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Original Research Article

Efficacy of prolene hernia system in comparison to Lichtenstein mesh repair

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ABSTRACT

Background: Inguinal hernia repairs consume an important part of health care resources because of the high incidence of the problem. It is estimated that 20 millions of inguinal hernia repairs are performed globally every year. Every recurrence after a primary repair will add an extra cost to health care economics. Moreover, secondary or tertiary operations after previous repairs carry higher risk of re-recurrence and specific complications like testicular atrophy. Therefore, every surgeon should know and perform a current repair method successfully in his/her daily practice. The aim was to compare the efficacy of prolene hernia system with that of lichtenstein mesh repair in terms of early and late complications, operating time, time of return to work, chronic pain and recurrence.
Methods: 200 patients reporting and found eligible for the study were selected. They were divided into two groups. One group of 100 patients underwent the prolene hernia system type of surgery. Other group of 100 patients was operated by using Lichtenstein mesh repair. VAS score was used to assess the pain among the patients post operatively. All patients of both the groups were followed for a period of 10 years from August 2006 yearly to assess the occurrence of complications and recurrence among them.
Results: It was found that mean duration of surgery was lesser in PHS group of 25 minutes compared to 35 minutes in other group. On comparison of post-operative pain assessed by VAS score, it was found that the PHS group patients experienced only mild pain compared to mild to moderate pain in other group patients. Patient compliance was excellent in the PHS group compared to the other group. Patients in the PHS group were able to return to their work within 15 days compared to 30 days in other group.
Conclusions: Reports of this device (PHS) are encouraging, operating time is shorter and there is quick recovery. PHS provides all advantages of a tension - free repair, provides a stable anterior repair with added benefits of a posterior as well as plug repair. The high risk group of patient may be a good target as superior primary repair.

Keywords: High risk group, Prolene hernia system, Tension free repair

INTRODUCTION

Abdominal wall hernias are common, with a prevalence of 1.7% for all ages and 4% for those aged over 45 years. Inguinal hernias account for 75% of abdominal wall hernias, with a lifetime risk of 27% in men and 3% in women. Repair of inguinal hernia is one of the most common operations in general surgery, with rates ranging from 10 per 100 000 of the population in the United Kingdom to 28 per 100 000 in the United States. In 2001-2 about 70 000 inguinal hernia repairs (62 969 primary, 4939 recurrent) were done in England, requiring more than 100 000 hospital bed days. Ninety five per cent of patients presenting to primary care are male, and in men

the incidence rises from 11 per 10 000 person years aged 16-24 years to 200 per 10 000 person years aged 75 years or above.[1]

Inguinal hernia repairs consume an important part of health care resources because of the high incidence of the problem. It is estimated that 20 millions of inguinal hernia repairs are performed globally every year. Every recurrence after a primary repair will add an extra cost to health care economics. Moreover, secondary or tertiary operations after previous repairs carry higher risk of re-recurrence and specific complications like testicular atrophy. Therefore, every surgeon should know and perform a current repair method successfully in his/her daily practice.[2]

Inguinal hernia recurrence is still too frequent in the large published series. Whatever the surgical technique used, its incidence is often inaccurately recorded because of inadequate follow-up in terms of methodology used, its duration or proportion of patients followed up as compared to the 'operated-again' patients. The rate of recurrence appears to be between 0.2 and 10%; these rates well explain the importance of the problem, considering that hernia is a common problem around the world. Recurrences occur as a result of different causes and promoting factors: old age, obesity, type of anesthesia, suture material used, way of dealing with the sac, type of repair and postoperative complications. Today, especially in the era when use of prosthesis is common, our attention is as focused on the anatomical, biological and mechanical factors as it is on the adequacy of repair, choice of technique used and the operative errors.[3]

The prolene hernia system (PHS) is a three-dimensional mesh device that combines three approaches to hernia repair, but its high cost precludes its widespread use in developing countries.[4]

In 1998, the prolene hernia system (PHS) mesh, consisting of an onlay and an underlay patch attached with a connector, was introduced as an option for tension-free open repair of inguinal hernias combining the benefits of a posterior and anterior repair from an open approach.[5]

Such types of studies are rare in India. Hence present study was planned to study the efficacy of Prolene Hernia System with that of Lichtenstein mesh repair in terms of early and late complications, operating time, time of return to work, chronic pain and recurrence.

METHODS

Hospital based prospective study was conducted from December 2003 to August 2006. All these operated patients were followed for 10 years from August 2006 onwards on a yearly basis to assess occurrence of complications and recurrence.

A total of 200 patients of inguinal hernia aged between 22 to 78 years during the study period (December 2003 to August 2006) were included based on inclusion and exclusion criteria. They were divided into two groups of 100 patients each with similar characteristics in terms of age, sex, type of hernia, laterality of hernia so that comparison between the two techniques was possible.

Institutional Ethics Committee permission was obtained prior to the study. Informed written consent was taken from all patients.

Inclusion criteria

- Patients willing to participate in the study
- Both uncomplicated and recurrent inguinal hernia
- Age above 18 years

Exclusion criteria

- Patients with complications associated with inguinal hernia
- Any hernia other than inguinal hernia

200 patients reporting and found eligible for the study were selected. They were divided into two groups. One group of 100 patients underwent the prolene hernia system type of surgery. Other group of 100 patients was operated by using lichtenstein mesh repair. VAS score was used to assess the pain among the patients post operatively. All patients of both the groups were followed for a period of 10 years from August 2006 yearly to assess the occurrence of complications and recurrence among them.

Data was entered in Microsoft Excel sheet and analyzed using proportions.

RESULTS

Table 1: Distribution of study subjects as per characteristics of hernia in two groups.

Characteristics		PHS group (N = 100)	Lichtenstein repair (N = 100)
Side of hernia	Right	50	45
	Left	46	47
	Bilateral	04	08
Occurrence of hernia	Primary	90	92
	Recurrent	10	08
Type of hernia	Direct	64	58
	Indirect	32	36
	Pantaloon	04	06

It can be found from the above table that the distribution of patients in the two groups in the aspects of side of hernia, occurrence of hernia and type of hernia is almost similar. That is both the groups are similar making it

easier to compare the outcome among the two groups of patients operated by two different techniques for hernia.

Table 2: Associated co-morbidities among the two groups.

Associated co-morbidities	PHS group (N = 100)	Lichtenstein repair (N = 100)
Obesity	02	04
Diabetes mellitus	05	07
Hypertension	08	06
Chronic obstructive pulmonary disease	04	05
Age > 60 years (old age)	08	10
Total	**27**	**32**

Distribution of associated co-morbidities was also similar among the two groups. Total of 27 patients in PHS group and 32 patients in Lichtenstein repair group were found to have associated co-morbidities.

Table 3: Comparison of post-operative characteristics among the two groups.

Characteristics		PHS group (N = 100)	Lichtenstein repair (N = 100)
Duration of surgery (minutes)	Mean	25	35
	Range	20-30	30-45
Post-operative pain	VAS score (10-100)	10-20 (mild)	20-30 (mild to moderate)
Hospital stay (days)		02 (2-8)	04 (4-8)
Patient compliance	Excellent	95%	40%
	Good	05%	55%
	Poor	00	05%
Return to work		15 days	30 days

It was found from above table that mean duration of surgery was lesser in PHS group of 25 minutes compared to 35 minutes in other group. On comparison of post operative pain assess by VAS score, it was found that the PHS group patients experienced only mild pain compared to mild to moderate pain in other group patients. Patient compliance was excellent in the PHS group compared to the other group. Patients in the PHS group were able to return to their work within 15 days compared to 30 days in other group.

It can be seen from above table that only 4 patients in PHS group reported some type of complication compared to 9 patients in lichtenstein repair group. Recurrence, chronic pain, deep wound infection was nil in PHS group. Incidence of superficial wound infection was same in both the groups. Seroma was 3 times more common in lichtenstein repair group compared to PHS group.

Table 4: Comparison of complications and recurrence among the two groups.

Complications	PHS group (N = 100)	Lichtenstein repair (N = 100)
Hematoma	01	00
Seroma	01	03
Superficial wound infection	02	02
Deep wound infection	00	02
Chronic pain	00	01
Recurrence	00	01
Total	**04**	**09**

DISCUSSION

200 patients reporting and found eligible for the study were selected. They were divided into two groups. One group of 100 patients underwent the prolene hernia system type of surgery. Other group of 100 patients was operated by using Lichtenstein mesh repair. It was found that mean duration of surgery was lesser in PHS group of 25 minutes compared to 35 minutes in other group. On comparison of post-operative pain assess by VAS score, it was found that the PHS group patients experienced only mild pain compared to mild to moderate pain in other group patients. Patient compliance was excellent in the PHS group compared to the other group. Patients in the PHS group were able to return to their work within 15 days compared to 30 days in other group.

It was observed that in PHS group reported some type of complication compared to 9 patients in Lichtenstein repair group. Recurrence, chronic pain, deep wound infection was nil in PHS group. Incidence of superficial wound infection was same in both the groups. Seroma was 3 times more common in Lichtenstein repair group compared to PHS group.

Sanjay P et al 6 found that Mean duration of surgery in the PHS group was 36 min (SD±11) versus 34 min in the Lichtenstein group (SD±8; P = 0.3). There was no significant difference in analgesic requirements (P = 0.65). Overall mean pain score was 3.5/10 versus 2.5/10 (P = 0.1). Mean time to return to work was 42 versus 30 days (P = 0.3), returning to driving was 20 versus 14 days (P = 0.2) and full activity was 21 versus 22 days (P = 0.8). Chronic groin pain developed in four patients in the PHS group (12.9%) and in five patients in the Lichtenstein group (15.1%; P > 0.05). One patient developed recurrent herniation in the PHS group. The median follow up was 4.2 years (range, 4 - 4.6 years). Patient satisfaction was very high with both the techniques. Dalenback J et al observed that the mean operation time was shorter for PHS (35.5 min, P < 0.001) and PHS (37.4 min, P < 0.02) versus lichtenstein repair group (40.4 min).[7] More than 85% of the procedures were performed under local anaesthesia. There were no statistically significant differences between the groups

concerning early or late complications, return to full functional ability, early pain response, analgesic consumption or the studied late-outcome parameters after 3 years of observation. Seven (1.5%) evenly distributed recurrences were registered.

Vironen J et al noted that median duration of operation for unilateral primary hernia was 37 min for the lichtenstein operation and 27 min for the PHS procedure ($P < 0.001$).[8] Postoperative pain was similar after both operations. Median sick leave was 7 days in both groups. Time to driving a car was 4 versus 3 days, and time to return to sporting hobbies 13 versus 11 days, in the Lichtenstein and PHS groups, respectively. Apart from a residual femoral hernia after Lichtenstein repair, no recurrent inguinal hernias were detected. Huang CS et al concluded that the additional protective patch in the preperitoneal space of the PHS may provide a further safeguard against recurrences, especially for those patients with attenuated inguinal floor. Long-term follow-up is needed.[9]

Mayagoitia JC et al retrospectively reviewed early and late complications in 250 patients who underwent inguinal hernioplasties 125 performed with the Lichtenstein technique and 125 performed with the PHS from March 1998 October 2002.[10] Patients who underwent lichtenstein hernia repair had nine complications, and those who underwent PHS surgery had only two, none of the complications were serious. Older male patients who underwent lichtenstein hernia repair were more likely to have complications ($P = 0.04$). One patient in the lichtenstein group had a recurrence of his hernia, but there were no recurrences in the PHS group. In conclusion, the results of inguinal hernioplasties performed with the PHS are comparable to those achieved with lichtenstein hernia repair, the criterion standard technique. Zhao G et al concluded that Lichtenstein's operation was similar to mesh plug or PHS repair in terms of time to return to work, complications, chronic pain, and hernia recurrence in the short- to mid-term, although mesh plug and PHS repair was associated with shorter surgical time.[11] Yew MK et al reported that inguinal hernia repair with bilayer polypropylene mesh is safe and has low complication and recurrence rates.[12]

CONCLUSION

Reports of this device (PHS) are encouraging, operating time is shorter and there is quick recovery. PHS provides all advantages of a tension - free repair, provides a stable anterior repair with added benefits of a posterior as well as plug repair. The high-risk group of patient may be a good target as superior primary repair. The higher cost of the PHS as compared to conventional mesh makes its widespread use difficult. No two patients are alike and therefore no two hernias are alike either. No single tension free operative approach nor single mesh product system is suitable for all patients of all hernias. However, Prolene hernia system (PHS) is our preferred choice for the repair of both primary and recurrent adult inguinal hernias.

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