World J Surg (2018) 42:19–25
DOI 10.1007/s00268-017-4173-6

ORIGINAL SCIENTIFIC REPORT

Impact of Abdominal Wall Hernias and Repair on Patient Quality of Life

Deepa V. Cherla[1,2,3] · Maya L. Moses[1] · Cristina P. Viso[1] · Julie L. Holihan[1,2] · Juan R. Flores-Gonzalez[1] · Lillian S. Kao[1,2] · Tien C. Ko[1] · Mike K. Liang[1,2]

Published online: 21 August 2017

Abstract

Background The modified Activities Assessment Scale (AAS) is a 13-question abdominal wall quality of life (AW-QOL) survey validated in patients undergoing ventral hernia repair (VHR). No studies have assessed AW-QOL among individuals without abdominal wall pathology. The minimal clinically important difference (MCID) of the modified AAS and its implications for the threshold at which VHR should be offered also remain unknown. Our objectives were to (1) establish the AW-QOL of patients with a clinical abdominal wall hernia versus those with no hernia, (2) determine the MCID of the modified AAS, and (3) identify the baseline quality of life (QOL) score at which patients derive little clinical benefit from VHR.

Methods Patient-centered outcomes data for all patients presenting to General Surgery and Hernia Clinics October–December 2016 at a single safety-net institution were collected via a prospective, cross-sectional observational study design. Primary outcome was QOL measured using the modified AAS. Secondary outcome was the MCID.

Results Patients with no hernia had modified AAS scores of 81.6 (50.4–94.4), while patients with a clinically apparent hernia had lower modified AAS scores of 31.4 (12.6–58.7) ($p < 0.001$). The MCID threshold was 7.6 for a "slight" change and 14.9 for "definite" change. Above a modified AAS score of 81, the risk of worsening a patient's QOL by surgery is higher than the chances of improvement.

Conclusions VHR can improve 1-year postsurgical AW-QOL to levels similar to that of the general population. The MCID of the modified AAS is 7.6 points. Patients with high baseline scores should be counseled about the lack of potential benefit in QOL from elective VHR.

Introduction

Abdominal wall hernias, including ventral and groin hernias, are among the most common diseases encountered by the clinician with a prevalence of 2–20% following abdominal surgery [1–3]. The most common reasons for repair are pain, functional limitations, and poor cosmesis due to bulging. There has subsequently been an increasing focus on patient-centered outcomes (PCO) and quality of life (QOL) in hernia treatment [4–7].

Many abdominal wall-specific surveys have been developed to assess abdominal wall QOL (AW-QOL) and have been shown to have greater utility than general health

✉ Deepa V. Cherla
deepa.cherla@uth.tmc.edu; cherladv@gmail.com

[1] Department of Surgery, University of Texas Health Science Center at Houston, Houston, TX, USA

[2] Center for Surgical Trials and Evidence-Based Practice, University of Texas Health Science Center at Houston, Houston, TX, USA

[3] Department of Surgery, Lyndon Baines Johnson Hospital (affiliated with the University of Texas Health Science Center at Houston), 5656 Kelley St, Houston, TX 77026, USA

surveys to evaluate patients with hernias [8]. The most widely utilized and studied surveys are the Activities Assessment Scale (AAS) and its derivatives. The AAS is a 13-question AW-QOL survey previously developed and validated in 2164 patients before and after hernia repair surgery [9]. The questionnaire investigates patient psychosocial QOL and abdominal wall function through questions covering mood, lifestyle, and physical activity [9–11]. Similar alternative versions of this survey have been developed, most recently with the modified AAS [8, 12], which is endorsed and utilized by the Americas Hernia Society and Ventral Hernia Outcomes Collaborative [13]. The modified AAS is an abdominal wall-specific survey and therefore has been shown to discriminate between abdominal wall-related pathology (i.e., hernias) and intraabdominal complaints, such as colorectal cancer and diverticulitis [8].

Multiple studies have demonstrated that the AAS and its derivatives are valid for evaluating AW-QOL among patients with hernias [8]. In addition, studies have shown that modified AAS scores improve following successful hernia repair [5, 8]. However, there have been no studies using these surveys to evaluate AW-QOL among individuals without abdominal wall pathology. Furthermore, it is unknown what the minimal clinically important difference (MCID) is in terms of improvement and its implications for the threshold at which ventral hernia repair (VHR) should be offered. MCID is defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" [14]. The MCID constitutes a threshold for patient-reported outcome scores at which a patient would consider a specific change in score to be meaningful. Distribution-based methods of assessing the MCID are variable and include calculations determined from the standard error of the mean (SEM) or standard deviation (SD) among longitudinal AW-QOL scores of patients undergoing no major intervention [14, 15].

This is a prospective study of patients presenting to surgery clinics at a safety-net hospital. Our aims were (1) to establish the AW-QOL of patients with a clinical abdominal wall hernia versus those with no physical or radiologic evidence of hernia, (2) to determine the MCID with an abdominal wall-specific health survey (the modified AAS), and (3) to identify the baseline AW-QOL score at which patients might be expected to derive little or no AW-QOL benefit with VHR.

Materials and methods

Patient-centered outcomes data for patients with abdominal wall- and non-abdominal wall-related pathology were collected via a prospective, cross-sectional observational study design. Strengthening the Reporting of Observational Studies in Epidemiology Reporting Guidelines were followed [16] (Online Resource 1). All patients presenting to General Surgery Clinics (Breast, Colorectal, Surgical Oncology, and Hernia) from October 2016 to December 2016 at a single safety-net healthcare system hospital who had had a CT scan of their abdomen/pelvis within the last year and no intervening abdominal surgery were approached to complete the modified AAS as well as to undergo a standardized physical exam to assess for ventral and inguinal hernias. Patients completed the modified AAS surveys independently unless they claimed illiteracy, following which the survey was read to them by a research assistant. Patients were compensated with a $10 gift certificate for participation. Longitudinal data of patients with known abdominal wall pathology were also prospectively collected from Hernia Clinic patients from June 2014 to December 2016. The methodology of these databases has previously been reported and is available online [17–19] (Clinical Trials #NCT02457364, #NCT02365194, #NCT02363790). All of the latter patients presented initially to the Hernia Clinic for abdominal wall-related pathology, attended multiple clinic visits, and completed the modified AAS survey during each visit. Follow-up was encouraged through the administration of $10 gift certificates. All scores were normalized to a 1 to 100 score in which 1 was considered poor and 100 perfect. Modified AAS surveys missing over 2 responses were omitted from analysis. Other variables (demographics and comorbidities) were obtained through standardized intake forms based upon definitions utilized by the American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP). The local Institutional Review Boards approved all studies.

Of note, the longitudinal data were collected from all patients presenting to the Hernia Clinic who satisfied the inclusion criteria for the referenced protocols, not just those who had a CT. To determine the AW-QOL of the control population, we needed to verify the absence of any abdominal wall hernia. Current publications estimate that clinical exam alone misses 23–31% of abdominal wall hernias [3, 20]. We therefore mandated that these patients had a CT scan to ensure the absence of any hernia.

The primary outcome was AW-QOL measured using the modified AAS. The control population was comprised of general surgery patients presenting to clinic with no clinical or radiographic abdominal wall hernia. Because these individuals presented with no abdominal wall pathology, they were considered appropriate controls.

Secondary outcome was MCID. MCID was determined by 2 distribution-based methods. For calculation of the MCID, the equation frequently utilized in previous literature is SEM = SD X SQRT (1-test retest reliability

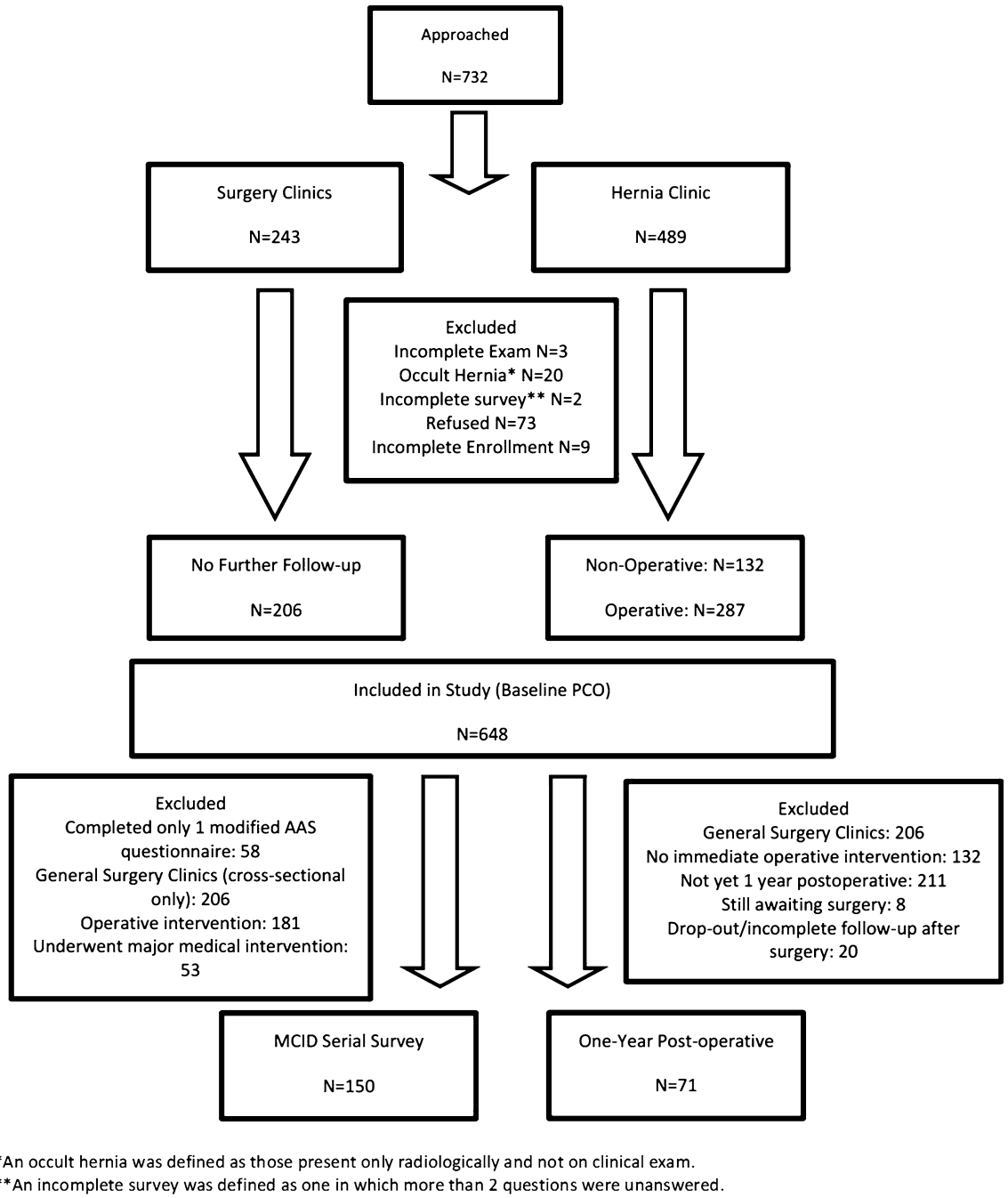

Fig. 1 Flowsheet of all patients enrolled in general surgery and hernia clinics

coefficient) [21]. To determine a "slight" change in AW-QOL, we used a required difference of at least 1 SEM. To determine a "definite" change in AW-QOL, we utilized a mandatory difference of at least 1.96 SEM to reflect a 95% CI, in keeping with the recommendations of prior AW-QOL literature [14, 15, 22]. The MCID was determined only from the data of patients for whom modified AAS scores were obtained at multiple time intervals in the longitudinal studies and who had not undergone a major hospital-based intervention between testing intervals. Testing intervals ranged from 1 to 18 months.

In order to estimate the mean modified AAS score of each population (clinical hernia versus no hernia) with a standard deviation of 10 points, an acceptable error of 2

Table 1 Patient variables

Variables	General surgery clinic patients		Hernia clinic patients ($n = 442$)
	No hernia ($n = 114$)	Clinical hernia ($n = 92$)	
Age (mean, SD)	45.9 (13.8)	50.1 (14.4)	49.7 (11.4)
Sex (# male, % male)	53 (46.5%)	52 (56.5%)	175 (39.6%)
ASA			
1–2	71 (62.3%)	57 (62.0%)	253 (57.2%)
3–4	43 (37.7%)	35 (38.0%)	189 (42.8%)
Race			
White	10 (8.8%)	17 (18.5%)	45 (10.2%)
Black	22 (19.3%)	16 (17.4%)	78 (17.6%)
Hispanic	81 (71.1%)	58 (63.0%)	310 (70.1%)
Other	1 (0.9%)	1 (1.1%)	9 (2.0%)
BMI, kg/m^2 (mean, SD)	28.3 (7.0)	32.3 (5.7)	32.8 (6.0)
Smoker (#, %)	31 (27.2%)	24 (26.1%)	61 (13.8%)
Diabetes mellitus (#, %)	17 (14.9%)	16 (17.4%)	99 (22.4%)
COPD (#, %)	1 (0.9%)	0	8 (1.8%)
Immunosuppression	16 (14.0%)	4 (4.3%)	14 (3.2%)
Previous abdominal operations (# patients, % patients)	64 (56.1%)	60 (65.2%)	359 (81.2%)
Previous hernia repairs (# patients, % patients)	10 (8.8%)	15 (16.3%)	101 (22.9%)
Reason for referral to surgery clinic[a]			
Hernia	8 (7.0%)	58 (63.0%)	442 (100%)
Non-hernia abdominal	96 (84.2%)	31 (33.7%)	0
Non-abdominal	10 (8.8%)	3 (3.3%)	0
Presence of abdominal wall hernia[b]			
Primary ventral hernia	0	23 (25.0%)	120 (27.1%)
Ventral incisional hernia	0	56 (60.9%)	322 (72.9%)
Inguinal hernia	0	33 (35.9%)	n/a
Modified AAS Scores (median, IQR)	81.6 (50.4–94.4)	45.4 (17.4–72.4)	28.1 (10.1–55.0)
Abdominal wall defect width (cm) (median, IQR)[c]	n/a	2.8 (1.6–3.8)	3.0 (2.1–5.1)
Presence of stoma	0	7 (7.6%)	10 (2.3%)

39 patients also presented with occult hernias, or those present only radiologically and not on clinical exam

ASA American Society of Anesthesiologist Score, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease, *SD* standard deviation

[a] Hernia = sent to clinic for hernia; Non-hernia abdominal = non-hernia diseases of the abdomen such as biliary colic or colon cancer; non-abdominal = non-abdominal diseases such as back lipoma or breast cancer

[b] Some patients presented with multiple abdominal wall (ventral and inguinal) hernias

[c] Defect width determined on computed tomographic imaging

points, and a confidence level of 0.95, we determined that 97 individuals were needed per population to complete a modified AAS survey.

Modified AAS scores were reported as median (interquartile range). Controls, or patients with no clinical or radiologic hernia, were compared to study groups that included (1) patients with clinical and radiologic hernia, (2) patients 1 year following VHR, and (3) any patient with a recurrent ventral hernia (on initial presentation or following repair during the study period). Scores were compared using Kruskal–Wallis. Matched scores were compared using Wilcoxon matched-pairs sign-rank test. A p value less than 0.05 was considered statistically significant. All statistical analysis was performed using STATA version 14.1®.

Results

A total of 648 patients were enrolled (Fig. 1). Relevant patient demographics are presented in Table 1. Reasons for non-abdominal wall hernia-related presentation to surgery

Table 2 Probability of improved abdominal wall quality of life 1 year following VHR

Preoperative modified AAS score	Postoperative probabilities					
	"Definite" change			"Slight" change		
	Improved	No change	Worsened	Improved	No change	Worsened
AAS score 0–20 ($n = 22$)	19 (86.4%)	3 (13.6%)	–	21 (95.5%)	–	1 (4.5%)
AAS score 21–40 ($n = 16$)	11 (68.8%)	4 (25.0%)	1 (6.3%)	13 (81.3%)	2 (12.5%)	1 (6.3%)
AAS score 41–60 ($n = 15$)	10 (66.7%)	5 (33.3%)	–	14 (93.3%)	1 (6.7%)	–
AAS score 61–80 ($n = 10$)	5 (55.6%)	4 (44.4%)	1 (11.1%)	6 (66.7%)	3 (33.3%)	1 (11.1%)
AAS score 81–100 ($n = 8$)	–	3 (37.5%)	5 (62.5%)	1 (12.5%)	1 (12.5%)	6 (75.0%)

AAS modified Activities Assessment Scale Score where 1 = poor QOL and 100 = ideal QOL

Definite change was defined as a change of 14.9 points or greater in the composite AAS score. Slight change was defined as a change of 7.6 points or greater in the composite AAS score

clinics included anal and colorectal ($n = 82$), breast ($n = 3$), miscellaneous ($n = 10$, included lipomas and trauma follow-ups), foregut ($n = 6$), hepatobiliary and pancreas ($n = 33$), and non-colorectal oncology ($n = 6$).

Patients with no hernia ($n = 114$) had modified AAS scores of 81.6 (50.4–94.4). In comparison, patients with a clinically apparent hernia ($n = 534$) had significantly lower modified AAS scores of 31.4 (12.6–58.7) ($p < 0.001$). The majority of clinical hernias were ventral as opposed to inguinal. Patients presenting with either a recurrent ventral or inguinal hernia ($n = 90$) had a baseline AAS score of 29.8 (14.7–55.0). There was no clinically or statistically significant ($p = 0.550$) difference in modified AAS scores between individuals having clinically palpable ventral and clinically palpable inguinal hernias.

Patients who presented with a hernia, underwent VHR, and completed 1-year follow-up after repair ($n = 71$) experienced significant improvements in AW-QOL [baseline 36.3 (15.6–63.3) versus post-VHR 73.3 (46.8–88.0), $p < 0.001$]. Scores following VHR were not statistically different than patients who initially presented with no hernia [81.6 (50.4–94.4), $p = 0.123$].

Mcid

A total of $n = 150$ patients with ventral hernias completed 2 to 6 sequential modified AAS surveys prior to undergoing any operative intervention. Baseline scores [28.2 (10.1–52.7)] did not significantly differ from follow-up scores [27.3 (9.2–64.2), $p = 0.700$] obtained up to 4–18 months later, prior to any operative intervention. On repeat surveys, patients showed a median maximal point difference in modified AAS score of 22.9 (9.9–42.9) when tested at repeated intervals. The median of the standard deviation for all patients was 11.7, and the individual intra-class correlation for all patients was 0.580, providing an SEM value of 7.6 for a "slight" change threshold of MCID and 14.9 for "definite" change threshold of MCID.

Who benefits from surgery?

Of the 71 patients for whom 1-year follow-up was performed following hernia repair, 62 (87.3%) demonstrated an improvement in modified AAS score. Above a modified AAS score of 81, the risk of worsening a patient's QOL by surgery is higher than the chances of improvement (Table 2).

Discussion

The AW-QOL among patients with a hernia is significantly worse compared to patients with no hernia. Surgical repair can improve AW-QOL to levels similar to that of the general population. However, not all patients achieve identical benefits with hernia surgery. In particular, patients with modified AAS scores of 81 or greater were unlikely to experience any AW-QOL improvements with surgery, and more than half had a worsened AW-QOL afterward.

These findings provide baseline reference data for abdominal wall studies assessing patient AW-QOL using the modified AAS or other similar derivatives. Currently, the Americas Hernia Society Quality Collaborative and Ventral Hernia Outcomes Collaborative utilize the modified AAS score [13]. Surprisingly, patients with no hernia had less than perfect modified AAS scores, suggesting that other factors unrelated to abdominal wall fascial defects may account for decreases in score. One reason for these lower than expected scores could be that only those individuals already seeking medical care in our surgical clinic were approached. These patients may have had other gastrointestinal complaints or prior abdominal surgeries that

affected their AW-QOL. Further studies should (1) delineate the modified AAS scores of healthy individuals not currently seeking any surgery-related medical care, (2) determine what factors affect modified AAS scores in patients without hernias, and (3) identify the MCID of the modified AAS scores in patients without hernias. The median modified AAS scores of patients with a clinical hernia presenting to the General Surgery Clinics also differed from those of patients presenting to the Hernia Clinic, which may reflect severity of hernia (including hernia type, size, symptoms).

In addition, this work provides important information on the MCID in modified AAS scores that should be considered in designing future patient-centered trials. Previous work with modified AAS scores among a different cohort of patients, 90 consecutive individuals presenting to 1 surgeon at a single academic institution for elective VHR, has demonstrated a change in mean score of 14.3 points 6 months following hernia repair (47.2 $\pm$ 15.6 points at baseline versus 61.5 $\pm$ 13.7 6 months postoperative)[5]. In combination with the results of our study, this would suggest a slight but clinically significant improvement following hernia repair. In our study cohort, patients undergoing surgery experienced a 37-point improvement in modified AAS scores, suggesting a definite improvement in the majority of our patients.

Our data reflect patient-reported outcomes data in hernia repair and highlight the questionable benefit a patient with a high pre-surgical QOL may receive from surgical intervention. We have provided high-quality information to guide management decisions for patients with abdominal wall hernias looking to improve their QOL through operative repair. Decisions concerning VHR require consideration informed by each patient's preexisting QOL. Patients already having high QOL should take into account the impact of surgery and postoperative complications on their QOL.

There are a number of limitations of this study. First, the generalizability of these findings is limited as surveys were obtained from patients seeking care at a safety-net hospital. Validation of these findings in other patients and populations is needed. However, results from multiple studies published in our patient population have been consistent with other results in the literature. In addition, although our patient population is largely underserved individuals (minority and/or low socioeconomic status), at least 1/3 to 1/2 of the American population are underserved. We also utilized distributional methods of approaching the MCID of patients with hernias. Anchor-based methods exist. It is unclear which technique is considered superior as both are widely used and reported. However, future studies should determine MCID utilizing different techniques in patients with and without hernias. Third, our study was limited to the modified AAS scale, which is a widely used AW-QOL survey endorsed by national hernia organizations. It is unclear if these findings are applicable to other abdominal wall-specific surveys.

Conclusions

Abdominal wall hernias are common pathologies, and patients have substantially worse abdominal wall QOL compared to patients with no hernia. The modified AAS is important for future clinical studies on hernia repair, but its clinical relevance and practicability require further elucidation. This is the first study to demonstrate that VHR can improve 1-year postsurgical abdominal wall QOL to levels similar to that of the general population. In addition, this study has demonstrated that the MCID when using the modified AAS survey is 7.6 points. Based on this, patients with a high baseline score should be carefully counseled about the lack of potential benefit in abdominal wall QOL from elective VHR.

Acknowledgements All listed authors contributed to the manuscript. No additional individuals contributed to the manuscript. Grant support for the research reported: The principal investigator received grants from the Center for Clinical and Translational Sciences, which is funded by National Institutes of Health Clinical and Translational Award UL1 TR000371 and KL2 TR000370 from the National Center for Advancing Translational Sciences. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources or the National Institutes of Health.

Compliance with ethical standards

Conflicts of interest The authors declare that they have no conflicts of interest.

References

1. Itatsu K, Yokoyama Y, Sugawara G et al (2014) Incidence of and risk factors for incisional hernia after abdominal surgery. Br J Surg 101(11):1439–1447
2. Le Huu NR, Mege D, Ouaissi M et al (2012) Incidence and prevention of ventral incisional hernia. J Visc Surg 149(5 Suppl):e3–e14
3. Deerenberg EB, Harlaar JJ, Steyerberg EW et al (2015) Small bites versus large bites for closure of abdominal midline incisions (STITCH): a double-blind, multicentre, randomised controlled trial. Lancet 386(10000):1254–1260
4. Langbach O, Bukholm J, Benth JS et al (2016) Long-term quality of life and functionality after ventral hernia mesh repair. Surg Endosc 30(11):5023–5033. doi:10.1007/s00464-016-4850-9
5. Holihan JL, Henchcliffe BE, Mo J et al (2016) Is nonoperative management warranted in ventral hernia patients with comorbidities?: A case-matched, prospective, patient-centered study. Ann Surg 264(4):585–590. doi:10.1097/SLA.0000000000001865
6. Ujiki MB, Gitelis ME, Carbray J et al (2015) Patient-centered outcomes following laparoscopic inguinal hernia repair. Surg Endosc 29(9):2512–2519. doi:10.1007/s00464-014-4011-y

7. Andresen K, Burcharth J, Rosenberg J (2015) The initial experience of introducing the Onstep technique for inguinal hernia repair in a general surgical department. Scand J Surg 104(2):61–65. doi:10.1177/1457496914529930
8. Krpata DM, Schmotzer BJ, Flocke S et al (2012) Design and initial implementation of HerQLes: a hernia-related quality-of-life survey to assess abdominal wall function. J Am Coll Surg 215(5):635–642. doi:10.1016/j.jamcollsurg.2012.06.412
9. Barber MD, Kenton K, Janz NK et al (2012) Validation of the activities assessment scale in women undergoing pelvic reconstructive surgery. Female Pelvic Med Reconstr Surg 18(4):205–210. doi:10.1097/SPV.0b013e31825e6422
10. Aasvang EK, Gmaehle E, Hansen JB et al (2010) Predictive risk factors for persistent postherniotomy pain. Anesthesiology 112(4):957–969. doi:10.1097/ALN.0b013e3181d31ff8
11. McCarthy M Jr, Jonasson O, Chang CH et al (2005) Assessment of patient functional status after surgery. J Am Coll Surg 201(2):171–178
12. Heniford BT, Lincourt AE, Walters AL et al (2016) Carolinas Comfort Scale as a measure of hernia repair quality of life: a reappraisal utilizing 3788 international patients. Ann Surg. doi:10.1097/SLA.0000000000002027
13. Poulose BK, Roll S, Murphy JW et al (2016) Design and implementation of the Americas Hernia Society Quality Collaborative (AHSQC): improving value in hernia care. Hernia 20(2):177–189. doi:10.1007/s10029-016-1477-7
14. Rai SK, Yazdany J, Fortin PR et al (2015) Approaches for estimating minimal clinically important differences in systemic lupus erythematosus. Arthritis Res Ther 17:143. doi:10.1186/s13075-015-0658-6
15. Gatchel RJ, Mayer TG (2010) Testing minimally clinically important difference: consensus or conundrum? Spine J 10:321–327
16. Strengthening the reporting of observational studies in epidemiology. Checklist [Internet]. http://strobe-statement.org/index.php?id=strobe-home. Accessed 11 Dec 2016
17. ClinicalTrials.gov. Non-op management of ventral hernia patients [Internet]. https://clinicaltrials.gov/ct2/show/NCT02457364?term=liang+hernia&rank=3. Accessed 11 Dec 2016
18. ClinicalTrials.gov. Modifying risk in ventral hernia patients [Internet]. https://clinicaltrials.gov/ct2/show/NCT02365194?term=liang+hernia&rank=1. Accessed 11 Dec 2016
19. ClinicalTrials.gov. Primary fascial closure with laparoscopic ventral hernia repair: a randomized controlled trial [Internet]. https://clinicaltrials.gov/ct2/show/NCT02363790?term=liang+hernia&rank=2. Accessed 11 Dec 2016
20. Baucom RB, Beck WC, Holzman MD et al (2014) Prospective evaluation of surgeon physical examination for detection of incisional hernias. J Am Coll Surg 218(3):363–366
21. Korakakis V, Sideris V, Giakas G (2014) Sitting bodily configuration: a study investigating the intra-tester reliability of positioning subjects into a predetermined sitting posture. Man Ther 19(3):197–202
22. Wyrwich KW, Nienaber NA, Tierney WM et al (1999) Linking clinical relevance and statistical significance in evaluating intra-individual changes in health-related quality of life. Med Care 37(5):469–478