

Evaluating quality of life following laparoscopic inguinal hernia repair using Modified Carolina Comfort Scale.

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ABSTRACT

Background: To predict the quality of life following laparoscopic inguinal hernia repair, using Carolina Comfort Scale is used.

Method: This study was a prospective observational study conducted at Government Medical College, Srinagar (tertiary care hospital). This study included 30 patients with inguinal hernias. Carolina Comfort Scale was used pre-operatively (modified for pre-operative use by omitting questions related to mesh). After proper consent 93.3% patients underwent TAPP and 6.7% patients underwent TEP by single surgeon. Dextile 3-D mesh was used in all patients which was fixed using tackers. Post operatively patients were followed up at 2 and 6 weeks CCS score was again assessed. Data was collected and statistical analysis was done.

Result: All of the patients completed all three questionnaires. All of the patients were male. The mean age was 54.7 ± 10.30 yrs. Half of the patients were having direct and the other half having indirect hernia. 80% patients were having unilateral and 20% were having bilateral hernias. 93.3% patients underwent TAPP and 6.7% TEP. It was found that there was significant improvement in quality of life following repair with p-value < 0.001 . Also it was found that patients having score of more than 20 pre-operatively were more likely to have persistent discomfort in post-operative period. Also patients having less score (< 10) pre-operatively were found to have high score at 2 weeks which reduced at 6 week.

Conclusion: There was significant improvement in quality of life following laparoscopic inguinal hernia repair. Also, pre-operative score can predict the outcome after surgery. Hence this scale should be used preoperatively as well for counseling the patients.

Keywords:

INTRODUCTION

Hernia is defined as protrusion of an organ or part of it through a defect in the wall of the cavity that contains it. One of the commonest type of hernia for which patients seek medical attention is inguinal hernia¹. Its repair is one of the commonest surgery performed by general surgeons². Its repair can be done by open or a laparoscopic technique³. Open techniques are divided into non mesh and mesh (tension free) repairs. The most common complication of non-mesh repair

is recurrence. However with the introduction of mesh, rate of recurrence has decreased^{4,5,6,7}. The two most commonly performed laparoscopic techniques are Trans abdominal pre-peritoneal repair and Totally extra-peritoneal repair^{8,9}. Laparoscopic techniques have certain advantages over the open technique, like less post operative pain, early return to daily work, less scars and better quality of life¹⁰.

With the introduction of mesh and subsequent decrease in recurrence, the attention of the researchers turned towards post operative outcome in terms of quality of life^{4,5,6,7}. Good quality of life after surgical repair is an important predictor of successful repair. Quality of life is measured indirectly by using scales. These scales are setup in the form of questionnaires¹¹. There are two types of scales :generic and disease specific. Generic are used to assess quality of life after any surgical procedure. SF 36(36-item short form health survey questionnaire) is one of the commonly used generic scale⁴. Although SF 36 is considered to be the gold standard for assessment of quality of life but in studies it was found that patients preferred disease specific scales as questions asked in these were more reflective of their symptoms^{12,13}.

One of the disease specific scales used in hernia repair is Carolina Comfort Scale¹⁴ (Table 1).It was developed by Physicians and researchers from Carolina laparoscopic and advanced surgery programme (CLASP) IN 2004⁴. It is a validated disease specific scale for patients who undergo mesh hernia repair. It is shown to be a superior tool compared to SF 36 for quality of life assessment in hernia repair patients¹⁵. It is a 23-item likert type questionnaire that measures on a scale of 0 to 5 severity of pain, sensation and movement limitations from the mesh in the following eight categories: laying down, bending over, sitting up, activities of daily living, coughing or deep breathing, walking or standing, walking up and down the stairs and exercise, resulting in a maximum score of 115^{4,13,14}. Added to the numerical scale is a descriptive scale: 0=no symptoms, 1=mild but not bothersome symptoms, 2=mild but bothersome symptoms, 3=moderate and/or daily symptoms, 4=severe symptoms, 5=disabling symptoms¹⁶. Its use has been done pre-op in one of the studies where it was modified for pre-op use by omitting questions related to mesh sensation in each of eight domains resulting in maximum score of 75¹.

The pre-op score serves as a baseline of patients function and allows to compare patients quality of life before and after the procedure¹⁵. It was concluded that pre and post operative s

MATERIALS AND METHODS

A prospective observational study was conducted in the Postgraduate Department of General Surgery, Government Medical College Srinagar over a period of one and a half years. The following criteria were followed during the course of the study:

Inclusion criteria:

- ✓ All the patients above the age of 18 years (male and female) undergoing laparoscopic inguinal hernia repair with primary unilateral or bilateral inguinal hernia.

Exclusion criteria:

- ✓ Patients with previous groin hernia repair with or without prosthetic material or recurrent hernias.
- ✓ Patients with previous abdominal surgery (pelvic surgeries, including appendectomy, prostatectomy).
- ✓ Patients undergoing inguinal hernia repair as a part of any other procedure.
- ✓ Patients with any significant comorbidities such as bronchial asthma, severe COPD.

The patients were subjected to detailed clinical history, examination and findings were recorded as per the pro-forma attached. All the patient variable factors: age, sex, risk factors, mode of presentation and previous operation were analysed. Other risk factors - obesity, hypertension, diabetes mellitus, COPD, and malignancy were also taken into consideration. These patients were made to undergo routine investigations i.e complete blood count, kidney function test, liver function test, routine urine microscopy, coagulation profile, serum electrolytes, chest x-ray, ECG, random blood sugar and ultrasonography of abdomen, pelvis and groin. Special radiological investigations, i.e, CT scan was done only in some patients to assess the exact defect size and contents. After explaining the procedure to the patient, informed and written consent was taken for the procedure and these patients were subjected to pre-anaesthetic checkup, those found fit for general anaesthesia were taken up for laparoscopic

hernia repair. Patients were advised to take light dinner on night before surgery and to fast 8-10 hours prior to surgery. Broad spectrum antibiotic was given to patients at the time of induction. All procedures were performed by single surgeon. Standard TAPP and TEP procedure was done. 3-D dextile mesh was used and fixed with Covidien Pro-tack Auto-suture fixation device 5mm.

The CCS was modified for pre-operative use (Modified Carolina Comfort Scale, Table-2) by omitting the questions related to mesh sensation in each of the 8 domains, resulting in a maximum score of 75. Total scores for each respondent was then converted to a percentage of the applicable maximum. Data was collected during clinical consultation pre-operatively, and at 2 and 6 weeks postoperatively. All scores were then converted to a percentage of the maximum possible score. All the data was tabulated, graphical analysis was made and statistical analysis was done using MS Excel. The suitable statistical tests were applied to the available data for subgroup analysis. From the data collected we assessed the improvement in quality of life and tried to find whether there is any relation between the pre operative scores and post operative scores that will help us in future to counsel patients on their expectations of pain and discomfort post repair.

Table-1:Carolina comfort scale.

Number	Question	Scores
1	While laying down, do you have Sensation of mesh Pain	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
2	While bending over, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
3	While sitting up, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 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 Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
5	When coughing or deep breathing, do you have Sensation of mesh Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A

6	<p>When walking or standing, do you have</p> <p>Sensation of mesh</p> <p>Pain</p> <p>Movement limitations</p>	<p>0 1 2 3 4 5 N/A</p> <p>0 1 2 3 4 5 N/A</p> <p>0 1 2 3 4 5 N/A</p>
7	<p>When walking up or down stairs, do you</p> <p>have</p> <p>Sensation of mesh</p> <p>Pain</p> <p>Movement limitations</p>	<p>0 1 2 3 4 5 N/A</p> <p>0 1 2 3 4 5 N/A</p> <p>0 1 2 3 4 5 N/A</p>
8	<p>When exercising (other than work-related),</p> <p>do you have</p> <p>Sensation of mesh</p> <p>Pain</p> <p>Movement limitations</p>	<p>0 1 2 3 4 5 N/A</p> <p>0 1 2 3 4 5 N/A</p> <p>0 1 2 3 4 5 N/A</p>

Number	Question	Scores
1	While laying down, do you have Pain	0 1 2 3 4 5 N/A
2	While bending over, do you have Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
3	While sitting up, do you have Pain Movement limitations	0 1 2 3 4 5 N/A 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 Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
5	When coughing or deep breathing, do you have Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
6	When walking or standing, do you have Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A
7	When walking up or down stairs, do you have Pain Movement limitations	0 1 2 3 4 5 N/A 0 1 2 3 4 5 N/A

8	When exercising (other than work-related), do you have	
	Pain	0 1 2 3 4 5 N/A
	Movement limitations	0 1 2 3 4 5 N/A

Modified Carolina Comfort Scale for pre-op assessment.

Maximum score: 115

Maximum score:75

RESULTS

Total of 30 male patients with inguinal hernia were enrolled in the study. All of the patients completed all three questionnaires. Most of the patients presented in the age group of 40 to 60 years, accounting for 63.4% followed by >60 years 33.3%. The mean age was 54.7 ±10.30 years. The most common underlying comorbidity was hypertension (52.6%) followed by T2DM, prostatomegaly and hypertension. Both the direct and indirect hernias accounted for 50% (n=15) each. We had 24 unilateral (80%) and 6 bilateral (20%) hernias. Amongst the patients having unilateral hernia, 15 were on the right side and 9 on the left side. Most common procedure done was TAPP, accounting for 93.3% and the rest were managed by TEP (6.7%). It was found that there was significant improvement in Carolina comfort scale score following laparoscopic inguinal hernia repair. Pre-operatively the CCS (MEAN±SD) was 15.40 ±10.20 which decreased to 8.03 ±2.45 at 2 weeks post operatively and further to 3.75 ±2.34 at 6 weeks with p- value of <0.001 (table 3a). Further it was found that patients who had high score (MCCS>20) preoperatively were more likely to have persistent but less pain than preoperative discomfort at 6 weeks (table 3b). Also patients who had low MCCS score (<10) preoperatively (mean=4.46) were found to have a higher score at 2 weeks (mean=6.9), which had reduced at 6 weeks (mean=1.6). (table 3c).

Table 3(a): CCS Score distribution			
	Pre-op	Post-op 2 weeks	Post-op 6 weeks
CCS Mean± SD	15.40 ±10.20	8.03 ±2.45	3.75 ±2.34
Table 3(b): MCCS Score distribution			
MCCS>20	28.13	9.86	6.12
MCCS<20	10.1	7.12	2.56
Table 3(c): MCCS Score(<10) Distribution			
MCCS Score<10	4.46	6.9	1.6

DISCUSSION

Inguinal hernias are common surgical issues and are frequently accompanied by unfavorable changes in the patient's life that have a negative impact on their productivity at work and result in a significant socioeconomic burden.

Surgical repair of inguinal hernias is one of the most frequently performed operations. An estimated 20 million hernias are repaired every year worldwide^{2,17}.

TAPP and TEP are the two commonly employed laparoscopic methods for hernioplasty³. The approach is easier for TAPP repair, and it also has a big workspace. Another benefit is that TAPP repair has a shorter learning curve^{4,5}.

The indirect comparisons among TAPP and TEP techniques have brought to light some questions regarding whether the two procedures yield comparable or dissimilar outcomes as regards immediate pain, complications, rates of recurrence, and chronic groin pain after operations. The relative profits and drawbacks of the two procedures are still unknown because there is insufficient data in order to properly compare them^{3,6,7,8}.

Nevertheless, few prior studies have examined the QoL following TEP versus TAPP surgery. Sufficient evidence was reported, concluding that TAPP and TEP are both successful approaches for laparoscopic inguinal hernia repair, making both procedures suitable choices for treating inguinal hernia⁶.

This study was conducted to evaluate both pain and QoL before and after laparoscopic inguinal hernia repair conducted in a prospective manner over a period of 18 months. A total of 30 patients, age group of more than 18 years with primary unilateral or bilateral hernia were included. Patient's with previous surgical history and significant morbidity were excluded.

In our study, a total of 30 male patients were enrolled who had primary inguinal hernia. Most of the patients presented in the age group of 40 to 60 years accounting for 63.4% (n=19) followed by more than 60 years of age 33.3% (n=10). Only one patient presented in the age group of 20 to 40 years who was 23 years old. The mean age was 54.7 ± 10.30 years (Table 1). Similar findings were reported by Holzheimer R et al¹⁸, where they reported 50 consecutive inguinal hernia which mostly affected patients in 5th and 6th decade of life. Iranha A et al¹⁹, reported 159 inguinal hernias which predominantly affected men with mean age of 53 years. Knox D et al¹ analysed a total of 104 inguinal hernias, of which 93.3% affected were males with mean age of 49.9 years.

In our study, the most common underlying comorbidity was hypertension, present in 10 (52.6%). Similar finding was reported by M.Ceresoli et al²⁰ where 65% patients were having hypertension. Other comorbidities seen were T2DM, BPH and COPD with equal distribution of 15.8% (n=3) (Table 2). Hung L et al²¹ in their study also found that benign prostatic hyperplasia was present in 15% patients. Showkal A B et al²² also found that 16.15% cases had urinary disturbances like frequent urination and 10.76% were having chronic cough.

Inguinal hernias are classified as direct or indirect. In direct inguinal hernia, a defect or weakness occurs in posterior wall of inguinal canal in area called Hesselbach's triangle. Through this defect, fatty tissue or bowel is forced directly through it into the inguinal canal. Indirect inguinal hernia, the abdominal contents enter the deep ring instead of piercing the posterior wall. It passes along the length of inguinal canal and exits via the superficial ring. In the present study we found equal distribution of both direct and indirect hernias each accounted for 50% (n=15) (Table 3). Puneet K Agarwal²³ in their study found the common type of hernias was indirect accounting for 60% of cases, 30% had direct type of hernia and 10% had bilateral hernia. This variation in our result can be due to less number of patients in our study.

In the present study, most of the hernias were unilateral accounting for 80% (n=24) while as 20% (n=6) hernias were bilateral (Table 4). Most of the hernias were repaired by the TAPP, that was done in 28 (93.3%), remaining 2 (6.7%) patients underwent TEP (Table 5). Maillet O et al²⁴, also reported similar findings in their study.

The preoperative symptom severity measured by modified CCS has been concluded as a significant predictor for reported postoperative symptoms. CCS-based questionnaire is used preoperatively and early post-operative period for assessing inguinal hernia repair techniques. In our study, the overall mean Modified Carolina Comfort Scale (MCCS) before the procedure was 15.40 ± 10.20 . At 2 weeks and 6 weeks of post-operative period mean MCCS was decreased to 8.03 ± 2.45 and 3.75 ± 2.34 . The difference in mean MCC between preoperative period and post-operative period was found statistically significant ($P < 0.001$). Our study showed a significant improvement in postoperative quality of life as compared to preoperative assessment with MCCS. On distributing patients with MCCS score of < 20 and > 20 , the mean MCCS score, preoperatively was 28.13 and 10.1 respectively. After surgery the MCCS score decreased to 9.86 and 7.12 in > 20 and < 20 groups respectively at 2 weeks of post-operative period. At the 6th week of post-operative period, the score decreased to 6.12 and 2.56 in the > 20 and < 20 groups respectively. It showed that patients having high MCCS score preoperatively were more likely to have persistent discomfort at 6 weeks. Patients with < 10 MCCS score had mean score of 4.46 in the pre-operative time, within first 2 weeks of post-operative period the mean score was increased upto 6.9 and then showed a gradual decrease at 6th week of post-operative period. Although patients with low score (less than 10) had more discomfort at 2 weeks post operatively than the pre operative discomfort, they had significant improvement at 6 weeks. These findings were corresponding with Muysoms E et al²⁵ who in their study reported that laparoscopic inguinal hernia resulted in a favorable outcome and significant improvement in quality of life compared with the preoperative assessment by modified CCS. Knox D et al¹ also concluded that preoperative assessment with MCCS is a sensitive tool that highlights the postoperative discomfort of TEP repair. Heniford B et al¹⁴ validated the CSS questionnaire for assessing quality of life after hernia repair. A study by Parseliunas A et al¹⁵ concluded that CCS is a valid tool for assessing QOL factors after the repair of inguinal hernia with mesh. Nielsen K et al²⁶ in their study had similar findings as our, that CCS is a better reflection of quality of life after hernia repair with mesh.

CONCLUSION

We found that there was significant improvement in the quality of life after laparoscopic inguinal hernia repair. In addition we found that patients having high score were more likely to have persistent discomfort lesser than the pre operative levels at 6 weeks and patients having low score could have increased discomfort at 2 weeks post operatively which decreased at 6 weeks. Overall at the end of 6 weeks patients were satisfied with the outcome of surgery.

Hence we came to the conclusion that this scale should be used frequently for assessing the patients as well as for counseling of the patients while planning for surgery.

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