



A PROSPECTIVE STUDY COMPARING OPEN MESH INGUINAL HERNIA REPAIR USING PROLENE HERNIA SYSTEM (PHS) AND LICHTENSTEIN REPAIR.

General Surgery

Neha Mahajan	Assistant Professor, Department of Surgery, Govt. Doon Medical College, Dehradun.
Nitin Sharma*	Assistant Professor, Department of ENT, Govt. Doon Medical College, Dehradun. *Corresponding Author
Nikhil Gupta	Associate Professor, Department of Surgery, Dr. Ram Manohar Lohia Hospital, New Delhi.

ABSTRACT

Introduction: Various methods of open inguinal hernia repair have been devised so far. This study compares PHS repair with Lichtenstein repair and describe their short- and medium- term outcomes for postoperative pain, period of convalescence and any complications (including recurrence) related to them.

Method: This prospective randomized controlled trial was conducted in a 600 bedded tertiary care health centre. The repairs were performed as previously described by Gilbert et al and Lichtenstein et al respectively and the data analysed statistically.

Results: Demographic data was similar in the two groups. The mean pain scores, analgesic requirements and convalescence period were similar in the two groups. Complications were slightly less with PHS group compared to Lichtenstein group, though not significant.

Conclusion: Nearly sutureless PHS technique results in faster or easier convalescence with less risk of chronic groin pain or complications compared to Lichtenstein repair.

KEYWORDS

Prolene Hernia System (PHS), Lichtenstein Mesh Repair (LMR), Groin Pain, Convalescence.

INTRODUCTION

Various methods of open inguinal hernia repair have been devised so far. Although the most important criteria for the choice of method are safety (morbidity and mortality), recurrence rates and convenience for the patient; the short-term comfort of the patient, measured by postoperative pain and the length of convalescence has gained great importance in the recent years.¹ The reported incidence of chronic pain 1 year after hernia repair varies from 0.7 percent to 28.7 percent. Considering the large number of such procedures performed annually, this postoperative pain represents a serious problem.²

Though some studies have confirmed the efficacy of the procedure in reducing the recurrence rates and postoperative complications, very few studies highlight postoperative pain, chronic groin pain, length of convalescence. This prospective study compares the PHS with the Lichtenstein repair and describes short- and medium- term outcomes for postoperative pain, quality of life and any complications (including recurrence) related to them.

MATERIAL AND METHODS

Study Design

100 adult patients attending OPD of ESI Hospital, New Delhi were included in the study. Randomization was done by sealed envelopes using computer-generated allotment. 50 hernioplasty were performed with the PHS repair and 50 hernioplasty with the Lichtenstein technique. The study spanned over a period of 18 months from April 2010 to Oct 2011.

Selection Criteria

Inclusion Criteria

Only the adult patients with uncomplicated primary unilateral inguinal hernias in the age group of 15-65 years were included in the study.

Exclusion Criteria

Patients with recurrent inguinal hernia, obstructive hernia, strangulated hernia, sliding hernia, or patients refusing to participate in the study were excluded from the study.

TECHNIQUE

All procedures were elective. The diagnosis of inguinal hernia was based on history and clinical examination. Patient characteristics were recorded. All patients received single dose of prophylactic antibiotic at the time of induction. All repairs were performed under regional anaesthesia. The Lichtenstein repair was performed as previously described by Lichtenstein et al.³ The PHS mesh repair was performed as described by Gilbert et al.⁴

Postoperative groin pain, period of convalescence, and any complications were recorded for each patient. Most patients were discharged on first post-operative day provided they exhibit no sign of complications. There were no restrictions on mobilization. Pain scores were recorded daily during hospital stay using VAS and pain was graded into none (VAS= 0), mild (VAS= 1-3), moderate (VAS= 4-6), severe (VAS= 7-10) accordingly. All patients were reviewed at 2 weeks, 6 weeks, 3 months and 6 months and physical examination was performed to detect any wound problems and note VAS scores and period of convalescence.

Statistical Analysis

The statistical analysis was performed using the SPSS (version 19.0, SPSS, Inc., Chicago, IL) software package. The primary end points included pain score by visual analogue scale, and the period of convalescence. The secondary end points were recurrence and any other complications.

OBSERVATIONS AND RESULTS

A total of hundred patients were randomly allotted to receive one of the two repairs. Patient characteristics and operative findings were comparable between the two groups (Table 1). All patients were followed for the first six months and eighty-six patients completed a median follow-up of 12 (range 6-18) months.

Table 1. Demographic Data Of The Study Population

Patient Characteristics	LMR (n=50)	PHS (n=50)	P-value
Mean Age(years)	41.52 (S.D.= 12.060)	40.58 (S.D.= 10.469)	0.852
Male sex	50	50	1
Manual occupation	40	38	0.629
Symptom duration(months)	15	17	0.668
Hernia, Type			
Direct	12	10	0.629
Indirect	38	40	
Hernia, Side			
Right	30	33	0.534
Left	20	17	
Coexisting conditions			
Urinary outlet obstruction	4	2	0.678
Chronic cough	2	0	0.495
Chronic constipation	8	4	0.218
Smoker	17	15	0.668
Hypertension	7	7	1
Diabetes	3	2	0.646

Congestiveheartdisease	1	0	0.315
PriorMyocardialinfarction	1	0	0.315
Alcoholconsumption>1drink/day	8	4	0.218
ASAclass			
I	8	8	1
II	38	40	0.629
III	4	2	0.678
IV	0	0	-

OPERATIVE RESULTS

Intraoperative complication included five cases of nerve damage, three in Lichtenstein and two in PHS. Damaged nerves were transected to avoid postoperative neuralgia. There was no injury to vessels or to vas deferens. All patients were observed for minimum period of 24 hours within hospital. The mean duration of hospital stay was 1.9 days (SD – 1.488) in the PHS group compared to 2.5 days (SD – 2.306) in the Lichtenstein group (P= 0.122, NS) (Table – 2).

Table – 2. Post-operative Hospital Stay.

	Number of Patients Discharged			Total
	a.1 st POD (24-48 hrs)	b.2 nd POD (48-72 hrs)	c.3 rd POD and onward s(>72 hrs)	

Table3. Pain Scores.

GROUP		VAS In 1 st 24 hrs	VAS In 24-48hrs	VAS On 7 th POD	VAS At 2 weeks	VAS At 6 weeks	VAS At 3 months	VAS At 6 months	VAS At 1 year
GROUP I (LICHTENSTEIN MESHREPAIR (LMR))	N	50	50	50	50	50	50	41	9
	Minimum	4	2	1	0	0	0	0	0
	Maximum	10	9	6	5	2	1	0	0
	Range	6	7	5	5	2	1	0	0
	Mean	6.98	4.36	2.42	1.54	.48	.04	.00	.00
	Std.Deviation	1.647	1.914	1.197	1.073	.614	.198	.000	.000
	Median	7.00	4.00	2.00	2.00	.00	.00	.00	.00
	Std.Error of Mean	.233	.271	.169	.152	.087	.028	.000	.000
GROUPII (PROLENE HERNIA SYSTEM (PHS))	N	50	50	50	50	50	49	38	7
	Minimum	4	1	0	0	0	0	0	0
	Maximum	9	9	6	4	1	0	0	0
	Range	5	8	6	4	1	0	0	0
	Mean	6.82	3.88	2.10	1.24	.34	.00	.00	.00
	Std.Deviation	1.848	1.955	1.282	.797	.479	.000	.000	.000
	Median	7.00	4.00	2.00	1.00	.00	.00	.00	.00
	Std.Error of Mean	.261	.276	.181	.113	.068	.000	.000	.000

CONVALESCENCE

There was no significant difference between the groups in terms of ambulation (P = 0.323, NS)(Table - 4). Ambulation was delayed more than 24 hours in one patient in the PHS group and two patients in the Lichtenstein group.

After PHS repair the patients tended to return to daily routine activities sooner than after Lichtenstein repair (P = 0.080, NS) (Table – 5). About 40 patients (80%) in the PHS group and 32 patients (64%) in the Lichtenstein group resumed their daily routine activities in less than 48 hours.

Patients with sedentary jobs returned to work earlier than those with heavy manual work. Fourteen patients in the PHS group and eleven patients in the Lichtenstein group returned to their work within one week. Mean time to return to manual work in patients who were employed was less in the PHS group [3.42 weeks (SD – 1.341)] as compared to the Lichtenstein group [4.02 weeks (SD – 1.464)] (P = 0.333, NS) (Table – 5).

Seven patients in the PHS group and four patients in the Lichtenstein group resumed driving and sporting hobbies in less than a week. However, mean time to return to driving and sporting hobbies was 4.14 weeks (SD – 1.325) versus 4.88 weeks (SD – 1.674) in the PHS versus Lichtenstein group (P = 0.227, NS) (Table – 5).

GROUP	GROUP I (LICHTENSTEIN MESH REPAIR (LMR))	Count	38	4	8	50
	%within GROUP		76.0%	8.0%	16.0%	100.0%
GROUP	GROUP II (PROLENE HERNIA SYSTEM (PHS))	Count	42	6	2	50
	%within GROUP		84.0%	12.0%	4.0%	100.0%
Total	Count	80	10	10	100	
	%within GROUP		80.0%	10.0%	10.0%	100.0%

Pain Scores (Table – 3)

Though the mean pain scores were less for the PHS group compared to the Lichtenstein group, no significant difference was seen between the two types of repairs in the incidence of pain at rest or while walking. The mean pain score in first 24 hours was 6.82/10 (SD – 1.848) in the PHS group compared with 6.98/10 (SD – 1.647) in the Lichtenstein group (P= 0.758, NS). Pain scores decreased markedly at two weeks after surgery. At two weeks, the PHS pain score was 1.24/10 (SD – 0.797) and the Lichtenstein pain score was 1.54 (SD – 1.073) (P= 0.116, NS). At six weeks, the mean pain score was 0.34/10 (SD – 0.479) in the PHS group compared with 0.48/10 (SD – 0.614) in the Lichtenstein group (P= 0.308, NS). All patients were pain-free at three months in the PHS group, though two patients in the Lichtenstein group continued to complain of some discomfort in the groin.

Table – 4. Ambulation.

			Number of Patients Ambulatory				Total
			a. Immediate with support (< 12 hrs)	b. Immediate without support (< 12 hrs)	c. In 12-24 hrs	d. After 24hrs	
GROUP	GROUP I (LICHTENSTEIN MESH REPAIR (LMR))	Count	33	9	6	2	50
		% within GROUP	66.0%	18.0%	12.0%	4.0%	100.0%
	GROUP II (PROLENE HERNIA SYSTEM (PHS))	Count	27	17	5	1	50
		% within GROUP	54.0%	34.0%	10.0%	2.0%	100.0%
Total		Count	60	26	11	3	100
		% within GROUP	60.0%	26.0%	11.0%	3.0%	100.0%

Table – 5. Summary Of Results.

GROUP		P O S T O P E R A T I V E H O S P I T A L S T A Y - I N D A Y S	T I M E T O R E T U R N T O D A I L Y R O U T I N E A C T I V I T I E S - I N D A Y S	T I M E T O R E T U R N T O W O R K I N W E E K S	T I M E T O R E T U R N T O D R I V I N G A N D S P O R T I N G H O B B I E S - I N W E E K S
GROUP I (LICHTE NSTEIN M E S H R E P A I R (LMR))	N	50	50	50	50
	Minimum	1	1	2	2
	Maximum	10	5	8	12
	Range	9	4	6	10
	Mean	2.50	1.60	4.02	4.88
	S t d . Deviation	2.306	1.107	1.464	1.674
	Median	2.00	1.00	4.00	4.00
	Std. Error of Mean	.326	.156	.207	.237
GROUP II (PROLEN HERNIA SYSTEM (PHS))	N	50	50	50	50
	Minimum	1	1	1	2
	Maximum	8	3	6	8
	Range	7	2	5	6
	Mean	1.90	1.32	3.42	4.14
	S t d . Deviation	1.488	.587	1.341	1.325
	Median	1.50	1.00	3.00	4.00
	Std. Error of Mean	.210	.083	.190	.187

COMPLICATIONS AND RECURRENCE

There was no significant difference in the postoperative wound complications. Ecchymosis was noted in four patients in the PHS group compared with eight in the Lichtenstein group ($P=0.218$, NS). Two patients in PHS group and four in Lichtenstein group developed postoperative wound infection ($P=0.408$, NS). They were managed using antibiotics and analgesics. Patients with infection tend to have higher pain scores and required more analgesics.

There was equal incidence of urinary retention in both the groups, seven in each group. One patient in the Lichtenstein group developed scrotal swelling compared with none in the PHS group ($P=0.315$, NS). He was managed using antibiotics and analgesics. None of the patients required re-exploration or removal of the mesh, though this prolonged the patients' postoperative hospital stay.

Two patients developed chronic groin pain in the Lichtenstein group compared with none in the PHS group ($P=0.153$, NS). There were no reported instances of restriction of daily activities secondary to the groin pain. Chronic groin pain prolonged consumption of analgesics. Two patients in the PHS group and three in the Lichtenstein group developed postoperative anaesthesia of the groin ($P=0.646$, NS). One patient, who was a smoker, developed recurrent herniation in the Lichtenstein group but no patient did in the PHS group ($P=0.315$, NS). The recurrence was noted within six months of the original operation.

DISCUSSION

The ideal inguinal hernia repair should provide effective coverage of the myopectineal orifice, have the lowest possible recurrence rate, have minimal operative and postoperative discomfort, and allow rapid return to normal activities. Furthermore, it should be applicable to most types of hernias encountered.⁵ In this study the hernia repair techniques of Lichtenstein and PHS are compared.

Demographic data of the study was similar to the previous studies conducted in the subject. Inguinal hernias present mostly in middle age group with most of the patients belonging to 26-35 years (33%) age group followed by 36-45 years (26%) age group. 78% of the patients were found to have indirect inguinal hernias. Right sided hernias were more common (63%).

OPERATIVE RESULTS

Postoperative Hospital Stay

The mean duration of hospital stay was less for the PHS group than

the Lichtenstein group. Metzger et al in their study have shown that the duration of sick leave is influenced mainly by the advice given by the doctors.⁶

Pain And Analgesia

Like most studies we have used VAS pain score because it is a simple way to monitor pain. However, the main drawback of using this scale is that pain is a complex phenomenon that is inadequately measured with a one-dimensional scale such as the VAS pain score or by recording the number and type of analgesics. Subjective pain assessment may not be suitable to distinguish the sensory changes that result from different operative techniques, as this measurement includes patients' perception of pain.²

In our study, the two treatment groups did not show any significant difference in the intensity or duration of postoperative pain. 80% of the patients were discharged on the first postoperative day with mild pain and no signs of complications. 83% of the patients reported no more than mild pain when walking one week after the operation. At two weeks only 4% of patients after either of the operation reported more than mild pain; the majority had no pain at all. These results are in line with earlier results of open mesh techniques.^{7,8} Kingsnorth et al in their study found that pain and analgesic consumption was significantly less in PHS group compared to the Lichtenstein group.⁹

Convalescence

After PHS repair the patients tended to return to work and sporting hobbies sooner. Vironen et al¹ and Kingsnorth et al⁹ have shown similar results in their study. Since Bay-Nielsen et al had realized that the hernia recurrence rate is independent of both time off work and the type of work done, ever shorter convalescence has been reported in the literature.¹⁰ The mean time to return to work in our study was 3 weeks in PHS group compared to 4 weeks in the Lichtenstein group. All patients were encouraged to return to work as soon as possible, but patients with heavy manual jobs returned to work approximately 6 days later than those with sedentary jobs.

Complications And Recurrence (Table 6)

Overall, complications were less for the PHS group compared with Lichtenstein group though not statistically significant. Mayagoitia has shown similar results in his study.⁸ Huang et al showed decreased neuralgia with the PHS repair when compared with the plug and patch technique.¹¹ Our study showed similar results with one case of postoperative neuralgia in the Lichtenstein group while none in the PHS group.

PHS aims to prevent any form of hernia recurrence through the myopectineal orifice, including occult femoral hernias.⁷ In contrast to laparoscopic preperitoneal repairs, the underlay of PHS is not fixed to the surrounding structures, allowing for greater flexibility of the underlay to contour to the abdominal wall in a tension-free manner.¹² In our study only one recurrence was reported in the Lichtenstein group while no recurrence occurred in the PHS group. Recurrence in Lichtenstein repair occurred between the posterior wall and the mesh as has been described by Gilbert⁴ and required repeated surgery for repair of hernia.

Table 6. Various Studies Showing Zero% Recurrence In PHS Repair.

Study	Year of study	Number of patients	Recurrence in PHS	Recurrence in Lichtenstein repair
Gilbert A et al ⁴	1999	759	0	-
Kingsnorth A et al ⁹	2002	206	0	2
Safwat Y et al ¹³	2002	55	0	-
Mayagoitia J C ⁸	2004	250	0	1

CONCLUSIONS

On the basis of observations made, it can be safely concluded that there is no significant difference in intensity and duration of postoperative pain between the two groups. Convalescence period was similar in both the groups.

However, PHS has some advantages over the Lichtenstein repair which can be summarized as follows:

- Learning curve for PHS is short which is equivalent to the Lichtenstein repair and better than Laparoscopic repairs.
- The application of PHS mesh is quite easier which can be done

through a small incision.

- PHS offers complete protection against all types of groin hernias including femoral hernias as well, which are not taken care of by the Lichtenstein repair.
- PHS has zero% chance of recurrence which is not yet achieved by the Lichtenstein repair.
- Nearly sutureless PHS technique results in faster or easier convalescence with less risk of chronic groin pain or complications compared to the Lichtenstein repair.
- Considering its overall benefits and earlier convalescence further studies can be encouraged.

REFERENCES

1. Vironen J, Nieminen J, Eklund A et al. Randomized clinical trial of Lichtenstein patch or Prolene Hernia System for inguinal hernia repair. *Br J Surg.* 2006; 93(1): 33-39.
2. Nienhuijs SW, van Oort I, Keemers-Gels ME et al. Randomized clinical trial comparing Prolene Hernia System, mesh plug repair and Lichtenstein method for open inguinal hernia repair. *Br J Surg.* 2005; 92(1): 33-38.
3. Lichtenstein IL, Shulman AG, Amid PK. The tension-free hernioplasty. *Am J Surg* 1989; 157: 188-193.
4. Gilbert AI, Graham MF, Voigt WJ. A bilayer patch device for inguinal hernia repair. *Hernia* 1999; 3: 161-166.
5. Awad SS, Fagan SP. Current approaches to inguinal hernia repair. *Am J Surg (Suppl. Dec 2004);* 188: 9S-16S.
6. Metzger J, Lutz N, Laidlaw I. Guidelines for inguinal hernia repair in everyday practice. *Ann R Coll Surg Engl* 2001; 83: 209-214.
7. Sanjay P, Harris D, Jones P et al. Randomized controlled trial comparing prolene hernia system and Lichtenstein method for inguinal hernia repair. *ANZ J Surg.* 2006; 76(7): 548-552.
8. Mayagoitia JC. Inguinal hernioplasty with the Prolene Hernia System. *Hernia* 2004; 8: 64-66.
9. Kingsnorth AN, Wright D, Porter CS et al. Prolene Hernia System compared with Lichtenstein patch: a randomised double blind study of short-term and medium-term outcomes in primary inguinal hernia repair. *Hernia* 2002; 6: 113-119.
10. Bay-Nielsen M, Thomsen H, Andersen FH et al. Convalescence after inguinal herniorrhaphy. *Br J Surg* 2004; 91: 362-367.
11. Huang CS, Huang CC, Lien HH. Prolene hernia system compared with mesh plug technique: a prospective study of short- to mid-term outcomes in primary groin hernia repair. *Hernia.* 2005; 9: 167-171.
12. Awad SS, Bruckner B, Itani KMF. Transperitoneal view of the Prolene Hernia System open mesh repair. *Int Surg.* 2005; 90 (suppl): S63-66.
13. Safwat YM, Fahmy AM, Ibrahim HA et al. Prolene Hernia System Repair Of Inguinal Hernias. *EJS.* 2002; 21(4): 1083-1087.