards and a member of the AID drew one envelope for each patient. AID counseled all the patients about benefits of high fiber diet and avoidance of straining at stools. AID also gave yoga lessons to the YE patients.

The YE aimed at pulling the rectum up (confirmed by asking the patient to squeeze the examining finger during DRE) and squeezing the buttocks. The patients were asked to maintain this pull and squeeze and then release it. They were told to do this hold up and release in cyclical succession for 5-10 times and then maintain the pulled up squeezed position for as long as possible. They were advised to try to do this during their all awake moments at least three times in a day for 10 minutes duration each. They were told to keep doing it after the surgery without asking their surgeon. This exercise is known as "MOOLBANDH" in yoga. 'Mool' means anal orifice & 'Bandh' means 'to close' in Sanskrit, the language used for Yoga descriptions.

The patients were sent to the surgeon after 10 days of counseling with AID. Surgeon was kept blind about the randomization. Diagnosis of hemorrhoids was based upon clinical examination including anoscopy. Patients were operated under general anesthesia (GA) or regional anesthesia (RA), if GA was contraindicated.

Standard technique for PPH as described in literature<sup>3</sup> without any variation was followed. A standard 33 mm circular hemorrhoid stapler (Ethicon PPH03) was used as reported by others<sup>1</sup>. Hemostasis was always ensured at the completion of the procedure. The resected

“doughnut” was sent for histopathological examination (HPE) to rule out any presence of squamous anal mucosa in it. Patient needing an operative relook for bleeding or presence of squamous anal mucosa on HPE were to be excluded from data analysis.

Once assessed by the anesthetist for recovery from GA/RA, patients were allowed normal diet and no intravenous fluids were given beyond 2 hours of surgery. In case of acute retention of urine, a catheter evacuation was done. All patients were operated on day care basis and discharged with 6-8 hours of surgery in case of GA or within 24 hours in case of RA.

Intraoperative antibiotic chemoprophylaxis (cefuroxime + metronidazole) was followed with 3 days of oral antibiotics and metronidazole. Paracetamol 650 mg every 6 hrs was used as an analgesic. Diclofenac (NSAID) was used on demand for pain >5 on a 10 point visual analog scale (VAS). Need for diclofenac usage after 3 days was taken as an indicator of significant pain. Patients were followed over the telephone till their 1<sup>st</sup> visit to us on 3<sup>rd</sup> postoperative day. They were advised to resume their normal Activity, Bath, Commitments, Diet, Exercise, Family / Fun life (ABCDEF) thereafter. After 3<sup>rd</sup> day use and quality of analgesia were regulated according to demand and requirement.

Patients were evaluated by the AID at the end of 1<sup>st</sup> week, 2<sup>nd</sup> week and 3<sup>rd</sup> week. The study points recorded by AID were significant pain (pain requiring NSAID or pain >5 on a 10 point VAS), painful defecation, anal irritation / burning pruritus, failure to discriminate between flatus or feces, difficult hygiene / perianal soiling, rectal urgency and return to normal activity (RNA). For any symptoms the patients were managed by AID.

The data was prospectively tabulated in Microsoft Excel Sheet. Student ‘t’ test and ‘test for proportions’ were used for statistical analysis.

## RESULTS

This study was conducted on hemorrhoid patients presenting with bleeding as the main symptom. One hundred consecutive patients were prospectively randomized and included from December 2005 – November 2007. Control Group (n=50) had PPH without any peri-operative Yoga Exercises. Study Group (n=50) had PPH with peri-operative Yoga Exercises. The two groups were well matched for age, gender, and grades of hemorrhoids, other symptoms and the type of anaesthesia used for PPH. These data are shown in Table 1.

**Table 1: Showing Demographics & Symptoms**

Characteristics	Control(non-Yoga)	Study(Yoga)	p value
<b>Age (years)</b>			
Mean	48.4	48.2	0.94
Range	22-84	23-86	
<b>Gender</b>			
Male	40	42	0.37
Female	10	8	0.37
<b>Clinical</b>			
Grade2	14	14	0.39
Grade3	24	25	0.39
Grade4	12	11	0.39
<b>Other Symptoms</b>			
Prolapse	14	17	0.35
Mucus discharge	11	13	0.37
Itching	13	14	0.39
Pain	12	12	0.39
Difficult Hygiene	9	8	0.39
Perianal soiling	6	5	0.38
<b>Anesthesia</b>			
General	32	36	0.33
Regional	18	14	0.33

There was significant improvement in the study group for post-operative pain & painful defecation. This improvement was seen consistently during the follow up from week 1 to week 3 as shown in Table 2.

Failure to discriminate between flatus and feces was not reported by any patient in either arm of the study. Anal-irritation/ burning or pruritus were reported to be significantly less in the Yoga Practicing group. This improvement was consistent throughout from week 1-

**Table 2: Patients having significant pain (VAS scale) / requiring NSAID**

End points	Pain			Painful Defecation		
	Week1	Week2	Week3	Week1	Week2	Week3
Control Group. n (%)	34(68)	21(42)	5(10)	34(68)	20(40)	5(10)
Study Group. n (%)	1(2)	1(2)	0(0)	11(22)	5(10)	0(0)
p Value	<0.0005	0.00001	0.02	0.0004	0.01	0.024

week 3 follow up as shown in Table 3.

**Table 3: Outcomes about Perianal irritation/burning/pruritus**

End points	Anal-Irritation/Burning/Pruritus		
	Week1	Week2	Week3
Control Group. n (%)	22(44)	19(38)	12(24)
Study Group. n (%)	3(6)	0(0)	0(0)
p Value	0.0004	<0.0008	0.0001

Difficult hygiene and peri-anal soiling showed improvement in the study group only at the Week1 follow up. Incidence of Difficult hygiene / Peri-anal soiling and rectal urgency though comparatively lower in the Yoga Practicing group was statistically not significant. Rectal urgency resolved completely on its own by the Week3 follow up in both the arms of the study. These data are shown in Table 4.

**Table 4: Showing hygiene and rectal urgency outcome**

End points	Difficult Hygiene			Urgency †	
	Week1	Week2	Week3	Week1	Week2
Control Group. n (%)	15(30)	10(20)	1(2)	10(20)	7(14)
Study Group. n (%)	3(6)	3(6)	0(0)	4(8)	2(4)
p Value	0.02	0.11	0.23	0.17	0.17

† Rectal urgency was not reported by any patient in either arm at Week3

Both groups had similar incidence of urinary retention and postoperative bleeding needing surgical intervention. Urinary retention (n=2) and reactionary hemorrhage (n=2) were seen only in patients operated under RA irrespective to Yoga practice or not. Yoga practice or non-practice did not seem to affect the incidence of either post-operative bleeding or urinary retention. All the patients excluding those needing intervention for bleed were discharged within 24 hours. Patient with postoperative reactionary hemorrhage (n=2) were managed within 4-6 hours of first surgery (PPH). They needed blood transfusion and hospitalization for 3 days. In all other patients (n=98) there was no prolonged hospitalization, technical failure, failure to get a complete doughnut, need to convert to open hemorrhoidectomy, blood transfusion, rehospitalization, or mortality. No secondary hemorrhage was noticed in either arm of the study during a 3-week follow up.

Squamous anal mucosa was not reported in any HPE of the doughnuts hence there was no exclusion.

## DISCUSSION

Hemorrhoids present in >50% of population over 40 years of age require treatment only if symptomatic<sup>1</sup>. Thomson demonstrated that in symptomatic patients, the hemorrhoidal cushions slide downwards, together with anal mucosa owing to fragmentation of Parks ligament<sup>5</sup>. All the patients had adequately tried the available non-surgical methods such as Sitz bath, stool softeners, fiber supplements and variety of local applications before opting for surgical consultation<sup>12</sup>. They were tried by all the patients in both the arms of this study. This indicates that surgery is not the first option exercised by symptomatic hemorrhoid patients. Nonsurgical option like band ligation etc are popular but are not practiced in our surgery. Fear of postoperative pain is an important limiting factor for patients seeking treatment. Neither patient nor surgeon wants unnecessary pain<sup>13</sup>. The surgeons have contemplated addition of sphincterotomy, anal dilatation and use of anal relaxant etc to reduce pain but without total satisfaction<sup>2</sup>.

Development of the technique of stapled mucosectomy was a giant step in addressing this concern about pain. Pescatori et.al<sup>14</sup> described stapled mucosectomy for the first time in 1997. PPH has become popular over a short period since its introduction about a decade ago<sup>4</sup> mainly due to being less painful<sup>1</sup>. This pain related advantage attributable to PPH has been cited by a systematic review on PPH as a “trade off” for long term disadvantages like prolapse and recurrence<sup>15</sup>. Short term benefits of PPH have ensured its popularity ignoring the long term adverse outcomes<sup>15</sup> It has been accepted as a safe, effective and day care procedure<sup>3</sup>. It's results are theoretically premised upon disruption of the superior hemorrhoidal artery<sup>3</sup>, restoration of hemorrhoid cushions to their physiological position<sup>3</sup>, and placing the site of surgical resection safely proximal to the sensitive zone i.e. dentate line<sup>3</sup>. Anticipated progressive shrinkage of external portion due to discontinuity in vascular supply has been recently disproved<sup>16</sup>. Despite these theoretical premises and perceived popularity some concerns persist. Some workers have even titled their work on this subject as “Stapled hemorrhoidectomy: pain or gain”<sup>13</sup>.

Complementary and alternative medicine intervention incorporating Yoga have been helpful in painful conditions<sup>17</sup>. Yoga has been shown to decrease edema, improve lymphatic circulation, decrease antibiotic requirements and symptoms<sup>18</sup>. Benefits of yoga to pelvic floor/structures have been successfully incorporated in assisting non-interventional deliveries in Breech presentation<sup>19</sup>. Symptoms relating to anorectal pain are due to sphincter spasm as a reflex to passage of stool<sup>5</sup>. The voluntary sphincter like any other muscle can be trained, strengthened and made supple by exercise. Thus yoga exercise i.e. Moolbandh, is likely to reduce the symptoms of sphincter origin. Total absence of significant pain (no demand for NSAID painkiller) in the study group as against pain upto 3 wks in control group supported the benefit of yoga. This was further substantiated by absence of painful defecation from 3<sup>rd</sup> week onwards in the patients practicing yoga.

Moolbandh, a yogic exercise aims at invoking cyclical stretch and relaxation. Moolbandh is specifically targeted at the muscles and connective tissue in the anorectal region. Yoga has been found to be useful in management of painful conditions<sup>7</sup>. It has been known that mechanical stretch moderates the reparative actions of transforming growth factor  $\beta$ -1 favorably<sup>8</sup>. Biosynthetic synergism has been seen between transforming growth factor  $\beta$ -1 and cyclical stretch<sup>9</sup>. These effects have been recorded within 7 days of just 20%-30% stretch for 10 minutes twice a day<sup>8</sup>. Cyclical stretch induces significant increase in transforming growth factor  $\beta$ -1 synthesis in 12 hours and also increases the cellular Matrix-Metalloproteinase-2 activity in 24 hours<sup>11</sup>. All these actions help in repair of tissues by facilitating matrix remodeling<sup>11</sup>. This is expected to help a patient by expediting a healthier response to surgical trauma<sup>8</sup>. The stretch related benefits are not limited to contractile muscular tissues alone. They have been shown to improve connective tissue contractility induced by subcutaneous tissue stretch<sup>10</sup>. Moolbandh is expected to train only the external sphincter but these observations support a beneficial impact on all the tissues around anorectum. A better and synergistic repair response is expected. It should lead to patient comfort and lesser pain.

Postoperative pain has been reported as a deterrent in taking decision to go for surgery<sup>5</sup>. The accepted definition of pain is with the VAS score. Present study used VAS scoring to determine whether the patients had significant pain (needing NSAIDs or needing Paracetamol beyond three days or the pain being > 5 on VAS ). As none of the patients in the study (YE) group had such significant

pain, the need to compare individual VAS scores with the control group did not arise. Absence of pain in our study group enabled the patients to return to normal activity within 2 days (range 1-6) as against thrice longer in the control group. A recent systematic review of PPH reports significant benefit in 95% of the trials included after checking their compliance to defined criteria for inclusion<sup>15</sup>. Yet post-evacuation pain remains a valid concern. This new onset post-evacuation pain may compromise the life style, including the ability to return to work<sup>20</sup>. A variety of treatments like topical 0.2% glyceryl trinitrate ointment, metronidazole or even Botox infiltration have been used for post-evacuation pain. Thaha et.al<sup>20</sup> have reported success in treating this post-evacuation pain by using oral Nifedipine therapy. Adequate sphincteric control is necessary for hygiene. Lower incidence of soiling, anal irritation, burning or pruritus in the study group supported the efficacy of yoga. Chronic anal pain and fecal urgency are specific complications of PPH<sup>21</sup>. These are distinct disadvantages verses conventional hemorrhoidectomy<sup>22</sup>. A consensus statement on PPH has recommended inclusion of such symptomatic outcomes in the informed consent<sup>23</sup>. Fecal urgency, the culprit sited in these studies was helped by the yoga exercises as shown by lesser incidence in comparison to control group. Urinary retention has been reported and attributed to regional anesthesia. Fluid restriction has been shown to help this<sup>3,12</sup>. Present study had similar observation. Retention of urine was not affected by yoga exercises. Incidence of reactionary hemorrhage was also noticed to be same in both the arms of the study. Reactionary hemorrhage manifested within 4-6 hours of surgery. This was also noticed only in PPH performed under regional anesthesia, unaffected by the yoga exercises. This seems to be related to technical aspect of the surgery, as an identifiable bleeder was found in both cases at the staple line. We probably missed it on the table. Absence of secondary hemorrhage supports the technical failure being the only cause of the bleeding.

PPH has rightly earned its place of acceptance and popularity. Its outcome has become better with experience and adherence to the standard technique over and over again<sup>12</sup>. PPH has widely been perceived as an appropriate procedure for Grade III & IV hemorrhoids. Initial treatment for the lower grade hemorrhoids is non-surgical. Surgical intervention may become necessary if non-surgical measures fail<sup>15</sup>. Patients with Grade II hemorrhoids were included in the present study only after exhausting the non-surgical options available. This is supported by inclusion of eleven trials with Grade II hemorrhoids in a recent systematic analysis of twenty seven randomized trials on PPH<sup>15</sup>. The symptomatology, grading<sup>24</sup> and clinical appearance are known to be deceptive in predicting symptoms after surgery<sup>12</sup>. Yet the evaluation of the symptoms has been considered a useful tool for evaluation of the technique of PPH<sup>5</sup>. Hence any endeavor that improves the symptomatic outcome will help in making the procedure even more effective and popular. Biofeedback therapy or pelvic physical therapy has been incorporated in Western societies to help achieve it. Yoga aimed at or around the Perianal region is a kind of pelvic physical therapy. Available literature is silent about any similarities between the two. Application of Yoga into modern medical sciences has not been investigated at all especially in context of the surgical procedures for the hemorrhoidal disease. Improvement in postoperative pain & painful defecation were the most striking benefits of Yoga in the present study. Postoperative pain, a specific complication of PPH is reportedly associated with higher anal sphincteric pressures<sup>20</sup>. Nifedipine has been reported to alleviate this pain without lowering the anal sphincteric pressures<sup>20</sup>. Thus aetiology of this pain remains unclear & functioning of rectal muscle is thought to more relevant than the

anal sphincter<sup>20</sup>. The benefits of Yoga in our study may have improved the functioning of rectal muscles in addition to the anal sphincter & the perianal connective tissue.

Yoga is seen not only as a set of esoteric exercises but also as an integral part of oriental culture. It's inherent non-invasiveness and harmlessness emanates from the test of time and voluntary integration in the culture. The ancient wisdom has been recognized as a supportive inspiration even for the basic sciences. In the present study yoga was seen to reduce most of the symptoms affecting the outcome negatively. The benefits of Yoga in PPH outcomes are significant because of the good number of patients in the study (n=100). Studies for PPH with 20 or more participants have been considered as having adequate power even for rare outcomes<sup>15</sup>. Present study's results are encouraging considering a much larger sample size for evaluating a much common outcome measure i.e. pain. Present study to evaluate application of this yogic benefit had a limitation of the AID being a common team giving yoga lessons and doing postoperative evaluation. Yoga, a non-invasive tool does not require marshalling of any fresh resources and is popularly seen as harmless. It can be incorporated in surgical practice of PPH. Quantification of the molecular basis of benefits by Yoga Exercises is theoretically possible in light of the available wisdom<sup>8, 9, 10, 11</sup>. The available scientific literature is silent about the efficacy of Yoga in modern surgical practice. Present study can be a useful index for larger, multicentre double blind randomized trials. Also long term impact of Yoga on PPH needs to be studied.

## CONCLUSION

PPH outcomes may be improved by incorporation of yoga perioperatively.

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## PITAVASTATIN

### DRUG PROFILE

A novel statin i.e Pitavastatin, a potent agent for lowering LDL cholesterol level, without affecting glycemic control in patients with diabetes, as seen often atorvastatin group. No significant changes occur in Fasting plasma glucose and HbA1c levels. Thus, Pitavastatin may be more suitable for the treatment of hyperlipidemia in patients with type-2 diabetes.

Statins and HMG-CoA reductase inhibitors, in addition to lowering LDL-C levels is also known to suppress the progression of atherosclerosis by their pleiotropic effects. Glucose uptake by differentiated 3T3-L1 cells was reported to be unaffected by pitavastatin. Simvastatin or a Atorvastatin seem to have a potential adverse effect on glucose metabolism. The CHIBA study also demonstrated that liver enzymes like AST, ALT and YGTP increase significantly in patients receiving atorvastatin but not in those receiving pitavastatin. Pitavastatin 2mg/day is associated with significantly greater increases in Apo A-I levels.

Various comparative clinical trails have concluded that: 1) statins marginally affect HbA1c levels and sometimes produce diabetes; however, pitavastatin does not show adverse effect on HbA1c levels; (2) pitavastatin is a safer drug to use as compared to other statins since it has no effect on lipoactive functions; (3) pitavastatin has been shown to have no effect on the plasma glucose levels, which makes it a favorable drug for patients with type-2 diabetes.