



Clinical and Functional Outcome After Abdominal Wall Incisional Hernia Repair: Evaluation of Quality-of-Life Improvement and Comparison of Assessment Scales

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Abstract

Background Hernias severely impact patient quality of life (QoL), and 80% of patients need surgical operation. The primary outcome of the study is to assess improvements in balance, posture and deambulation after abdominal hernia repair. Moreover, the study investigated the improvement in the postoperative QoL.

Methods Patients operated at the Policlinico “Paolo Giaccone” at Palermo University Hospital between June 2015 and June 2017 were identified in a prospective database. The functional outcome measures and QoL assessment scales used were numeric rating scale for pain, performance-oriented mobility assessment (POMA) scale, Quebec back pain disability scale, center of gravity (barycenter) variation evaluation, Short-Form (36) Health Survey (SF-36 test), sit-up test and Activities Assessment Scale (AAS). The timepoints at which the parameters listed were assessed for the study were 1 week before the surgical operation and 6 months later.

Results The POMA scale showed a significant improvement, with an overall preoperative score of (mean; SD) 18.80 ± 2.17 and a postoperative score of 23.56 ± 2.24 with a $p < 0.003$. The improvement of the barycenter was significant with $p = 0.03$ and 0.01 for the right and left inferior limbs, respectively. Finally, common daily activities reported by the SF-36 test and by the AAS were significantly improved with a reported p of ≤ 0.04 for 5 of eight items and ≤ 0.002 for all items, respectively.

Conclusions The improvement in such physical measures proves the importance of abdominal wall restoration to recover functional activity in the muscle–skeletal complex balance, gait and movement performance.

Introduction

The incisional wall hernia remains one of the major issues in the field of abdominal surgery. Its estimated incidence is approximately 20% and increases to 40% in high-risk populations such as cirrhotic patients with uncontrolled disease, those undergoing emergency surgery and those with connective tissue disorders [1].

The ventral hernia is responsible for considerable anatomical and physiological alterations not only in the hemodynamic and respiratory system but also in the skeletal–muscle system. The presence of a voluminous uncontainable mass in the anterolateral abdominal wall could be responsible for significant modifications of the barycenter and the vectorial forces that support the vertebral column. Such alterations affect deambulation and posture maintenance [2].

The surgical operation, for which indications are pain, functional limitations and poor appearance due to bulging, should provide not only anatomical restoration of the abdominal wall but also improvement in cardiovascular, pulmonary and postural functions. The magnitude of this

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field of interest is significant, as 80% of patients require surgical operation [3].

Currently, major hernia societies are focused on the hard issue of determining the best surgical approach and technique—i.e., performing laparoscopy versus laparotomy, mesh positioning, etc.—as well as defining the outcome of the surgical operation in terms of quality of life (QoL) and recovery of skills in carrying out daily activities. Subsequently, the focus on patient-centered outcomes (PCO) and QoL in hernia treatment has increased [4–7].

The impact of ventral hernia and consequently abdominal wall restoration on balance, gait and posture is actually unknown because of the absence of homogeneous clinical data focused on this kind of topic. Moreover, many authors have developed specific surveys for the assessment of QoL after abdominal wall restoration, but the results presented are often inconclusive or discordant, generating great confusion in their interpretation. The most important reason for this confusion is a lack of rigorous methods used for data collection or questionnaire administration.

This study aims to investigate (1) the functional outcome after abdominal wall hernia repair using physiatric measurement scales to assess the expected improvement in the balance, posture and deambulation that arises by surgical correction of the ventral hernia and abdominal wall restoration and (2) the expected improvement in performance of daily activities measured by specific scale items on two different scales, one generic and one specific, for postoperative QoL assessment. The measures considered and the QoL item scores were obtained through pre- and postoperative data collection.

Patients and methods

Patients with abdominal wall incisional hernia treated with surgical operation at the Policlinico “Paolo Giaccone” at Palermo University Hospital between June 2015 and June 2017 were identified in a prospective database, and the data collected were retrospectively reviewed. Approval by the Regional Ethics Review Board in Palermo was obtained (ID number 0022019). Patients’ medical and surgical records were collected from the charts and surgical registries.

The diagnosis of abdominal wall incisional hernia was obtained after physical examination and US/CT scan execution. The inclusion criteria in the study proposed were a primary incisional hernia requiring surgical treatment, single-operator casuistry and patient willingness to participate in the study.

The surgical operation performed was the open intraperitoneal onlay mesh (IPOM) positioning technique. Since 2000, this operation has been the procedure of choice

for ventral hernia repair using a highly standardized technique in high complex abdominal wall hernias. All operations were performed by one skilled general surgeon with patients under general anesthesia, receiving preoperative antibiotic prophylaxis (ceftazidime 2 gr at least 1 h before the skin incision). For all surgical operations, a three-dimensional (3D) textile monofilament polyester (PET) mesh with bioabsorbable collagen film (pore size 3.3 mm × 2.3 mm, density 66 g/m², thickness 0.7 mm) was used (Symbotex, Covidien). The midline was always reconstructed, and compartmentalization of the prosthesis was performed. No bridging mesh or component separation technique was used. The dimension of the mesh used was large enough to cover the fascia 5 cm over the hernia defect borders (overlap) in all directions. Postoperative EHS classification was obtained taking into account the site of the hernia, the width of the defect and the number of orifices.

Urgent surgical operations and recurrent incisional hernias were excluded from the study.

Follow-up was performed for at least 1 year. After discharge from the hospital, all patients were examined weekly during the first month, monthly for 6 months and then annually.

The demographic preoperative data collected were age; sex; body mass index (BMI); tobacco use; comorbidities including diabetes, hypertension, cardiovascular diseases, pulmonary diseases, and liver diseases; and risk group according to the American Society of Anesthesiologists (ASA).

The intraoperative data evaluated were the duration of the operation (skin-to-skin time) and the size of the hernia.

Among the postoperative data, in-hospital stay (IHS) and complications were evaluated. The complications were divided into two groups: early complications (up to 30 postoperative days), such as wound infection, hematoma, seroma and late complications including hernia recurrence.

The functional outcome measures and the QoL assessment scales used were the numeric rating scale for pain (NRS); performance-oriented mobility assessment (POMA) scale or Tinetti assessment tool for adult gait and balance abilities; Quebec back pain disability scale (QBPDs) to measure the level of functional disability for patients with low back pain (LBP); barycenter variation evaluation with a Nintendo Balance Board Wii; Short-Form (36) Health Survey (SF-36 test) for patient-reported health and QoL measurement; sit-up test to measure the strength and endurance of the abdominal and hip-flexor muscles; and finally the Activities Assessment Scale (AAS) as a reliable, valid and clinically responsive instrument to evaluate patient functioning after hernia surgery. These scales and measures were used to collect data both pre- and postoperatively. The timepoints at which the parameters

listed above were assessed for the study were 1 week before the surgical operation and 6 months later, at the end of the maturation and remodeling time for the wounded tissues.

Data were analyzed in Excel 2016 and IBM SPSS software, version 21. The mean and median were obtained for continuous variables. Comparisons of continuous variables were made using Student's *t* test or the Mann–Whitney test where appropriate. A comparison of categorical variables was made with the Chi-squared (χ^2) test or Fisher's exact test. The statistical significance level was set to a *p* value <0.05.

The description of the functional outcome measures and the QoL assessment scales used is listed below.

Numeric Rating Scale (NRS) for pain

The NRS is a single 11-point numeric pain intensity scale broadly validated across myriad patient types. Data obtained via the NRS are easily documented and intuitively interpretable and meet the regulatory requirements for pain assessment and documentation [8].

POMA scale (or Tinetti scale)

The performance-oriented mobility assessment (POMA) scale is a task-oriented test that measures balance and gait abilities on an ordinal scale. The tests included thirteen position changes as well as eight gait observations. By combining the various balance and gait observations, it is possible to obtain the total score for single abilities (POMA balance and POMA gait) and the overall score by summing them (POMA total) [9].

QBPDS scale

One of the leading causes of disability is low back pain (LBP). Most of the time, LBP is benign and self-limiting and can be considered nonspecific LBP. It interferes with quality of life and work performance and is the most common reason for medical consultation. The Quebec back pain disability scale (QBPDS) was developed in 1995. It is based on a conceptual model of disability. The developers of the QBPDS used the World Health Organization's definition of disability as "any restriction or lack of ability to perform an activity in a manner or within the range considered normal for a human being." Disability was operationally defined in terms of difficulty experienced while performing simple tasks. The QBPDS should be highly reliable and discriminative over a wide range of disability levels, while also being practical and acceptable to both patients and clinicians. The 20 QBPDS items are scored on a 6-point scale (0 "not difficult at all," 5 "unable to do").

The total score is calculated by a summation of the scores for each item and ranges from 0 ("not being disabled") to 100 ("being maximally disabled") [10].

Barycenter variation evaluation

Due to force platforms, it is possible to measure ground reaction forces and moments, which are used to calculate force development and position of the center of pressure (COP). The COP reflects the neuromuscular response to movements in the center of gravity (i.e., the vertical projection of the center of mass) and closely approximates the center of gravity under slow moving or static conditions. The Wii Balance Board (WBB; Nintendo, Kyoto, Japan) has been investigated as an alternative to other laboratory-grade force platforms due to its relatively low cost (currently approximately USD\$100) and portability (<4 kg).

Its validation was explored with a systematic review, which concluded that the WBB can provide data that are concurrently valid with typical commercial force platforms and has reliability characteristics similar to force platforms for static standing computerized posturography [11]. Participants were asked to perform the task standing up with both inferior limbs on the balance with eyes open and feet a comfortable distance apart. During the test, participants observed a fixed point approximately 1 m away from them. The length of the standing test was 25 s. WBB data acquired were collected as a percentage of load distribution on both the inferior limbs. The ideal measurement is fixed for 50% in both the inferior limbs. The means were obtained, and the comparison between the preoperative and the postoperative data was made.

Sit-up test (SUT)

The sit-up test was performed to examine the core muscle endurance [12]. The 60-s SUT was proposed, with collection of preoperative and postoperative data and means detection.

Short-Form (36) Health Survey (SF-36 test)

The 36-Item Short-Form Health Survey questionnaire (SF-36) is a very popular instrument for evaluating general health-related quality of life. The SF-36 measures eight scales: physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role emotional (RE) and mental health (MH). Component analyses showed that there are two distinct concepts measured by the SF-36: a physical dimension, represented by the Physical Component Summary (PCS), and a mental dimension, represented by the Mental Component Summary (MCS). All scales contribute

in different proportions to the scoring of both PCS and MCS measures [13].

Activities Assessment Scale

The Activities Assessment Scale (AAS) consists of 13 items with 3 subscales for abdominal wall quality-of-life evaluation. The activities are classified as sedentary (questions 1–4), ambulatory (questions 6–8) and work activities (questions 11–13) [13, 14]. The Activity Assessment Scale (AAS) is a measure of functional activity designed for use in the perioperative period. The AAS measures a full spectrum of low-intensity to high-intensity activities, references a more immediate time interval than many other measures and requires less time to complete than most health status assessment scales. This instrument was originally constructed to assess patient-level outcomes in a multicenter randomized clinical trial of open versus laparoscopic inguinal herniorrhaphy. The AAS is reliable, valid and responsive using longitudinal data from 2164 men enrolled in this trial [14, 15].

Results

Between June 2015 and June 2017, a total of 209 patients met the inclusion criteria and were considered in the study group. The mean follow-up time was 28 months, and 68% of the population considered ($n = 142$) adequately completed the follow-up time proposed and the variables considered for the study. The mean (SD) patient age was 61.2 yo (± 13.62), and 61% were male. The median (SD) BMI was 29 (± 3.74), and 62% of patients were current smokers. The most frequent comorbidities were hypertension 68%, diabetes 46%, cardiovascular diseases 37%, pulmonary diseases 35% and controlled liver diseases 16%. Patients were classified as ASA II (29%), ASA III (66%) or ASA IV (5%). The mean (SD) operation time was 88.3 (± 45) min, the mean hernia size (SD) was 138.5 (± 2.63) cm², and the mean width of the defect was 10 (± 5) cm. The mean (SD) in-hospital stay was 5.3 (± 3.4) days. The early wound complication rate was 13–4% wound infection well-controlled with antibiotics, 4% hematoma and 5% seroma, both of which were conservatively treated; the recurrence rate was 1%. The recurrences were assessed with a physical examination and then confirmed after a dynamic CT scan. The recurrences were diagnosed at least 1 year after the surgical operation: 8.6% were Clavien–Dindo grade I, and 3.8% were Clavien–Dindo grade II (see Table 1).

The results of the functional outcome measures and QoL assessment scales used are reported in Table 2 and detailed below.

The difference between the preoperative ($\mu_{\text{preop}} = 2.60$) and postoperative ($\mu_{\text{postop}} = 2.89$) mean NRS was not significant, with $p = 0.83$. The difference between the preoperative and postoperative mean of single abilities POMA was highly statistically significant, as shown in Table 2, as was the difference between the overall mean POMA with a preoperative score of $\mu_{\text{preop}} = 18.80$, a postoperative score of $\mu_{\text{postop}} = 23.56$ and a p value < 0.003 . The preoperative QBPDS mean was 25.67, and the postoperative mean was 14.40; the comparison of the means showed no significant difference, with $p = 0.31$. The improvement in the percentage of load, barycenter, was significant, with $p = 0.03$ and 0.01 for the right and left inferior limbs, respectively. The sit-up test results were not significant: the preoperative mean was 22.20, the postoperative mean was 19.11, and the p value was 0.40. The comparison between the preoperative and postoperative means of each scale that composes the SF-36 questionnaire showed a significant difference on five of the eight scales: PF ($\mu_{\text{preop}} = 44$; $\mu_{\text{postop}} = 70.56$; $p = 0.04$), RP ($\mu_{\text{preop}} = 12$; $\mu_{\text{postop}} = 43.89$; $p = 0.03$), GH ($\mu_{\text{preop}} = 46.60$; $\mu_{\text{postop}} = 74.67$; $p = 0.04$), VT ($\mu_{\text{preop}} = 48$; $\mu_{\text{postop}} = 68.33$; $p = 0.03$) and SF ($\mu_{\text{preop}} = 54.80$; $\mu_{\text{postop}} = 84.78$; $p = 0.01$). Finally, the comparison between the preoperative and the postoperative means of each scale that composes the AAS questionnaire showed a significant difference on every scale with an overall $p < 0.002$ (see Table 2).

Discussion

The functional outcome after abdominal wall hernia repair among patients treated with the open IPOM technique and the use of a composite mesh was significantly better than the preoperative assessment. In fact, surgical repair seemed to improve the scores on the physiatric measurement tools used to assess the balance, posture and deambulation variables. The POMA scale and evaluation of the barycenter through the measurement of the percentage of load on the legs confirm the hypothesis that the surgical operation for abdominal wall reconstruction significantly improves the patient's abilities in terms of balance and gait performance. The measurement of pain intensity before the surgical operation and 6 months after the surgical operation showed no significant differences, similar to the QBPDS—whose preoperative and postoperative means were so low, they suggested poor correlations of the incisional hernia with LBP and the SUT.

In addition, this work provides important information on the preoperative and postoperative QoL. The results of the comparison between the preoperative and postoperative items of the two different scales used for assessment of postoperative QoL—SF-36 and AAS—demonstrated that

Table 1 Demographic, intraoperative and postoperative data

<i>Demographic data</i>	
Age (mean; SD)	61.2 ± 13.62
Sex	
M (%)	61
BMI (kg/m ²) (median; SD)	29 ± 3.74
Comorbidities	
Hypertension (%)	68
DM type 2 (%)	46
Cardiovascular disease (%)	37
Pulmonary disease (%)	35
Controlled liver disease (%)	16
ASA (%)	
II	29
III	66
IV	5
<i>Intraoperative data</i>	
Operation time (min) (mean; SD)	88.3 ± 45
Hernia size (cm ²) (mean; SD)	138.5 ± 2.63
<i>Postoperative data</i>	
In-hospital stay (days) (mean; SD)	5.3 ± 3.4
Early wound complication rate	13%
Wound infection	4%
Hematoma	4%
Seroma	5%
Late wound complication rate recurrence	1%
Clavien–Dindo	
I	8.6%
II	3.8%

the surgical operation for abdominal wall hernia repair significantly improved daily activities and confirmed the role of surgery in the indications of the operative approach.

Among both scales used, only the AAS showed an overall significant difference, unlike the SF-36. It was not surprising that the “bodily pain” item showed poor significance; this finding was predicted previously by the poor significance of the NRS scale. Conversely, it was surprising that the “role emotional” and the “mental health” items also showed poor significance, suggesting a low impact of the disease on the Mental Component Summary. The AAS is instead a purely physical health indicator, which perhaps is the reason for the overall significance. Additionally, Snyder et al. [16], using 1998 US population norms, found significant improvement in the SF-36 physical domains at the 5-year follow-up, but not in the mental scales, after open and laparoscopic repair for incisional hernia. Further studies should identify any possible correlation between abdominal wall hernia and mental health if present.

The data about the magnitude of the surgical operation on postoperative functional outcome and QoL in the literature are among the poorest for this surgical issue, and both of them are rarely investigated in the same study. Moreover, studies on QoL assessment after ventral hernia repair are not common and are highly heterogeneous [17–24].

The follow-up conducted in our study after ventral hernia repair considered a rigorous multimodal approach for data collection of both the functional outcome measures and the QoL tool assessments, proving to be the most complete data reported, considering different subjective and objective variables. The tests and questionnaires used have been proven to have high reliability and reproducibility, and they are widely used, especially in physiatric medicine [8–15]. Patients reported their own data and were guaranteed anonymity to reduce collection bias.

The most recent evidence about the impact of ventral hernia repair on the postoperative QoL arises from a study conducted by Cherla et al. [19]; they demonstrated that the QoL among patients with a hernia is significantly worse than that among patients with no hernia and that surgical repair can improve QoL to levels similar to that of the general population or to levels higher than before the hernia condition [19]. The tool used for QoL assessment was the modified AAS.

Previous studies by Mussack et al. [20] investigated any possible difference between laparoscopic and open hernia repair on QoL and found an absence of significance. Rogmark et al. [21] reported significant improvement 6 weeks after laparoscopic surgery compared to open mesh repair. Eriksen et al. [22] demonstrated deterioration of the physical domains in SF-36 after laparoscopic repair but normalization after 6 months compared to open repair. Colavita et al. [23] conducted a large prospective study comparing laparoscopic hernia repair and open hernia repair using the CCS questionnaire. He found no difference in pain, movement limitation, mesh sensation or overall symptoms at 6 and 12 months postoperatively.

Despite the heterogeneous presentation of past data reviewed in the literature, the results indicate an overall clinically significant improvement following ventral hernia repair.

In addition to being one of the most complete functional outcome and QoL assessment studies, our data reflect and support the importance of abdominal wall functionality. The hypothesized QoL benefits often attributed to the restoration of the functional abdominal wall in complex open abdominal wall reconstruction are evident in long-term follow-up [24].

Table 2 Results of the functional postoperative outcome measures and QoL assessment scales

	Preoperative	Postoperative	<i>p</i> value
<i>NRS</i> (mean; SD)	2.60 ± 2.07	2.89 ± 2.67	0.83
<i>Tinetti scale</i>			
Balance (mean; SD)	10.20 ± 1.30	12.44 ± 1.94	0.03
Gait (mean; SD)	8.60 ± 1.14	11.22 ± 0.67	0.004
Total (mean; SD)	18.80 ± 2.17	23.56 ± 2.24	<0.003
<i>QBPDS</i> (mean; SD)	25.67 ± 21.53	14.40 ± 17.17	0.31
<i>Barycenter</i>			
Right (mean; SD)	45.90 ± 3.10	52.00 ± 1.66	0.03
Left (mean; SD)	54.30 ± 6.04	49.00 ± 2.19	0.01
<i>Sit-up test</i>	22.20 ± 6.80	19.11 ± 4.62	0.40
<i>SF-36</i>			
Physical functioning (PF) (mean; SD)	44 ± 19.17	70.56 ± 21.86	0.04
Role physical (RP) (mean; SD)	12 ± 16.43	43.89 ± 32.96	0.03
Bodily pain (BP) (mean; SD)	58.40 ± 12.50	53.11 ± 21.63	0.57
General health (GH) (mean; SD)	46.60 ± 19.09	74.67 ± 23.27	0.04
Vitality (VT) (mean; SD)	48 ± 7.58	68.33 ± 22.50	0.03
Social functioning (SF) (mean; SD)	54.80 ± 15.51	84.78 ± 23.55	0.01
Role emotional (RE) (mean; SD)	39.20 ± 42.35	66.44 ± 37.34	0.27
Mental health (MH) (mean; SD)	63.20 ± 8.67	55.11 ± 16.94	0.26
<i>Activity assessment scale</i>			
Lying in bed	39.1 ± 9.81	25.4 ± 7.64	0.002
Sitting	40.8 ± 7.36	23.4 ± 8.52	0.001
Getting in or out of bed or chair	43.6 ± 5.88	26.7 ± 8.32	0.001
Reaching or stretching	41.2 ± 5.63	25.3 ± 9.31	0.002
Lifting 3 to 5 lb	55.3 ± 7.84	39.7 ± 7.42	0.001
Walking around inside	35.4 ± 6.92	20.2 ± 5.49	0.001
Climbing up or down stairs	40.2 ± 8.59	22.8 ± 6.38	0.002
Walking outside or at work	32.9 ± 4.16	21.8 ± 5.44	0.001
Engaging in sedentary activities, such as typing, talking on the phone, playing cards, watching TV	30.2 ± 7.28	22.7 ± 9.15	0.001
Engaging in light physical activities, cooking, dusting, clerical work, visiting friends	36.8 ± 6.32	24.2 ± 8.73	<0.001
Engaging in moderate physical activities such as sweeping, washing the car, dancing, playing golf, hiking	40.8 ± 9.54	28.5 ± 6.09	0.001
Engaging in vigorous physical activities such as construction work, shoveling, playing tennis or basketball, weight lifting	60.7 ± 4.77	30.1 ± 7.42	0.001
Engaging in sexual intercourse	58.7 ± 8.69	24.7 ± 5.16	0.001

Conclusions

Open ventral hernia repair is a secure and reliable surgical choice for ventral hernia repair with a low level of short- and long-term complications. The proposed data provide high-quality information to guide management decisions for patients with abdominal wall hernias. This information is more likely to demonstrate the utility of the surgical operation in improving physical measures and the QoL. Decision making about which surgical technique to adopt requires tailoring the surgery to patient requirements and must therefore be considered before every single case. The

improvement in such physical measures, as demonstrated in the study, proves the importance of the abdominal wall anatomy restoration in order to recover its functional activity in the muscle–skeletal complex balance, gait and movement performance. The QoL is now considered by the expert consensus of worldwide hernia societies the milestone of the patient-centered outcome. The assessment of the QoL must be taken into account through the use of validated and reproducible tests, such as SF-36 and AAS, as currently suggested by the Americas Hernia Society Quality Collaborative and Ventral Hernia Outcomes Collaborative. This is the first study that combines the

functional outcome, through the use of physiatric tools for balance and gait assessment, and the QoL measures in the most complete way, demonstrating the effective impact of surgery for abdominal wall hernia repair on daily activity.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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