



ORIGINAL RESEARCH PAPER

General Surgery

SHOULD QUALITY OF LIFE BE A CONSIDERATION TO OPERATE LARGE VENTRAL HERNIAS: A PROSPECTIVE STUDY

KEY WORDS: Quality of Life, ventral hernia, incisional hernia, component separation

Aslam Baba Diamond	Department of GI Surgery, GI Oncology, Minimal Access & Bariatric Surgery, Medanta Medicity Hospital, Gurugram, Haryana, India.
Vikas Singhal*	Department of GI Surgery, GI Oncology, Minimal Access & Bariatric Surgery, Medanta Medicity Hospital, Gurugram, Haryana, India. *Corresponding Author
Amanjeet Singh	Department of GI Surgery, GI Oncology, Minimal Access & Bariatric Surgery, Medanta Medicity Hospital, Gurugram, Haryana, India
Azhar Perwaiz	Department of GI Surgery, GI Oncology, Minimal Access & Bariatric Surgery, Medanta Medicity Hospital, Gurugram, Haryana, India
Adarsh Chaudhary	Department of GI Surgery, GI Oncology, Minimal Access & Bariatric Surgery, Medanta Medicity Hospital, Gurugram, Haryana, India.

ABSTRACT

Context: Advances in Abdominal Wall Reconstruction including abdominal component separation techniques have enabled repair of complex ventral hernias whereas patients may have been denied surgery earlier. Traditionally the reason to operate ventral hernias has been the risk of strangulation. Something that is under studied is the effect of complex ventral hernias on Quality of Life (QoL) and how does it change after surgery. Whether techniques that require division of abdominal wall components impair abdominal wall function and consequently affect QoL is not determined.

Aim: To assess the change in QOL at three months after surgery and compare it to the QOL immediately before surgery. Apart from the primary outcome of change in QOL, short term complications were also studied. A subgroup analysis of change in QOL after component separation technique was also done

Settings and Design: A prospective analysis was carried out on consecutive patients undergoing open complex ventral hernia surgery over two-year period at our institution, a tertiary care hospital.

Methods and Material: Patients with complex ventral hernias including those with hernia defect diameter more than 6 cm, recurrent hernia, multiple Swiss cheese defects, or patients requiring abdominal component separation were studied. Patients requiring emergency surgery and laparoscopic surgeries were excluded from study. The "Hernia-Related Quality-of-Life Survey" (HerQLes) which is a validated instrument was used.

Statistical analysis used: After sample size estimation by a statistician forty-five consecutive patients meeting the study criteria between April 2017 and March 2019 were included in the study. Statistical analyses were done using SPSS version 24 software.

Results: Of the 45 patients enrolled in the study, 19 (42.2%) required abdominal component separation. The mean size of the defect was 130 cm² in component separation (CS) group and 39.0 cm² in non-component separation (NCS) group. The mean preoperative QoL score in CS group was 53.9±11.2, while in the NCS group it was 45.7±13.6. QoL score postoperatively in CS group was 16.4±4, while in NCS group it was 13.8±1.5. There was a statistically significant improvement in QoL three months after surgery in both the groups (p<0.0001).

Conclusion: In our study we found complex ventral hernias to be associated with a poor Quality of Life. The Quality of Life was seen to improve significantly within three months after surgery. Use of a component separation technique does not seem to impair the Quality of life.

INTRODUCTION

Large complex ventral hernias remain a commonly seen problem in surgical clinics. Advances in Abdominal Wall Reconstruction (AWR) surgery such as development of abdominal component separation techniques have facilitated repair of large complex ventral hernias whereas patients may have been denied surgery earlier. Traditionally the reason to operate ventral hernias has been the risk of strangulation. One often overlooked aspect of a large ventral hernia is the physical disability and mental trauma associated with it. Something that has not been studied much is the effect of a complex ventral hernias on Quality of Life (QoL) and how does it change after surgery. Whether Abdominal Wall Reconstruction techniques that require division of abdominal wall components impair abdominal wall function and consequently affect QOL also remains to be seen.

Although hernia recurrence is an important outcome measure, from a patient's perspective Quality-of-life is also an important parameter. Generic outcomes measurement instruments such as the SF-36 were designed to compare large populations over time and are not particularly suited to evaluate the impact of a specific operation on quality of life

[1]. Hence specific quality of life instruments developed for chronic diseases [2,3] and specific operations [4-6]. Generic quality-of-life forms such as the SF-36 are a potential option for measuring quality of life after incisional hernia repair [7-10]. Few questionnaires have been developed and validated that specifically assess patients undergoing Hernia surgery. One such questionnaire is the Hernia-Related Quality-of-Life Survey (HerQLes) which has great utility for assessing the patient-centred health outcomes of abdominal wall reconstruction [11]. Particularly this aspect has not been studied in Indian patients.

The HerQLes questionnaire has got 12 questions covering several aspects including core abdominal function, ability to perform activities etc, with 6 options on a Likert scale for each question. Minimum score for each question is 1 and maximum score 6. So, the minimum QOL score for the patient is 6 and maximum possible score is 72. The lower the score, the better is quality of life.

Complex ventral hernias have generally been taken as hernias with large defects, recurrent hernias etc, although there isn't a definition per say. Surgery may be undertaken

laparoscopically or open however large complex hernias especially those needing an abdominoplasty may require an open approach. As including both laparoscopic and open surgeries would add variability, we restricted the studied patients to open surgeries a excluded laparoscopic surgeries. In open surgeries typically mesh placement is undertaken in the retro-rectus position or sometimes onlay placement depending on the specific indications of the surgery. Further, if the defect cannot be closed primarily an abdominal component separation technique is utilized. Either Anterior component separation as described by Ramirez et al [12] or the relatively new Posterior component separation with transverse abdominis muscle release as described by Novitsky et al [13] is carried out.

With the recent growth of advanced reconstructive techniques for ventral hernia repairs, it is important to evaluate the effect on quality of life and abdominal wall function of these innovative procedures. There is little data on whether these techniques that require division of abdominal wall components impair abdominal wall function.

In our study we assess the Quality of life in patients with complex ventral hernia before and 3 months after surgery with evaluation of short-term outcomes of the surgery and subgroup analysis of component separation techniques.

MATERIAL AND METHODS

A prospective analysis was carried out on consecutive patients undergoing open complex ventral hernia surgery over two-year period at our institution. We included in our study consecutive patients with relatively large defect size more than 6 cm diameter, recurrent hernias, or those that required a component separation technique. To reduce the heterogeneity patients requiring emergency surgery and laparoscopic surgeries were excluded from study. The "Hernia-Related Quality-of-Life Survey" (HerQLes) which is a validated instrument was used to assess the immediate preoperative and 3 months postoperative QoL.

As the study was undertaken in North India, the questionnaire was also translated into Hindi language. The new translated questionnaire was approved by our hospital ethics committee. It was an exact simulation to HerQLes which was already validated and published. The QOL questionnaire in Hindi was given to sample subjects before implementing on the patients included in the study after ensuring there was no difficulty in answering the questionnaire. The questionnaire was answered by the patients after due consent the day before surgery. Post operatively after 3 months of surgery the questionnaire was answered by the patients either during follow up in outpatient department otherwise the patients were called and the questionnaire completed. Apart from the primary outcome of change in QOL, immediate post-operative complications were also studied. A subgroup analysis of change in QOL after component separation technique was also done. After sample size estimation, forty-five consecutive patients meeting the study criteria between April 2017 and March 2019 were included in the study.

Statistical methods:

For estimation of sample size, the following formula was used $n = (Z\alpha * \sigma)^2 / E^2$
 $Z\alpha$ = Value of standard normal variate corresponding to level of significance
 σ = Standard deviation of parameter of interest
 E = Margin of error

Assumptions:

σ = Standard deviation of the parameter = 15.6

(Reference Article: Design and Initial Implementation of HerQLes: A Hernia-Related Quality-of-Life Survey to Assess Abdominal Wall Function [20].)

Confidence level = 95%
 The standard normal deviate for $\alpha = Z\alpha = 1.96$
 E = Margin of error = 5%
 With these assumptions the sample size works out as 38.

The analysis included profiling of patients on different demographic, laboratory and clinical parameters. Descriptive analysis of quantitative parameters was expressed as mean and standard deviation. Ordinal data was expressed as absolute number and percentage. Cross tables were generated and Chi square test was used for testing of associations. Student t test was used for comparison of quantitative parameters between two sub groups. P-value < 0.05 was considered statistically significant. Analysis was done using SPSS software version 24.0.

RESULTS

Of the 45 patients 19 (42.2 %) were male and 26 (57.8%) female. The mean age of the study population was 53.4 ± 14.5 years. The major co-morbidities are listed in Table 1. The most common co-morbidities were Hypertension (46.7%) and Type 2 Diabetes Mellitus (42.2%).

Table 1: Comorbidities In Patients With Complex Ventral Hernia

Comorbidity	Number (n=45)	Percent (%)
Hypertension	21	46.7%
Diabetes Mellitus	19	42.2%
Hypothyroidism	7	15.6%
CAD	5	11.1%
Seizure	2	4.4%
Ankylosing Spondylitis	1	2.2%
Asthma	1	2.2%
COPD	1	2.2%
Dyslipidemia	1	2.2%
Lymphoma	1	2.2%
Potts Spine	1	2.2%
Stroke	1	2.2%
TIA	1	2.2%

Patient Presentation

All the patients presented with the complaint of abdominal swelling. 16 patients (35.6%) also reported pain. One patient had previous episodes of subacute intestinal obstruction managed medically.

Site Of Hernia

Most common site of hernia was midline with 40 patients (88.8 %) having midline defects. Two patients had a subcostal defect, one in a Pfannenstiel incision and one lumbar defect. Two patients had both a midline hernia and stoma closure site hernia. Thirty-six patients (80%) had a primary incisional hernia, while 7 patients (15.6%) had a recurrent incisional hernia, rest being ventral hernias.

Intra-operative Variables

Adhesiolysis was performed in 43 patients (95.6%). The mean size of the defect was 130 cm^2 in component group and 39 cm^2 in non-component group. The difference was statistically significant (p - 0.0001). Mesh was used in all the cases, polypropylene being the most commonly used mesh. Closed suction drain was placed in all the patients.

Component Separation

Component separation was performed in 19 patients of which 6 (31.8%) underwent anterior component separation and 13 (68.2%) underwent posterior component separation.

Post-operative Morbidity And Short-term Complications

There was no post-operative mortality. Three patients had need for either Intensive care unit (ICU) or High dependency unit (HDU) stay. One patient required transient ventilatory support. Seven patients (15.6 %) developed wound seroma, 4 patients (8.9 %) had partial wound necrosis needing

debridement, 8 patients (17.8%) needed prolonged dressings post hospital discharge. Two patients were managed with Vacuum Assisted Closure (VAC) dressing. Two patients were readmitted to hospital for wound management and rest managed on outpatient basis. There was no recurrence in the short term follow up period.

Quality Of Life Scores Pre-operative And Post-operative

The mean pre-operative QOL score in component separation group was 53.9±11.2, while in non-component separation group it was 45.7±13.6. The post-operative QOL score showed significant improvement in both the groups with QOL score post-operative in component group being 16.4±4, and in non-component group 13.8±1.5 (P-0.0001) (Table 2).

Table 2: Quality Of Life Scores In Both The Groups Statistical Analysis

QOL Score	Component Group (n=19)	Non-Component Group (n=26)	Total (n=45)	t-value	p-value
Pre-Operative	53.9±11.2	45.7±13.6	49.1±13.2	2.152	0.037*
Post-Operative	16.4±4	13.8±1.5	14.9±3.1	3.04	0.004*
Δ = (Pre op - Post op)	37.5±12.8	31.9±13.5	34.3±13.4	1.415	0.164*
t-value	12.819	12.024	17.209		
p-value	0.0001*	0.0001*	0.0001*		

*p-value < 0.05, statistically significant

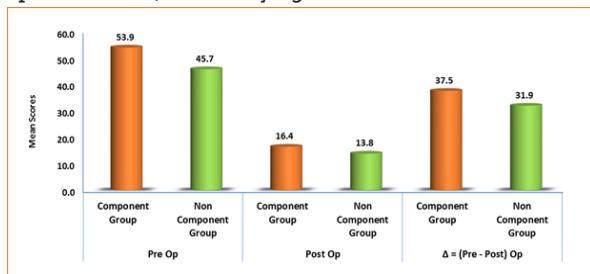


Figure 1: Change In Quality Of Life After Surgery In Both Groups

Post-operative Outcomes Comparison Between Component Separation And, No Component Separation Groups

Short term morbidity was noted to be higher in the group of patients requiring Component separation as outlined in the graph (Figure 2).

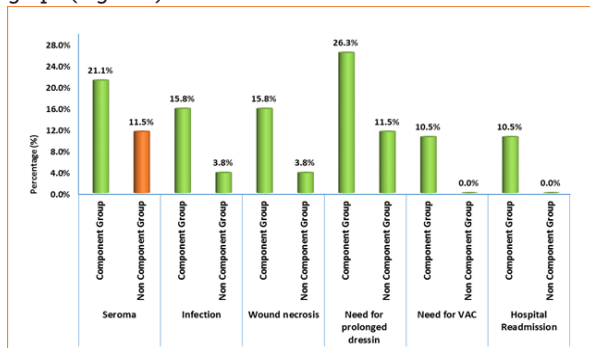


Figure 2: Comparison Between Groups In Terms Of Short Term Post-operative Morbidity

DISCUSSION

Quality of Life assessment may vary between different populations. To our knowledge our study is the first such study done in the Indian population assessing QoL before and after surgery in large ventral hernias. Our study supports that QoL is poor in patients with large ventral hernias as these can lead

to extreme disability. Krapta et al validated and published the HerQLes survey and showed that core abdominal function plays a major role in people's lives and weakening of the core muscles has been correlated with symptoms such as low back pain, poor gastrointestinal function, and difficulty with micturition [14,15]. For this reason, questions in the survey pertained to overall impact of the hernia on health, pain, and activities (strenuous and moderate activity, walking, climbing stairs, and essential activities of daily living). As our study was in the Indian population and it is very important in a study of this kind that patients understand the questions, we translated the questionnaire to Hindi language with help of professional translators. The patients were given the option of answering the questionnaire in either English or Hindi language. The Carolinas Comfort Scale (CCS) is another questionnaire [16] that has been utilized for QoL assessment in patients undergoing hernia surgery. Christoffersen et al in their study looked at the change in CCS scores after various types of hernia surgery including inguinal hernias and laparoscopic repairs [17]. Carolinas comfort scale cannot be used pre-operatively as the questionnaire includes term 'mesh' so it was not apt for our study.

In our study using the HerQLes questionnaire we found the pre-operative quality of life scores were high suggesting a poor quality of life in patients with complex ventral hernias. The mean pre-operative score was significantly higher in patients requiring component separation surgery suggesting that the QoL correlates with complexity of hernia and extremely high scores may in fact be a tool to help predict which patients may need a component separation surgery but this needs to be further assessed in larger studies. At three months after surgery all operated patients reported a significantly improved QoL including those who had undergone abdominal component separation.

One of the criticisms of Posterior component separation with transverse abdominis release has been that it may lead to loss of spinal stabilization and possibly respiratory compromise. The component separation techniques have also been noted to be associated with increased wound morbidity partly explained by the nature of the hernia itself. In a study by Ross et al, where they defined surgical outcomes and quality of life after massive ventral hernia repairs, the patients had longer length of stay, and more complications including hematoma, wound infection, and pneumonia. On multivariate analysis early postoperative pain and activity limitation were greater in massive ventral hernia repairs [18]. Another analysis by Desai et al based on the American College of Surgeons-NSQIP database demonstrated that, in comparison with risk-adjusted controls the use of component separation increased operative duration, length of stay, return to the operating room rate and 30-day morbidity without increase in mortality. Though significantly improved hernia recurrence rates were reported when components separation allowed for primary fascial closure [19].

In our subgroup analysis of patients requiring some form of abdominal component separation we also observed that the wound morbidity was higher with increased need for wound debridement, seromas and prolonged wound dressings. However, our study demonstrates that in spite of these immediate problems, at three months after surgery even these patients reported a significantly higher QoL. The QoL scores were in fact similar to patients who had not undergone separation of abdominal wall components. With this fact we can infer that division of abdominal wall components appears unlikely to impair the abdominal wall function although this again needs to be corroborated in further studies.

We recognize the limitations of our study that there is no absolute definition of complex ventral hernias and we have included only open surgeries for the sake of reducing variability. However the strength of our study lies in the fact

that it involves a direct comparison in the quality of life after large ventral hernia repair, recurrent hernias and those patients undergoing component separation, before and 3 months after surgery.

CONCLUSION

In our study we found complex ventral hernias to be associated with a poor Quality of Life. The Quality of Life was seen to improve significantly after surgery. Use of a component separation technique does not seem to impair the Quality of life. Poor QOL maybe an important parameter in complex ventral hernias that may need to be considered in surgical decision making.

Appendix

Hernia quality of life questionnaire - English

- I. often stay home because of my abdominal wall.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- II. I accomplish less at work because of my abdominal wall.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- III. My abdominal wall interferes when I dress myself, take showers, and cook.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- IV. My abdominal wall interferes with my sexual activity.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- V. I often feel blue because of my abdominal wall.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- VI. My abdominal wall interferes when I walk or climb stairs.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- VII. I accomplish less at home because of my abdominal wall
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- VIII. My abdominal wall causes me physical pain.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- IX. My abdominal wall affects how I feel every day.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- X. My abdominal wall has a huge impact on my health.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- XI. My abdominal wall interferes when I perform moderate activities, eg, bowling, bending over.
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree
- XII. My abdominal wall interferes when I perform strenuous

- activities, eg, heavy lifting
1.Strongly disagree 2.Moderately disagree 3.Slightly disagree 4.Slightly agree 5.Moderately agree 6.Strongly agree

Acknowledgement:

We acknowledge the support of the hospital statistics department in study design and help with statistical calculations.

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