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A Comparative Study of Efficacy of GPRVS [Giant Prosthetic Reinforcement of Visceral Sac] Stoppa's Repair Over Lichtensteins Tension Free Mesh Repair for Bilateral Inguinal Hernias

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Abstract

Background and Objectives: Inguinal hernia is one of the most common surgical problems that present to a surgeon in his outpatient department, making hernia repair one of the most common operations performed by general surgeons. Various other methods of repair of hernia defect are also theorized. Stoppa's repair i.e the Giant Prosthetic Reinforcement of visceral sac is one of the methods which uses large prosthetic mesh placed in preperitoneal plane covering both the hernia orifices i.e it covers the whole myopectenial orifice bilaterally and is useful in cases of bilateral hernias, recurrent and unilateral hernias where risk of recurrence is more i.e when associated with COPD BPH, poor abdominal tone and previous surgery.

In this study the objectives are

1. To evaluate the efficacy of Stoppas repair in bilateral inguinal hernias.

2. To study the advantages of Stoppas repair with respect to,

a. Post Operative complications like wound infection, seroma formation, immediate post operative pain, chronic groin pain, rejection of mesh.

b. Duration of hospital stay

c. Days taken to return to normal activity.

d. Early recurrence.

Method: This prospective study was conducted in Department of General Surgery, ESICMC AND PGIMSR, Bengaluru, between November 2017 to March 2019.All patients aged above 18 with diagnosis of bilateral inguinal hernia were selected for the study after taking history and performing clinical examination and were randomized into two groups GROUP-LC(Lichtenstein Tension Free Mesh Repair) and GROUP-GPRVS(STOPPA'S REPAIR) group. The patients were randomly allocated to LC (Lichtenstein Tension Free Mesh Repair) and GPRVS (STOPPA'S REPAIR) group by computer generated randomization. A minimum of 70 were collected with 35 patients allotted to the Group GPRVS and 35 to the Group-LC.

Results: 70 patients, 35 in each group i.e. GROUP-LC and GROUP-GPRVS completed the study.The results showed that there was no significant decrease in the post operative complications such as wound infection, rejection of mesh, post operative pain, and early recurrence.

However 2 cases in GROUP-GPRVS developed seroma formation compared to 4 cases in GROUP-LC.

There were 5 cases of Chronic Groin pain in GROUP-LC compared to only 1 case in GROUP-GPRVS.

The duration of hospital stay was 5.23 days and 5.19 days in GROUP-GPRVS and GROUP-LC with no significant difference.

The duration taken to return to normal activity was a mean of 13.1 in GROUP-GPRVS and 11.3 in GROUP-LC which was found to be statistically significant.

Conclusion: Bilateral approach through a single incision for bilateral Inguinal Hernias provide better patient satisfaction with decreased incidence of seroma formation and lesser incidence of Chronic Groin pain.

It can be concluded that GPRVS(Giant Prosthetic Reinforcement of Visceral Sac) STOPPA'S repair can be considered as alternative to the Lichtenstein tension free mesh repair for Bilateral Inguinal Hernias since there was not much of difference seen with respect to post operative pain, wound infection, mesh rejection, Early recurrence, and duration of hospital stay. However further RCTs and Multicenter trials are needed to study the pros and cons of the procedure.

Introduction

Hernias may be generally defined as a "Protrusion of a viscus or part of a viscus through an abnormal opening in the walls of its containing cavity'. [1,2,3]

*"A protrusion of any viscus from its proper cavity is denominated a hernia. The protruded parts are generally contained in a bag by a membrane with which the cavity is naturally invested"– **Sir Astley Cooper 1804.***

Since the mid 1980's dramatic progress has been made in the evolution of hernia surgery by the increasing use of prosthetic mesh.[4,5,6] There are various methods in the placement of prosthetic mesh in hernioplasty.[7]

Inguinal hernia is one of the most common surgical problem that presents to a surgeon in his outpatient department, making hernia repair one of the most common operations performed by general surgeons. Hernia repair is one of the cornerstones of a general surgery practice.

Bassini revolutionized the surgical repair of the groin hernia who performed his first operation in 1884 and published the outcomes in 1889.

The concept of avoiding tension by onlay mesh repair was championed by Lichtenstein. Lichtenstein theorized that by using a mesh prosthesis to bridge the hernia defect rather than closing it with sutures tension is avoided, ostensibly resulting in a less painful operation. Now Lichtenstein's tension free mesh repair is considered as Gold standard for hernia surgery.[8]

Various other methods of repair of hernia defect are also theorized. Stoppa's repair i.e the Giant Prosthetic Reinforcement of visceral sac is one of the methods which uses large prosthetic mesh placed in preperitoneal plane covering both the hernia orifices i.e it covers the whole myopectenial orifice bilaterally and is useful in cases of bilateral hernias, recurrent and unilateral hernias where risk of recurrence is more i.e when associated with COPD BPH, poor abdominal tone and previous surgery.

In this study it is intended to compare the efficacy of GPRVS Stoppa's repair with the conventional Lichtenstein tension free mesh repair for bilateral inguinal hernias.

Materials and Methods

This prospective study was conducted in Department of General Surgery between November 2017 to March 2019.All patients aged above 18 with diagnosis of bilateral inguinal hernia were selected for the study after taking history and performing clinical examination and were randomized into two groups GROUP-LC(LICHTENSTEIN TENSION FREE MESH REPAIR) and GROUP-GPRVS(STOPPA'S REPAIR) group. The patients will be randomly allocated to LC (LICHTENSTEIN TENSION FREE MESH REPAIR) and GPRVS (STOPPA'S REPAIR) group by computer generated randomization.

All patients who presented with uncomplicated bilateral direct inguinal hernia were included in the study. Patients were allocated to two groups randomly. The inclusion into the study was done after explaining the purpose and procedure of the study and after obtaining informed consent from the patients. The two groups of patients comparable in age, body weight index, comorbidities, size and type of hernia. Informed consent was obtained from patients. Preoperative investigations include Hb, TC, DC, platelet count, ESR, chest and abdomen x-ray, RBS, S. Electrolytes, ECG. Mesh to be used in both methods of repair is polypropylene mesh. During postoperative period the incidence of wound infection, seroma formation, immediate post operative pain and chronic groin pain and rejection of mesh was compared in both groups of patients. Duration of hospital stay, was also compared in each group. In all cases on review, examination was done for early recurrence of hernia formation.

Source of Data: ESIC MC & PGIMSR, Bangalore.

Study Design: Prospective comparative study.

Study Period: From November 2017 to March 2019.

Sample Size: A minimum of 70 was collected.

Following formula has been used to calculate the sample size:

$$n = \frac{\left[Z_\alpha \sqrt{2 * \bar{P}(1-\bar{P})} + Z_\beta \sqrt{P_0(1-P_0) + P_1(1-P_1)}\right]^2}{(P_0 - P_1)\text{^}2}$$

Where, Z_α = 1.645, Z_β = 0.5244, P_0=.15, P_1= 0.01and $\bar{P} = \frac{P_0 + P_1}{2}$

Method of Collection of Subjects

The prospective study (comparative analytical study) was carried out in 70 patients of bilateral inguinal hernia admitted in ESIC MC AND PGIMSR BENGALURU

Inclusion Criteria

1. Patients ready to give informed written consent for participation in the study.
2. Patients admitted in the Department of General Surgery in ESIC MC and PGIMSR Bengaluru diagnosed to have Bilateral Inguinal Hernias.
3. Age > 18 years
4. Recurrent Inguinal Hernias

Exclusion Criteria

1. Obstructed or Strangulated Hernias
2. Primary Unilateral Hernias
3. Patients with Retroperitoneal Mass or Carcinoma Prostate
4. Sepsis of abdominal Wall
5. Previous midline scar from any other abdominal surgery
6. Congenital Inguinal Hernia

Statistical analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square (χ^2) test was used for association between two categorical

variables. The formula for the chi-square statistic used in the chi square test is:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript "c" are the degrees of freedom. "O" is observed value and E is expected value.

The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\overline{x_1} - \overline{x_2}) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where $\bar{x}_1$ = mean of sample 1

$\bar{x}_2$ = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

s_1^2 = variance of sample 1 = $\frac{\Sigma(x_1 - \bar{x}_1)^2}{n_1}$

s_2^2 = variance of sample 2 = $\frac{\Sigma(x_2 - \bar{x}_2)^2}{n_2}$

If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23.0. and Microsoft office 2007.

Results and Observations

Table 1: Distribution of Age between Study Groups

AGE(YRS)	GPRVS		LC		p value
	N	%	N	%	
31-40	4	11.4%	6	17.1%	0.017*
41-50	8	22.9%	18	51.4%	
51-60	18	51.4%	6	17.1%	
61-70	5	14.3%	5	14.3%	
Total	35	100.0%	35	100.0%	

Note: * significant at 5% level of significance (p<0.05)

Figure 1: Distribution of Age Between Study Groups

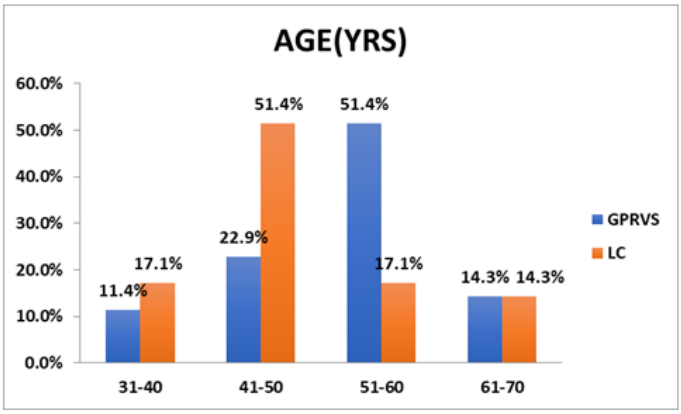


Table 2: Mean Age between Study Groups

Parameters	GPRVS		LC		p value
	Mean	SD	Mean	SD	
AGE(YRS)	52.3	8.5	47.8	7.9	0.026*

Note: * significant at 5% level of significance (p<0.05)

The mean age of patients in Group-GPRVS was 52.3+/-8.5 years and the mean age of patients in Group-LC was 47.8+/-7.9 with a p value of 0.026 which is statistically significant.

Figure 2: Mean Age between Study Groups

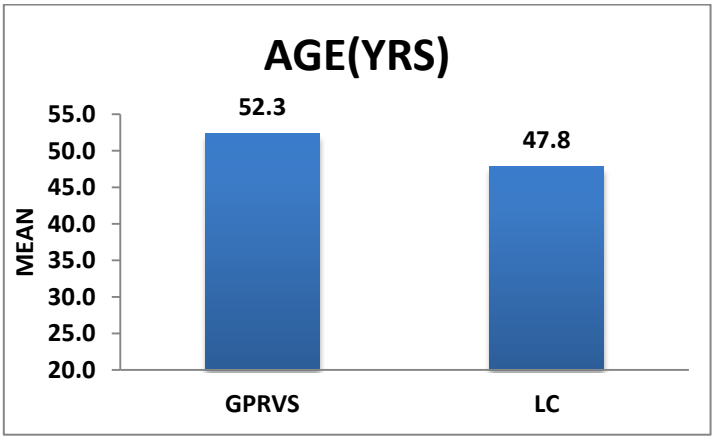


Table 3: Distribution of Sex Between Study Groups

Sex	GPRVS		LC		P Value
	N	%	N	%	
Male	35	100.0%	35	100.0%	-
Female	0	0.0%	0	0.0%	
Total	35	100.0%	35	100.0%	

All patients in both Groups were Males since Bilateral Hernias are found to be more common in Males.

Figure 3: Distribution of Sex between Study Groups

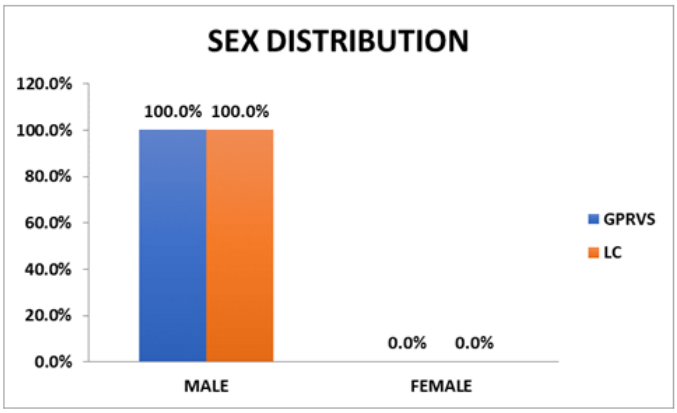


Table 4: Duration of Illness between Study Groups

		GPRVS	LC	Total	P Value
Duration Of Ilnness	<6m	15	17	32	0.064
	6m-1yr	13	14	27	
	>1yr	7	4	11	
Total		35	35	70	

Figure 4: Duration of illness

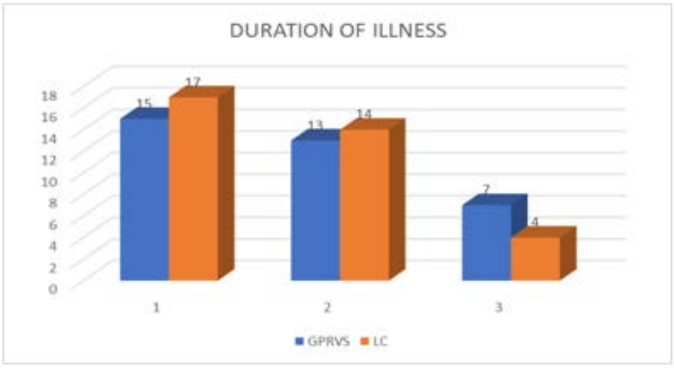


Table 5: Mode of Presentation between Study Groups

		GPRVS		LC		P-Value
Mode of Presentation	Swelling Only	18	51.4%	23	65.7%	0.166
	Swelling With Pain	17	48.6%	12	34.3%	
Total		35	100%	35	100.0	

51.4% patients in Group-GPRVS and 65.7% in Group-LC presented with Swelling in the Inguino-Scrotal region and 48.6% in Group-Gprvs and 34.3% in Group-LC had associated pain. Which shows that Swelling is the more common mode of presentation of Inguinal Hernia in my study.

Table 6: Type of Hernia between Study Groups

Type Of Hernia	GPRVS		LC		P Value
	N	%	N	%	
B/L Direct Inguinal Hernia	17	48.6 %	12	34.3 %	0.417
B/L Indirect Inguinal Hernia	14	40.0 %	18	51.4 %	
Combination	04	11.4 %	05	14.3 %	
Total	35	100.0 %	35	100.0 %	

48.6% in Group-GPRVS and 34.3% in Group-LC presented with Bilateral Direct Hernia whereas 40% in Group-GPRVS and 51.4% in Group-LC with Bilateral Indirect Hernia.With 11.4% in Group-GPRVS and 14.3% in Group-LC with Combined Direct And Indirect Hernias

Figure 5: Type of Hernia between Study Groups

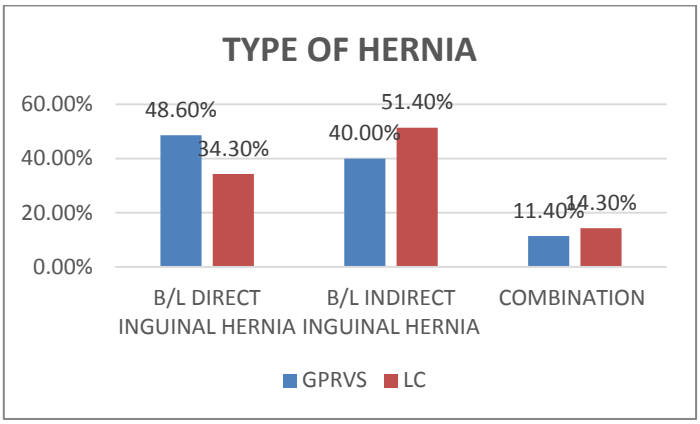


Table 7: Wound Infection between Study Groups

Wound Infection	GPRVS		LC		P Value
	N	%	N	%	
Yes	3	8.6%	3	8.6%	1.00
No	32	91.4%	32	91.4%	
Total	35	100.0%	35	100.0%	

3 patients in each of the two Groups developed Wound Infections which were treated as per Culture and Sensitivity Reports and Discharged later.

Figure 6: Wound Infection between Study Groups

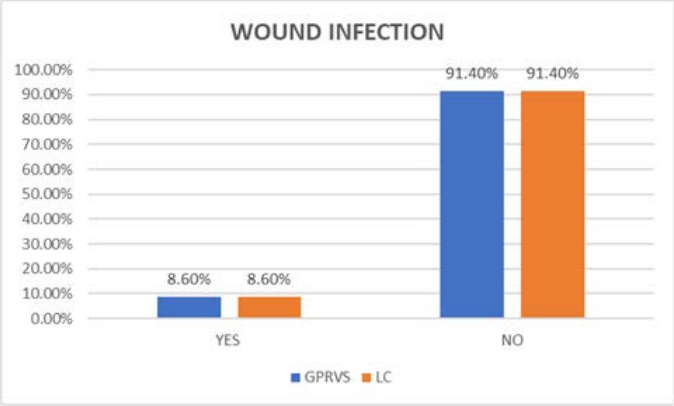


Table 8: Distribution of Seroma Between Study Groups

Seroma	GPRVS		LC		p value
	N	%	N	%	
Yes	2	5.7%	4	11.4%	0.393
No	33	94.3%	31	88.6%	
Total	35	100.0%	35	100.0%	

2 patients in Group-GPRVS and 4 patients in Group-LC developed Seroma which was confirmed through USG and Aspirated or Let out by opening of wound Sutures/Staples. p value of 0.393 was obtained which is not Statistically significant.

Figure 7: Distribution of Seroma between Study Groups

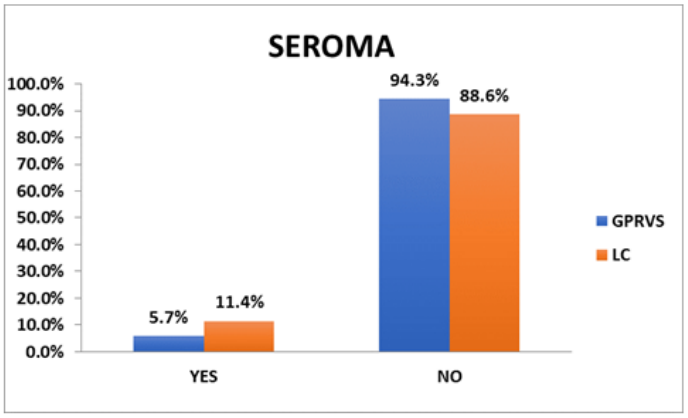


Table 9: Immediate Post Operative Pain Between Study Groups

Immediate Post Operative Pain	GPRVS		LC		P Value
	N	%	N	%	
1-2	0	0.0%	0	0.0%	0.382
3-4	0	0.0%	0	0.0%	
5-6	29	82.9%	26	74.3%	
7-8	6	17.1%	9	25.7%	
9-10	0	0.0%	0	0.0%	
Total	35	100.0%	35	100.0%	

Immediate Post Operative pain was assessed using VISUAL ANALOGUE SCALE on a score of 0-10 with 82.9% patients in Group-GPRVS and 74.3% patients in Group-LC had a score of 5-6 whereas 17.1% patients in Group-GPRVS had a score of 7-8 and 25.7% in Group-LC i.e. Less Post Operative Pain was Experienced in Group-GPRVS.a p value of 0.382 was obtained which was not found to be statistically significant.

Figure 8: Immediate Post Operative Pain between Study Groups

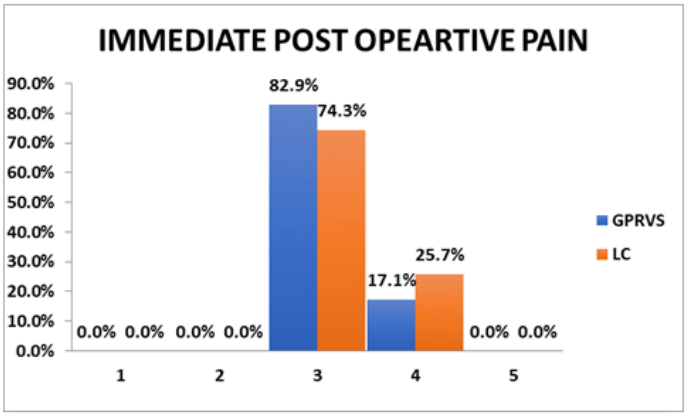


Table 10: Chronic Groin Pain Between Study Groups

Chronic Groin Pain	GPRVS		LC		p value
	N	%	N	%	
Yes	1	2.9%	5	14.3%	0.088
No	34	97.1%	30	85.7%	
Total	35	100.0 %	35	100.0 %	

14.3% patients in Group-LC and 2.9% patients in Group-GPRVS developed Chronic Groin Pain with a p value of 0.088 which was statistically not significant. However the incidence of chronic Groin pain being high in Group-LC.

Figure 9: Chronic Groin Pain between Study Groups

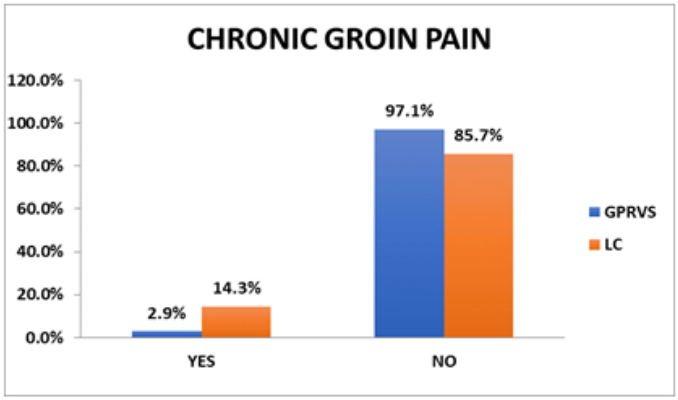


Table 11: Mesh Rejection between Study Groups

Mesh Rejection	GPRVS		LC		p value
	N	%	N	%	
Yes	0	0.0%	0	0.0%	-
No	35	100.0%	35	100.0%	
Total	35	100.0%	35	100.0%	

No cases of Mesh rejection were reported in the follow up period of 6 months.

Figure 10: Mesh Rejection between Study Groups

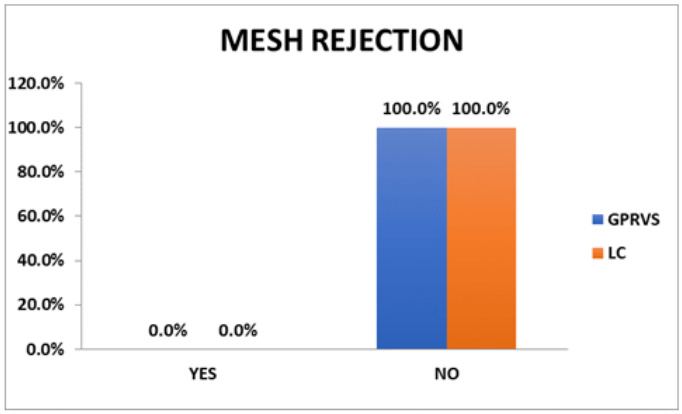


Table 12: Early Recurrence between Study Groups

Early Recurrence	GPRVS		LC		p value
	N	%	N	%	
Yes	1	2.9%	1	2.9%	1.00
No	34	97.1%	32	97.1%	
Total	35	100.0%	35	100.0%	

Patients were followed up at 1 week,2 weeks,1 month, 3 months and 6 months Post Operatively. 1 patient in each of the Group developed Recurrence. Both were unilateral Recurrence and treated as per EHS guidelines.

Figure 11: Early Recurrence between Study Groups

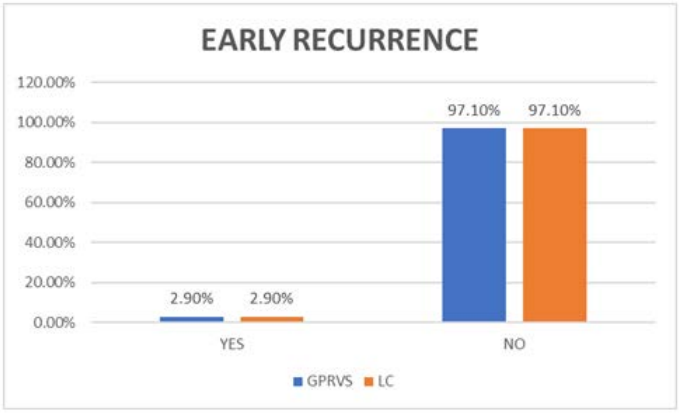


Table 13: Duration of Hospital Stay between Study Groups

Parameters	GPRVS		LC		p value
	Mean	SD	Mean	SD	
Duration of Hospital Stay (Days)	5.23	0.5	5.17	0.4	0.417

The duration of hospital stay was 5.23+/-0.5 in Group-GPRVS and 5.17+/-0.4 in Group-LC with a p value of 0.417 which is not statistically significant.

Figure 12: Duration of Hospital Stay Between Study Groups

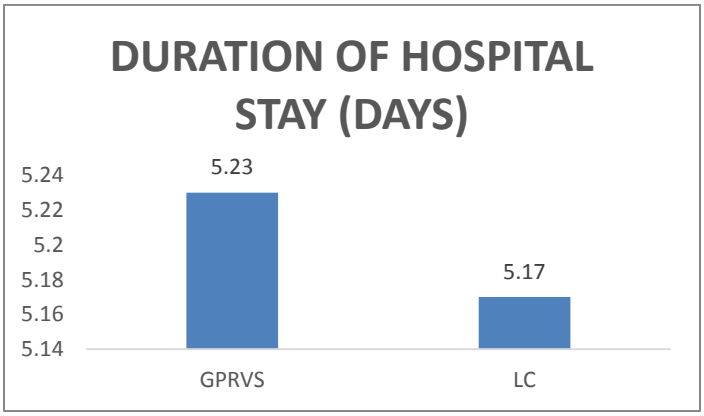


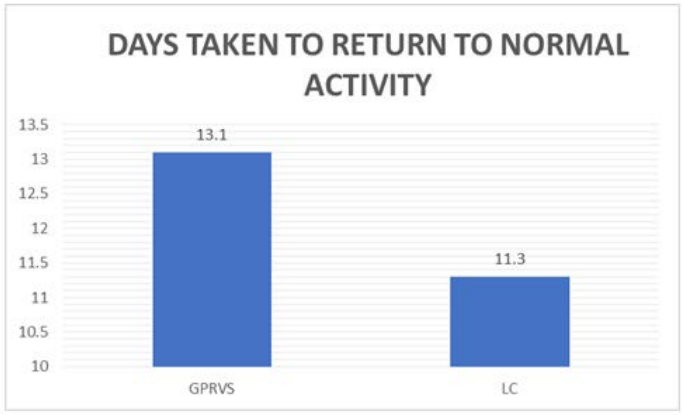
Table 14: Days taken to Return to Normal Activity between Study Groups

Parameters	GPRVS		LC		P Value
	Mean	SD	Mean	SD	
Days Taken To Return To Normal Activity	13.1	1.4	11.3	1.6	<0.001*

Note: * significant at 5% level of significance (p<0.05)

Patients of Group-GPRVS took 13.1+/-1.4 days to return to normal activity where as Patients of Group-LC took 11.3+/-1.6 days to return to normal activity with a p value of <0.001 which is statistically significant.

Figure 13: Days taken to return to normal activity between study groups



Discussion

The present study was conducted to compare the efficacy of GPRVS Stoppa's repair with the conventional Lichtenstein tension free mesh repair for bilateral inguinal hernias.

The hernia repair is most common procedure done by the general surgeon. The essential feature of GPRVS is the replacement of the transversalis fascia in the groin by a large prosthesis that extends far beyond the myopectineal orifice (MPO). The prosthesis envelops the visceral sac, held in place by intra-abdominal pressure and later by connective tissue ingrowth. The mesh adheres to the peritoneum and renders it inextensible so that it cannot protrude through the parietal defect. Parietal defects are not and, in fact, should not be closed.

The European Hernia Society elaborated guidelines for the treatment of bilateral inguinal hernias and recommended a one-stage procedure (Lichtenstein or laparoscopic). The Stoppa procedure can be another alternative for bilateral inguinal hernia treatment, but only for the surgeons familiar with it.[9],[10] This led us to carry out this study to compare the Stoppa procedure with bilateral Lichtenstein hernioplasty for the treatment of bilateral inguinal hernias.[11]

In present study, a total of 70 subjects went for hernia repair, 35 in GPRVS Stoppa's repair and 35 in conventional Lichtenstein tension free mesh repair. The Subject in GPRVS group was significantly older as compared to the Lichtenstein tension free mesh repair, which was similar to Youssef et al and contradictory with Z Abbas et al , Gavit et al. All the subject were males. Approximately 25% of all men will ever experience an (double) inguinal hernia. In contrast to this high percentage, only 2% of women are affected by inguinal hernias.[12],[13],[14],[15]

Related to type of hernia, B/L Direct Inguinal Hernia were more in GPRVS and B/L Indirect Inguinal Hernia were more in Lichtenstein group. However, there was no significant difference. Previous studies suggests that the indirect inguinal hernia is the most common type of inguinal hernia. It often occurs in premature babies, where the inguinal canal has not fully developed. However, this type of inguinal hernia can also occur at any other time in life and occurs mainly in men. A direct inguinal hernia usually occurs in adults. Often it is mistakenly thought that weak muscles during the adulthood lead to a direct inguinal hernia.[15]

In the past decade Lichtenstein repair has become the gold standard for treatment of inguinal hernias mainly due to the reduction in recurrences noted and due to the reproducibility of the procedure. It is used as a gold standard surgery for all types and sizes of bilateral inguinal hernia with very few exceptions but with two separate inguinal incisions. Several other complications of mesh repair include hematoma, seroma, ischemic orchitis, testicular atrophy, mesh infection and sinus formation. Young patients especially those undergoing mesh repair for Indirect Hernias are affected mostly with a risk of infertility in future. [16],[17]

However, in the present study .there was no significant difference in wound infection, distribution of stroma and immediate post-operative pain between the groups. Which was similar to previous studies done by Youssef et al, Z Abbas et al and Gavit et al.

Table 15: Comparison Of Incidence Of Seroma,Immediate Post Operative Pain And Wound Infection Between Studies

Studies	Seroma Formation			Immediate Post Operative Pain			Wound Infection	
	L	S	P Value	L	S	P Value	L	S
Yousseff Et Al				2.86=/-1.6	2.4=/-1.9	0.09	2.7%	1.4%
Zaheer Abbas Et Al				3.5=/-0.97	2.86=/-0.70	0.0004		
Gavit Et Al	2	3	0.099	5.93=/-1.12	4.39=/-1.03	<0.0001	3.6%	3.6%
Present Study	2	4	0.393			0.382	8.6%	8.6%

There were 5 cases of chronic groin pain reported in Lichtenstein group compared to 1 in GPRVS. This difference was found to be statistically insignificant. Increased incidence of chronic groin pain in Lichtenstein group may be due to the increased dissection in subaponeurotic neurovascular plane and also due to constant contact and impingement of the nerves with the mesh. The ilioinguinal and the iliohypogastric nerves are generally injured during the elevation of the external oblique fascial flaps for fixation of mesh, while the

genitofemoral nerve is most likely to be injured during the isolation of the cord and stripping of the cremasteric muscle fibres in Lichtenstein repair. While taking the bites for fixing the polypropylene mesh, the nerves may be injured accounting for the increased incidence of inguinal pain. There was no mesh rejection as there was no serious surgical site infection in either group, which required removal of mesh.

Table 16: Comparison of Incidence of chronic groin pain and early recurrence between other studies

Studies	Chronic Groin Pain			Early Recurrence		
	L	S	P Value	L	S	P Value
Gavit Et Al	14.3%	3.6%	0.35	0%	0%	
Present Study	14.3%	2.9%	0.088	2.9%	2.9%	1

A meta-analysis was carried out by Li et al. This meta-analysis pooled the effects of outcomes of a total of 2860 patients enrolled into 10 randomized-controlled trials and two comparative studies for comparison between preperitoneal and Lichtenstein repair for unilateral inguinal hernia and recorded that there was no significant difference between both groups in postoperative complications. Our results were comparable with those of Malazgirt et al. and Junsheng et al. as we did not find any significant difference between both groups in postoperative complications.[17],[18],[19]

There is no obvious difference in recurrence rates and there was no significant difference in duration of hospital days, but number of days taken to return to normal activities is more for Stoppa's repair and for return to previous work is more for Lichtenstein repair.

Table 17: Comparison of mean duration of hospital stay and days taken to return to normal activities with other studies.

Studies	Mean duration of hospital stay			Days taken to return to normal activity		
	L	S	P Value	L	S	P Value
Latheef Aa Et Al	5.78	7.04	0.496	9	12	0.041
Present Study	5.17	5.23	0.417	11.3	13.1	<0.001

Conclusion

In the present Study conducted on 70 patients with 35 each in Group LC undergoing Bilateral Lichtenstein Tension Free Mesh Repair and Group- GPRVS undergoing Stoppa's Repair For Bilateral Inguinal Hernias with all patients completing the study protocol fully at ESIC MC AND PGIMSR, Bengaluru.

After analysing the data and observations it can be concluded that ..,

Bilateral approach through a single incision for Bilateral Inguinal Hernias provides better patient satisfaction in terms of lesser incidence of post operative complications such as seroma formation, Lesser Incidence of Chronic Groin Pain , Lesser Incidence of Post Operative pain in comparison to Bilateral Lichtenstein Tension Free Mesh Repair.Also, There is no much difference seen with respect to wound Infection, Early Recurrence, Rejection of Mesh, Duration Of Hospital Stay.

Thereby The GPRVS(Giant Prosthetic Reinforcement of Visceral Sac) Stoppa's Repair can be considered as an alternative to Lichtenstein Tension Free mesh Repair for Bilateral Inguinal Hernias. However, more randomized Control Trials as well as Multicenter Studies are to be taken in order to study the pros and cons of the procedure.

Summary

Results analysed showed that bilateral approach through a single incision for Bilateral Inguinal Hernias provides better patient satisfaction in terms of lesser incidence of post operative complications such as seroma formation, Lesser Incidence of Chronic Groin Pain , Lesser Incidence of Post Operative pain in comparison to Bilateral Lichtenstein Tension Free Mesh Repair.Also, There is no much difference seen with respect to wound Infection, Early Recurrence, Rejection of Mesh, Duration Of Hospital Stay.

Thereby The GPRVS(Giant Prosthetic Reinforcement of Visceral Sac) Stoppa's Repair can be considered as an alternative to Lichtenstein Tension Free mesh Repair for Bilateral Inguinal Hernias.

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