



Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Featured Article

Establishing the minimal clinically important difference for the Hernia-Related Quality of Life Survey (HerQLes)

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ARTICLE INFO

Article history:

Received 23 April 2021

Received in revised form

15 June 2021

Accepted 28 June 2021

Keywords:

MCID

Hernia

Quality of life

ABSTRACT

Background: Hernia-Related Quality of Life Survey (HerQLes) assesses quality of life (QoL) after hernia repair, but the minimal clinically important difference (MCID) is unknown.

Methods: Using 2013–2019 data from the Abdominal Core Health Quality Collaborative, HerQLes summary scores were calculated for VHR patients at baseline and 1-year. MCID was calculated using distribution-based method. Multivariate regression identified factors associated with exceeding MCID at 1 year.

Results: 1817 patients met criteria. MCID was identified as a change in HerQLes of at least 15.6 points. Mean 1-year post-op score was 74.9 (SD ± 26.2), which exceeded the MCID threshold ($p < 0.001$). Patients with increasing hernia width had higher odds of exceeding MCID at 1 year post-op (OR 1.04, $p < 0.01$), as did patients with greater ASA class (OR 8.9, $p < 0.01$).

Conclusion: Using MCID can help identify patients who may significantly improve QoL after VHR, as well as power clinical trials with QoL as primary outcome.

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Introduction

The minimal clinically important difference (MCID) is the threshold value for a change that would be considered meaningful by patients and care providers typically in the context of Patient Reported Outcomes (PROs).¹ This is a highly valuable tool in the research setting, as well as in discussions of shared-decision making with patients choosing to undergo elective surgery. However, one limitation of MCID is that it does not have a threshold that can be universally applied.² Thus, the MCID value for a particular PRO must be identified and subsequently validated for each patient population in order to reflect their unique clinical considerations.² The Hernia-Related Quality of Life Survey (HerQLes) is a validated PRO used to assess disease specific quality of life in hernia patients.³ Defining the MCID in this specific population using this tool is critical to assess changes in quality of life for various interventions and products. We sought to determine the MCID for HerQLes using

data from the Abdominal Core Health Quality Collaborative (ACHQC).

Methods

Design overview

This was a retrospective study of prospectively collected data within the Abdominal Core Health Quality Collaborative (ACHQC) database. After IRB approval, data was obtained for this study through a data use agreement with the ACHQC. Patient-reported responses to the Hernia-Related Quality of Life Survey (HerQLes) were first assessed at baseline and 1-year postoperatively. Summary scores were calculated for each, ranging from 0 (worst quality of life) to 100 (best quality of life). The minimal clinically important difference (MCID) was then calculated using the distribution-based method of standard error of measurement.^{4,5} Multivariate

Abbreviations: Minimal clinically important difference, (MCID); Hernia-Related Quality of Life Survey, (HerQLes); Quality of life, (QoL); Abdominal Core Health Quality Collaborative, (ACHQC); Ventral hernia repair, (VHR); Odds ratio, (OR).

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<https://doi.org/10.1016/j.amjsurg.2021.06.018>

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regression was employed to identify factors associated with exceeding the MCID threshold at 1-year postoperatively, indicating a significant increase in patient-reported quality of life.

Study population and data source

The ACHQC is a national initiative for quality improvement in hernia surgery and includes a national registry database of patients undergoing ventral hernia repair. The database includes data from more than 400 participating surgeons spanning academic medical centers, community hospitals, and private practices across the country. The ACHQC database uses standardized definitions and methodology for capturing all variables, which have been previously reported.⁶

The Abdominal Core Health Quality Collaborative (ACHQC) database was queried to identify all patients undergoing elective ventral hernia repair between 2013 and 2019. All surgical approaches (open, laparoscopic, robotic) were included. Patients were excluded from the study if they did not have HerQLes survey response data available at both baseline and 1-year postop.

MCID in HerQLes summary score (“More than MCID”) and those below the MCID in HerQLes summary score (“Below MCID”).

Primary outcome measure

The primary outcome of interest in this study was binary and indicated whether or not patients met or did not meet the MCID threshold for a meaningful change in HerQLes summary score at 1-year postop.

Statistical analysis

HerQLes summary scores were calculated for each patient at baseline and 1-year postoperatively (Fig. 1). Summary scores were calculated using the following formula: (120-[(20/12)*(raw score)]). Using the summary scores for each time point (1-year, 2 year and 3 year post-op), we identified a reliability estimate (test retest reliability) for the HerQLes survey. We then calculated the standard error of measurement (SEM) using the following formula:

$$SEM = \text{Standard Deviation of HerQLes summary score at baseline (SDbaseline)} * \sqrt{(1 - r)}$$

Comparison groups

Once the MCID threshold was determined for a significant change in HerQLes summary score from baseline to 1 year postop, two distinct study groups were identified: those exceeding the

Based on the SEM, we then calculated the MCID of the HerQLes survey using the formula: MCID = 1*SEM (change from baseline).^{4,5} Finally, we compared the baseline and 1-year mean HerQLes summary score for the sample using a Paired *t*-test. Statistical

For the following statements, please circle the number that is most appropriate for you.	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1. My abdominal wall has a huge impact on my health	1	2	3	4	5	6
2. My abdominal wall causes me physical pain	1	2	3	4	5	6
3. My abdominal wall interferes when I perform strenuous activities, e.g. heavy lifting	1	2	3	4	5	6
4. My abdominal wall interferes when I perform moderate activities, e.g. bowling, bending over	1	2	3	4	5	6
5. My abdominal wall interferes when I walk or climb stairs	1	2	3	4	5	6
6. My abdominal wall interferes when I dress myself, take showers and cook	1	2	3	4	5	6
7. My abdominal wall interferes with my sexual activity	1	2	3	4	5	6
8. I often stay at home because of my abdominal wall	1	2	3	4	5	6
9. I accomplish less at home because of my abdominal wall	1	2	3	4	5	6
10. I accomplish less at work because of my abdominal wall	1	2	3	4	5	6
11. My abdominal wall affects how I feel every day	1	2	3	4	5	6
12. I often feel blue because of my abdominal wall	1	2	3	4	5	6

Fig. 1. Hernia-Related Quality of Life Survey (HerQLes) Instrument
Originally published by Krpata et al. “Design and Initial Implementation of HerQLes: A Hernia-Related Quality-of-Life Survey to Assess Abdominal Wall Function” in Journal of the American College of Surgeons, Volume 215, Issue 5, November 2012. <https://doi.org/10.1016/j.jamcollsurg.2012.06.412>.

Table 1
Demographics of study population.

	Above MCID	Below MCID	Total	P-value
	1261 (69.4%)	550 (30.3%)	1817 (100%)	
Sex				0.39
Male	597 (49.8%)	321 (51.9%)	918 (50.5%)	
Female	602 (50.2%)	297 (48.1%)	899 (49.5%)	
Race				0.42
Black	71 (6%)	36 (5.9%)	107 (6%)	
Hispanic	13 (1.1%)	5 (0.8%)	18 (1%)	
Other	12 (1%)	2 (0.3%)	14 (0.8%)	
White	1082 (91.9%)	566 (92.9%)	1648 (92.2%)	
Age				0.08
18–40	139 (11.6%)	57 (9.2%)	196 (10.8%)	
41–64	653 (54.5%)	322 (52.1%)	975 (53.7%)	
65+	407 (33.9%)	239 (38.7%)	646 (35.6%)	
ASA Class				<0.001
1	47 (3.9%)	22 (3.6%)	69 (3.8%)	
2	408 (34.1%)	243 (39.3%)	651 (35.9%)	
3	706 (59%)	351 (56.8%)	1057 (58.2%)	
4+	36 (3%)	2 (0.3%)	38 (2.1%)	
BMI				0.03
Median (IQR)	32 (28, 36)	31 (27, 36)	32 (28, 36)	
Diabetes				0.18
No	956 (80.1%)	509 (82.8%)	1465 (81%)	
Yes	237 (19.9%)	106 (17.2%)	343 (19%)	
COPD				0.55
No	1129 (94.6%)	586 (95.3%)	1715 (94.9%)	
Yes	64 (5.4%)	29 (4.7%)	93 (5.1%)	

Table 2
Clinical characteristics of study population.

	Above MCID	Below MCID	Total	P-value
	1261 (69.4%)	550 (30.3%)	1817 (100%)	
Hernia Width				<0.001
Median (IQR)	15 (4, 23)	10 (3, 20)	14 (4, 22)	
Hernia Length				<0.001
Median (IQR)	9 (4, 15)	7 (3, 13)	8 (3, 15)	
Approach				0.16
Open	904 (75.4%)	461 (74.6%)	1365 (75.1%)	
Lap	81 (6.8%)	50 (8.1%)	131 (7.2%)	
Robotic	138 (11.5%)	81 (13.1%)	219 (12.1%)	
Other	76 (6.3%)	26 (4.2%)	102 (5.6%)	
OR Time >2 Hr.				0.03
No	421 (35.1%)	249 (40.3%)	670 (36.9%)	
Yes	778 (64.9%)	369 (59.7%)	1147 (63.1%)	
Length of Stay				0.35
Median (IQR)	4 (3, 6)	4 (2, 6)	4 (3, 6)	
Post-Op Complication				0.64
No	906 (77.9%)	474 (78.9%)	1380 (78.2%)	
Yes	265 (22.1%)	127 (21.1%)	384 (21.8%)	
Readmission				0.005
No	1101 (94.7%)	548 (91.2%)	1649 (93.5%)	
Yes	62 (5.3%)	53 (8.8%)	115 (6.5%)	

significance was set at $p < 0.05$ for all the tests. SAS Enterprise Guide software v7.1 was used for completing all analyses.⁷

Results

A total of 1817 patients were included in the study (Table 1). The majority were white (92.2%, 1648) and male (50.5%, 918). The study population was primarily in the 41–64 age range (53.7%, 975), with 10.8% (196) in the 18–40 years range and 35.6% (646) aged 65 or older. The majority of repairs (75.1%, 1365) were performed in an open fashion, with 7.2% (131) performed laparoscopically and 17.7% (321) performed robotically or in a hybrid approach (Table 2). Nearly all patients (94.1%, 1708) had an ASA class of 3 (58.2%, 1057) or 2 (35.9%, 651).

The study population was divided into two distinct groups for analysis based on their overall change in HerQLes summary score from baseline to 1-year postoperatively: those exceeding the MCID threshold and those falling below the MCID threshold (Tables 3 and 4). There were significant differences in median (interquartile range) BMI between the study groups (32 [28, 36] vs. 31 [27, 36]; $p = 0.03$). Other comorbidities, including diabetes (19.9% vs. 17.2%; $p = 0.18$) and COPD (5.4% vs. 4.7%; $p = 0.55$) were not significantly different between groups. There was no statistically significant difference in surgical approach used between groups ($p = 0.16$). However, hernia characteristics, including ASA class, and operative time differed significantly between groups.

The MCID of the HerQLes summary score was found to be 15.6. Individuals exceeding the MCID in HerQLes summary score (“more than MCID”) at 1-year postop had a median (interquartile range) hernia width of 15 (4, 23) compared to individuals below the MCID who had a median width of 10 (3, 20) ($p < 0.01$). Similar results were identified in hernia length, where individuals who exceeded the MCID had a median length of 9 (4, 15) while individuals below the MCID had a median length of 7 (3, 13) ($p < 0.01$). Those exceeding the MCID threshold at 1-year postoperatively also more frequently had operating times greater than 2 h (64.9% vs. 59.7%, $p = 0.03$). Those with baseline HerQLes summary scores in the “very low” range (0–20) had the greatest proportion of patients above the MCID at 1-year postoperatively (80.7%). Even patients with baseline HerQLes summary score in the “high” range (60–80) had a substantial proportion of patients exceed the MCID at 1-year postoperatively (61.2%). We did not identify a statistically significant difference between groups in experiencing any postoperative complication within 30-days of surgery (22.1% vs. 21.2%, $p = 0.64$), but readmission within 30-days of surgery was more common among patients who fell below the MCID threshold (8.8% vs. 5.3%, $p < 0.01$). The mean (standard deviation) HerQLes summary score for the sample was 46.1 (SD ± 27.8) at baseline and 74.9 (SD ± 26.2) at 1-year postoperatively, resulting in a mean difference in summary score of 28.9 (SD ± 29.13) ($p < 0.01$).

A two sample T-test was performed comparing patients who underwent repair for recurrent hernias as compared to patients undergoing repair for primary hernias (Table 5). Patients with recurrent hernias had significantly lower mean HerQLes summary score at baseline (38.2, SD 26), while patients with primary, or non-recurrent, hernias had a mean baseline score of 50.7 (SD 27.9,

Table 3
HerQLes summary scores at 1-year postop by baseline HerQLes summary score range.

Baseline HerQLes Summary Score Range	Total N (%)	1-Year Postoperative HerQLes Summary Score	
		Above MCID	Below MCID
Very Low 0–20	388 (21.4%)	313 (80.7%)	75 (19.3%)
Low 20–40	453 (24.9%)	354 (78.2%)	99 (21.9%)
Medium 40–60	415 (22.8%)	330 (79.5%)	85 (20.5%)
High 60–80	312 (17.2%)	191 (61.2%)	121 (38.8%)
Very High 80+	249 (13.7%)	11 (4.4%)	238 (95.6%)
Total	1817	1199 (66.0%)	618 (34.0%)

Table 4
Multivariable logistic regression model looking at which factors affect a person not meeting the MCID threshold in HerQLes summary score from baseline to 1 year post-op.

Variable	Odds Ratio	95% Confidence Limits		P-value
ASA Class				
1	Referent Group	Referent Group	Referent Group	<0.001
2	0.85	0.48	1.49	
3	1.08	0.61	1.94	
4	8.98	1.92	42.08	
Wound Status				
Clean	Referent Group	Referent Group	Referent Group	0.01
Clean-contaminated	0.64	0.44	0.93	
Contaminated	0.79	0.49	1.29	
Dirty/Infected	0.32	0.13	0.80	
Readmission				
No	Referent Group	Referent Group	Referent Group	<0.01
Yes	0.47	0.31	0.71	
Age in Years	0.98	0.97	0.99	<0.01
Hernia Width (cm)	1.04	1.02	1.06	<0.01

Table 5
Comparison of HerQLes summary score by recurrent status.

Variable	Non-Recurrent (N = 1133)	Recurrent (N = 675)	Total (N = 1808)	P-value
Baseline HerQLes Summary Score				
Mean (SD)	50.7 (27.9)	38.2 (26)	46.1 (27.8)	<0.01
Median (IQR)	48.3 (28.3, 73.3)	35 (18.3, 56.7)	43.3 (23.3, 66.7)	
1-year HerQLes Summary Score				
Mean (SD)	78.4 (24.4)	69.1 (28)	74.9 (26.2)	<0.01
Median (IQR)	88.3 (66.7, 96.7)	78.3 (48.3, 91.7)	85 (60, 93.3)	
Difference in Summary Score (Baseline to 1-Year)				
Mean (SD)	27.6 (28.8)	30.9 (29.5)	28.9 (29.1)	0.02
Median (IQR)	25 (6.7, 46.7)	30 (10, 53.3)	26.7 (8.3, 48.3)	

p < 0.01). These differences persisted at 1-year postoperatively, with non-recurrent repairs reaching a mean postoperative HerQLes summary score of 78.4 (SD 24.4) compared to only 69.1 (SD 28.0) for patients with recurrent hernias (p < 0.01). There was a significant difference observed in difference in summary score from baseline to 1-year between groups, with recurrent patients averaging 30.9 points (SD 29.5) on the HerQLes questionnaire as compared to non-recurrent patients, who averaged 27.6 (SD 28.8) points (p = 0.02).

Discussion

This study identified the minimal clinically important difference (MCID) for the Hernia-Related Quality of Life Survey (HerQLes) for patients undergoing elective ventral hernia repair (VHR). We demonstrated that a significant change in HerQLes from baseline to 1-year postoperatively was a change in summary score of 15.6. In our sample, we found the mean difference in HerQLes summary score from baseline to 1-year was 28.9, which exceeds the MCID threshold for a definitive change in HerQLes summary score.

Minimal clinically important difference (MCID) has gained significant recognition in recent years as the concept has been widely regarded as a way to bridge the gap between clinical outcomes and patient expectations and has also gained favor in clinical trials as a standard threshold for interpreting significant results.⁵ While PROs have varying utility in clinical decision-making, establishing the MCID threshold for these measures allows providers to have more tangible benchmarks by which to help guide conversations around decision-making. This is especially true in the field of elective hernia surgery, where operations are often performed to derive a

benefit in quality of life. Previous studies in the VHR population have defined the MCID for the modified Activities Assessment Scale (AAS), which has produced important knowledge regarding when the risk of worsening a patient’s quality of life by surgical intervention exceeds the likelihood of improving it.⁸ However, the MCID of the Hernia-Related Quality of Life Survey (HerQLes), which specifically assess quality of life in this patient population and is widely utilized, has not been ascertained.

Determining the MCID for the HerQLes instrument provides important context that may allow providers to interpret a patient’s current quality of life and make meaningful assessments of potential for improvement by surgical repair. Ventral hernias often carry significant morbidity and impaired quality of life, which is a key driver for patients seeking elective repair. Providing guidelines for projected 1-year postoperative HerQLes scores based on pre-operative summary scores may help guide conversations surrounding anticipated benefit to patients. This study also provided important context for patients undergoing recurrent vs. non-recurrent repairs, indicating that these patient groups may have experience different changes in quality of life depending on the chronic nature of their hernia disease. Although this study has described the MCID for HerQLes in a cohort of VHR patients, future studies could further explore the association of MCID with important clinical outcomes in different subsets of the VHR population. The heterogeneity of those undergoing VHR warrants additional study in specific patient subpopulations as it is possible that certain groups may derive greater benefit from elective VHR, such as patients with giant hernias, which may provide important context for interpreting the MCID in these cases.

This study has important limitations to note. Most notably, minimal clinically important difference (MCID) is a relatively newer methodology that has undergone frequent change and commentary since its first uses were reported in the literature. To that end, numerous methodologies exist to calculate the MCID value of a patient-reported outcome measure, of which we have used the standard error of measurement approach. It is therefore possible that employing a different approach, such as an anchor-based approach, could produce different values of the MCID threshold for the HerQLes survey. As no prior literature existed in regards to the MCID for this specific survey, we proceeded with the approach we believed to be best-suited for this data based on available scientific literature.

Despite this, establishing the MCID threshold value for the Hernia-Related Quality of Life Survey (HerQLes) marks an important development in informed decision-making for patients and

providers alike. We found that patients with lower baseline quality of life showed higher gains 1-year after VHR. Similarly, patients with increasing hernia width had higher odds of exceeding the MCID threshold at 1-year postoperatively, as did patients with more severe disease (ASA class 4) compared to otherwise healthy patients undergoing elective repair (ASA class 1). These results indicate that measuring the MCID threshold in the HerQLes survey can help identify patients who may be more likely to improve their quality of life by undergoing elective ventral hernia repair. In addition to aiding in individual decision-making, MCID may also be used to help power clinical trials in this disease space who include improvements to quality of life as an outcome.

Conclusions

Expectations as to potential improvements in quality of life are a key driver of patients seeking elective ventral hernia repair. This study demonstrated the minimal clinically important difference (MCID) for a significant change in the Hernia-Related Quality of Life Survey (HerQLes) as a summary score of 15.6. Patients with worse quality of life at baseline, larger hernias, and increased ASA class were more likely to derive meaningful benefit from elective repair. Assessing HerQLes summary scores in comparison to the MCID may be a valuable way for providers to help navigate difficult conversations regarding expectations for surgery in patients seeking elective VHR.

Funding

No funding was received for this study.

Meeting presentation

This work was presented at the 2020 meeting of the American College of Surgeons (Chicago, Illinois; October 2020).

Declaration of competing interest

Savannah Renshaw, BS: none.

Anand Gupta, MBBS, MPH: none.

Benjamin Poulouse, MD MPH FACS: Has received research support from Bard-Davol and Advanced Medical Solutions; he receives salary support from the ACHQC as the ACHQC Director for Quality and Outcomes.

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