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Original Research Article

Quality of Life Assessment after Laparoscopic Versus Open Mesh Hernioplasty for Inguinal Hernia

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Abstract

Background: Historically, the success of a hernia repair was measured by lack of recurrence. With the advent of mesh reinforcement and refinement in technique, recurrence rates after herniorrhaphy have significantly improved. Subsequently, postoperative Quality of life (QOL) has become an important outcome measure following herniorrhaphy. Our Aim in this study is to assess the Quality of life after open versus laparoscopic inguinal mesh hernia repair in severity of pain, sensation of mesh, movement limitation in different position by using Carolinas Comfort Scale.

Method: A total of 100 cases which met the inclusion and exclusion criteria were included in this hospital based prospective study. After taking informed and written consent of the patients, they have been operated by either open or laparoscopic methods of inguinal hernia repair randomly. The subjects were allocated into two groups according to the type of repair. Both the group of patients have been compared for various outcome measures for quality of life using Carolinas Comfort Scale on post-operative day 1 and 3.

Result: Present study concludes that there is less sensation of mesh, pain sensation and limitation of movement in different posture and activity after laparoscopic mesh hernioplasty as compared to open mesh hernioplasty in first three post-operative days

Conclusion: Present prospective randomised study concludes that there is difference in quality of life after laparoscopic and open mesh hernioplasty in first three post-operative days. So, quality of life after laparoscopic mesh hernioplasty is better than open mesh hernioplasty in the first three post-operative days.

Keywords: Inguinal Hernia, Laparoscopic Mesh Hernioplasty, Open Mesh Hernioplasty, Quality of Life, Carolinas Comfort Scale.

Introduction

Historically, the success of a hernia repair was measured by lack of recurrence. With the advent of mesh reinforcement and refinement in technique, recurrence rates after herniorrhaphy have significantly improved. Subsequently, postoperative Quality of life (QOL) has become an important outcome measure following herniorrhaphy. Formal, validated, and widely accepted QOL assessments are limited and are often similar to Short Form 36 (SF-36), which generically measures a patient's global health status, functional impairment, and emotional state as it relates to the patient's comorbidities and chronic illnesses. The major weakness of the SF-36 survey is that it does not query specific QOL outcomes pertaining to specialized procedures, such as hernia surgery. It has been demonstrated that SF-36 has a limited sensitivity and specificity in comparing hernia surgery outcomes between patients or changes in QOL during the postoperative period[1]. The literature strongly supports the notion that disease-specific questionnaires are more likely than generic QOL tools to detect change caused by treatment. Such instruments highlight the distinction between general health status and specific postoperative recovery.

In 2004, the Carolinas Comfort Scale (CCS) was developed to address this inadequacy. Using a 6-point Likert scale, patients rate 3 common hernia-related symptoms: pain, mesh sensation, and limitation of movement during 8 activities of varying intensity. Within 8 years after the publication of the initial validation in 2007, the CCS has been translated into 28 languages and is currently being used in most US states and more than 40 countries throughout the world. As the popularity of the CCS has increased, multiple national and international research trials and data registries have incorporated the CCS in their outcome measures including the French and British governments and the International Hernia Mesh Registry. [2,3]

Our Aim in this study is to assess the Quality of life after open versus laparoscopic inguinal mesh hernia repair in severity of pain, sensation of mesh, movement limitation in different position by using Carolinas Comfort Scale.

Materials and Method

A prospective observational study was performed at a tertiary care centre in Gujarat, India. The study was conducted after ethical clearance from the institutional review board. We included 100 patients who need inguinal hernia repair. Informed and written consent was obtained from all the participants of the study.

Inclusion Criteria:

- Male or female patients between the ages of 18 to 80 years.
- All patients who were planned for laparoscopic or open inguinal hernia repair.
- Subjects who gave written informed consent after reviewing the informed consent document.

Exclusion Criteria:

- Age less than 18 years and above 80 years.
- Patients who were taken for emergency inguinal hernia repair.
- Patients with coagulopathy and patients on anti-coagulation.
- Patients with intra-abdominal infection.

The patients were divided into two groups according to the type of repair, open inguinal hernia mesh repair or laparoscopic inguinal hernia mesh repair. All patients operated with open inguinal hernia mesh repair were kept in Group – A. All patients operated with laparoscopic inguinal hernia mesh repair were kept in Group – B. The open inguinal hernia repair group was operated with Lichtenstein Tension Free Hernioplasty while the laparoscopic group was operated with laparoscopic total extraperitoneal (TEP) or laparoscopic

trans- abdominal preperitoneal approach (TAPP).

Pre-medication with Inj. Cefotaxime 1gm I.V. were given 1 hour before giving skin incision.

All the steps of the operation was done according to the standard procedures in both open and laparoscopic inguinal hernia mesh repair.

All the cases was received the standard treatment for pain control in the postoperative period during the time of study

Injection tramadol 50 mg in 100 ml NS every 12h for 1st 24 hours.

Tab. Diclofenac 50 mg 1BD after 24hrs onwards for 7 days.

CCS questionnaire that measures severity of pain, sensation of mesh, and movement limitations from the mesh was ask to both group A and group B on follow up of 1st day, 3rd day. (follow up is in person or telephonically).

Carolinas Comfort Scale questionnaire as follows:

Carolinas Comfort Scale questionnaire

Number	Question	Scores
1	**While laying down, do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
2	**While bending over, do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
3	**While sitting up, do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
4	**While performing activities of daily living (getting out of bed, bathing, getting dressed), do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
5	**When coughing or deep breathing, do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
6	**When walking or standing, do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
7	**When walking up or down stairs, do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A
8	**When exercising (other than work-related), do you have**	
	Sensation of mesh	0 1 2 3 4 5 N/A
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A

Patients were asked to answer each question scoring 0 for no sensation of mesh, no pain, or no movement limitations and up to 5 for the worst symptoms.

N/A: Not applicable.

0 - No Symptoms

1 – Mild but not bothersome symptoms

2 – Mild and bothersome symptoms

3 – Moderate and/or daily symptoms
4 – Sever symptoms
5 – Disabling symptoms

Stastastical Analysis:

Statistical analysis was carried out using tabular and diagrammatic presentation. Statistical analysis was carried out using Med calc application and Microsoft Excel software. To examine the statistical significant of differences between two sets of qualitative data, the chi-square test was used, whereas for quantitative data, the unpaired t-test was utilized. A p value <0.05 was considered significant. Continuous variables were expressed as mean (standard deviation [SD]).

Result

In our current study we included a total of 100 patients diagnosed with inguinal hernia out of these 100 patients 60 patients were operated with open inguinal hernia repair and 40 patients were operated with laparoscopic inguinal hernia repair.

In the present study age of the patient varied from 18 to 70 years with highest prevalence noted in age group of 41 to 50 years. The mean age group in the laparoscopic group was 47.15 years while in open group was 48.42 years.

In the present study, there were 92 male patients and 8 female patients. In present study prevalence of hernia is more in male patients as compare to female.

In the present study there were 42 patients of inguinal hernia in this study had on the right side, 34 patients on left side, 24 patients had bilateral inguinal hernia.

Day-1 Result:

Table 1: Laparoscopic Group – Sensation of mesh:

	No. of Patients – Sensation of mesh (n=40)							
Score	**LD**	**BO**	**SU**	**ALD**	**CB**	**W**	**S**	**E**
0								
1								
2	18	11	11	8	15	3		
3	17	20	20	19	19	17		
4	5	9	9	13	6	14		
5							1	1
NA						6	39	39
Average score	2.675	2.95	2.95	3.125	2.775	3.32	5.00	5.00

[LD- Lying Down Position, BO- Bending over position, SU- Sitting up position, ALD- Activity of daily living, CB- Coughing or deep breathing, W- Walking or standing, S- Walking up or down stairs, E- Exercising]

Table 2: Open Group – Sensation of mesh:

	No. of Patients – Sensation of mesh (n=60)							
Score	**LD**	**BO**	**SU**	**ALD**	**CB**	**W**	**S**	**E**
0								
1								
2	10	4						
3	23	22	14	9	14	5		
4	23	27	39	32	38	29		
5	4	7	7	9	8	11	2	2
NA				10		15	58	58
Average score	3.35	3.62	3.89	4	3.9	4.13	5.00	5.00

Table 3: Laparoscopic Group – Pain

	No. of Patients – pain (n=40)							
Score	**LD**	**BO**	**SU**	**ALD**	**CB**	**W**	**S**	**E**
0								
1								
2	7	1	15		2	3		
3	16	15	20	10	16	8		
4	17	24	5	25	19	15		
5				5	3	8	1	1
NA						6	39	39
Average score	3.25	3.58	3.75	3.88	3.58	3.82	5.00	5.00

Table 4: Open Group – Pain

	No. of Patients – pain (n=60)							
Score	**LD**	**BO**	**SU**	**ALD**	**CB**	**W**	**S**	**E**
0								
1								
2	5	4	2	2	1			
3	19	13	11	5	10	2		
4	26	27	29	24	31	27		
5	10	16	18	19	18	16	2	2
NA				10		15	58	58
Average score	3.68	3.92	4.05	4.20	4.1	4.30	5.00	5.00

Table 5: Laparoscopic Group – movement limitation

	No. of Patients – movement limitation (n=40)						
Score	**BO**	**SU**	**ALD**	**CB**	**W**	**S**	**E**
0							
1	2						
2	23	14	7	17	1		
3	9	14	17	13	9		
4	6	8	11	8	16		
5		4	5	2	8	1	1
NA					6	39	39
Average score	2.48	3.05	3.35	2.88	3.91	5.00	5.00

Table 6: Open Group - movement limitation

	No. of Patients – movement limitation (n=60)						
Score	**BO**	**SU**	**ALD**	**CB**	**W**	**S**	**E**
0							
1							
2	12	6	4	6			
3	23	22	15	22	8		
4	19	22	18	22	29		
5	6	10	13	10	8	2	2
NA			10		15	58	58
Average score	3.32	3.6	3.8	3.6	4	5.00	5.00

Table 7: Total value of open and laparoscopic group on Day 1

	Open Group (n=60)				Laparoscopic Group (n=40)				P – value
Questions	**Sensation of mesh**	**Pain**	**Movement limitations**	**Total score**	**Sensation of mesh**	**Pain**	**Movement limitations**	**Total score**	
LD	3.35	3.68	0	7.03	2.68	3.25	0	5.93	< 0.001
BO	3.62	3.92	3.32	10.86	2.95	3.58	2.48	9.01	< 0.001
SU	3.89	4.05	3.60	11.54	2.95	3.75	3.05	9.75	< 0.001
ADL	4	4.20	3.80	12	3.13	3.88	3.35	10.36	< 0.001
CB	3.9	4.10	3.60	11.6	2.78	3.58	2.88	9.24	< 0.001
W	4.13	4.30	4.0	12.43	3.32	3.82	3.91	11.05	< 0.001
S	5.00	5.0	5.00	15	5.00	5.00	5.00	15	>0.05
E	5.00	5.00	5.00	15	5.00	5.00	5.00	15	>0.05
Total score				**95.46**				**85.34**	< 0.001

In our study on post-op day 1, the total average score (sensation of mesh, pain, movement limitation) of open group was 95.46 and laparoscopic group was 85.34.

In our study on post-op day 1, p-value was <0.001 (calculated by paired t-test) which is statistically significant.

Day-3 Result:

Table 8: Laparoscopic group – sensation of mesh:

	No. of Patients - sensation of mesh (n=40)							
Score	**LD**	**BO**	**SU**	**ADL**	**CB**	**W**	**S**	**E**
0								
1	14	15	14	11	15	12		
2	18	13	15	14	12	10		
3	7	9	8	9	11	11		
4	1	3	3	6	2	5	1	1
5						1	5	5
NA						1	34	34
Average score	1.875	2	2	2.25	2	2.31	4.8	4.8

Table 9: Open Group – sensation of mesh

	No. of Patients – sensation of mesh (n=60)							
Score	**LD**	**BO**	**SU**	**ADL**	**CB**	**W**	**S**	**E**
0								
1	15	11	6	6	6	9		
2	16	16	12	13	15	6		
3	20	20	26	18	23	16		
4	8	11	14	13	14	16	2	2
5	1	2	2	7	2	9	5	4
NA				3		4	53	54
Average score	2.4	2.62	2.9	3.04	2.85	3.18	4.71	4.66

Table 10: Laparoscopic Group – pain

	No. of Patients – pain (n=40)							
Score	**LD**	**BO**	**SU**	**ADL**	**CB**	**W**	**S**	**E**
0								
1	12	13	10	7	6	11		
2	17	13	16	11	10	7		
3	8	11	10	14	16	9		
4	3	3	4	6	7	9	2	2
5				2	1	3	4	4
NA						1	34	34
Average score	2.05	2.1	2.2	2.63	2.68	2.64	4.67	4.67

Table 11: Open Group – pain

	No. of Patients – pain (n=60)							
Score	**LD**	**BO**	**SU**	**ADL**	**CB**	**W**	**S**	**E**
0								
1	11	10	6	8	7	6		
2	16	13	13	8	12	7		
3	20	21	21	17	20	16		
4	10	13	15	16	16	16	3	3
5	3	3	5	8	5	11	6	5
NA				3		4	51	52
Average score	2.63	2.77	3.00	3.14	3.00	3.34	4.67	4.62

Table 12: Laparoscopic Group – limitation of movement

	No. of Patients – limitation of movement (n=40)						
Score	**BO**	**SU**	**ADL**	**CB**	**W**	**S**	**E**
0		3					
1	15	17	5	15	8		
2	17	14	11	10	7		
3	6	4	14	9	12		
4	2	2	8	5	9	2	2
5			2	1	3	2	3
NA					1	36	35
Average score	1.88	1.63	2.78	2.18	2.80	4.5	4.6

Table 13: Open Group – movement limitation

	No. of Patients – movement limitation (n=60)						
Score	**BO**	**SU**	**ADL**	**CB**	**W**	**S**	**E**
0							
1	16	11	10	13	8		
2	19	17	14	18	9		
3	17	21	12	18	16		
4	6	8	14	9	15	3	3
5	2	3	7	2	8	6	7
NA			3		4	51	50
Average score	2.32	3.58	2.90	2.48	3.11	4.67	4.70

Table 14: Total value of open and laparoscopic group on Day 3

	Open group				Laparoscopic group				P – value
Questions	**Sensation of mesh**	**Pain**	**Movement limitations**	**Total score**	**Sensation of mesh**	**Pain**	**Movement limitations**	**Total score**	
LD	2.4	2.63		5.03	1.88	2.05		3.93	< 0.001
BO	2.62	2.77	2.32	7.71	2	2.1	1.88	5.98	< 0.001
SU	2.90	3.00	3.58	9.48	2	2.2	1.63	5.83	< 0.001
ADL	3.04	3.14	2.90	9.08	2.25	2.63	2.78	7.66	< 0.001
CB	2.85	3.00	2.48	8.33	2	2.68	2.18	6.86	< 0.001
W	3.18	3.34	3.11	9.63	2.31	2.64	2.80	7.75	< 0.001
S	4.71	4.67	4.67	14.05	4.8	4.67	4.5	13.97	>0.05
E	4.66	4.62	4.70	13.98	4.8	4.67	4.6	14.07	>0.05
Total score				**77.29**				**66.05**	< 0.001

In our study on post-op day 3, the total average score (sensation of mesh, pain, movement limitation) of open group was 77.29, and laparoscopic group was 66.05.

In our study on post-op day 3, p-value was <0.001(calculated by paired t-test) which is statistically significant.

Discussion

There is a general consideration that a laparoscopic approach to inguinal hernia repair has better short-term and possibly long-term QOL outcomes when compared to an open repair. This prospective study, which recorded the outcome of 100 patients, detected a significant difference in physical symptoms using the Carolinas Comfort Score during the first three postoperative day when comparing laparoscopic and open mesh hernia repair. Due to reduced recurrence of hernia in current surgical practice with the use of tension-free hernia repair, focus is now being placed on functional outcomes of hernia repair, specifically on quality of life. Because of the complexities involving in quality-of-life measures, it is very important to consider what purpose the measure is going to serve when choosing between various quality-of-life surveys. [4]

Disease-specific quality-of-life measures are more sensitive for detection and quantification of small changes that are important to clinicians or patients. These have been promoted for years by many investigators in oncology [5,6] and in diseases such as gastroesophageal reflux disease [7,8] and Crohn's disease. [9] In contrast, generic measures are used primarily to compare outcomes across different populations and interventions [10]. For assessment of quality of life after mesh hernioplasty, a mesh-specific or hernia-specific questionnaire is crucial to effectively understand how surgical repair with mesh affects patient quality of life. One of the disease specific quality of life measures is Carolinas Comfort Scale (CCS) which uses patient questionnaire to ascertain quality measure for pain. [11]

One argument against a disease-specific quality of-life survey is that it may be too specific and detects insignificant changes that do not affect overall mental and physical well-being. It is true that the CCS is concerned only with physical well-being and seems to have more power when comparing mesh types or repair techniques. But it still represents a powerful tool for overall health because the total CCS score is highly correlated with the physical and mental summary scores for the SF-36, providing evidence that the CCS does measure overall mental and physical well-being.

In our study on post-operative day 1:

- The average score of CCS for mesh sensation was between 2.67-5.00 in laparoscopic group while it was between 3.35 – 5.00 in the open group.
- The average score of CCS for pain sensation was between 3.25-5.00 in laparoscopic group while it was between 3.68-5.00 in the open group.
- The average score of CCS for limitation of movement was between 2.48-5.00 in laparoscopic group while it was between 3.32-5.00 in the open group.
- The average of total CCS score in laparoscopic group was 85.34 and in the open group was 95.46 with p value <0.05. This difference was found to be statistically significant.
- In our study on post-operative day 3:
- The average score of CCS for mesh sensation was between 1.88-4.8 in laparoscopic group while it was between 2.4-4.7 in the open group.
- The average score of CCS for pain sensation was between 2.05-4.68 in laparoscopic group while it was between 2.63-4.67 in the open group.
- The average score of CCS for limitation of movement was between 1.88-4.60 in laparoscopic group while it was between 2.32-4.70 in the open group.
- The average of total CCS score in laparoscopic group was 66.05 and in the open group was 77.29 with p-value <0.05. This difference was found to be statistically significant.
- In our study on post-operative day 1 and day 3 there was significant difference in CCS score for mesh sensation, pain

sensation and limitation of movement between both group.

Conclusion

Present prospective randomised study concludes that there is difference in quality of life after laparoscopic and open mesh hernioplasty in first three post-operative days. Present study also concludes that there is less sensation of mesh, pain sensation and limitation of movement in different posture and activity after laparoscopic mesh hernioplasty as compared to open mesh hernioplasty in first three post-operative days. So, quality of life after laparoscopic mesh hernioplasty is better than open mesh hernioplasty in the first three post-operative days.

Limitations

The present study had its small sample size (expected sample size could not be achieved due to COVID 19 pandemic). A larger study sample may help to further substantiate the findings or reveal variations which were not observed in the present study. The study was a single centred study. A multi centric study with larger population belonging to various socioeconomic classes should be assessed to decide its effectiveness. There was no long term follow up of patients of both group so complications like recurrence of hernia and other complications were not recorded. In the present study laparoscopic group was not subdivided into TEP and TAPP group thus we could not assess the difference in the quality of life between TEP and TAPP by using CAROLINAS COMFORT SCALE.

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