The American Journal of Surgery (2016) 212, 81-88

The American Journal of Surgery®

Clinical Science

Patient reported outcomes after incisional hernia repair—establishing the ventral hernia recurrence inventory

Rebeccah B. Baucom, M.D.[a,*], Jenny Ousley, B.S.[a], Irene D. Feurer, Ph.D.[a,b], Gloria B. Beveridge, B.A.[a], Richard A. Pierce, M.D., Ph.D.[a], Michael D. Holzman, M.D., M.P.H.[a], Kenneth W. Sharp, M.D.[a], Benjamin K. Poulose, M.D., M.P.H.[a]

[a]Department of Surgery, Vanderbilt University Medical Center, Nashville, 1161 Medical Center Drive, D-5203 Medical Center North, TN 37232, USA; [b]Department of Biostatistics, Vanderbilt University Medical Center, Nashville, TN, USA

KEYWORDS:
Patient reported outcomes (PROs);
Hernia recurrence;
Ventral hernia recurrence inventory (VHRI);
Ventral incisional hernia

Abstract

BACKGROUND: Assessing incisional hernia recurrence typically requires a clinical encounter. We sought to determine if patient-reported outcomes (PROs) could detect long-term recurrence.

METHODS: Adult patients 1 to 5 years after incisional hernia repair were prospectively asked about recurrence, bulge, and pain at the original repair site. Using dynamic abdominal sonography for hernia to detect recurrence, performance of each PRO was determined. Multivariable regression was used to evaluate PRO association with recurrence.

RESULTS: Fifty-two patients enrolled with follow-up time 46 ± 13 months. A patient-reported bulge was 85% sensitive, and 81% specific to detect recurrence. Patients reporting no bulge and no pain had 0% chance of recurrence. In multivariable analysis, patients reporting a bulge were 18 times more likely to have a recurrence than those without (95% confidence interval, 3.7 to 90.0; $P < .001$).

CONCLUSIONS: This preliminary study demonstrates that PROs offer a promising means of detecting long-term recurrence after incisional hernia repair, which can help facilitate quality improvement and research efforts.

Assessing the long-term success of incisional hernia repair is critical when evaluating techniques, devices, and quality improvement efforts. Recurrence rates, combined with quality-of-life metrics and functional assessments of the abdominal wall, represent the standard by which therapies for incisional hernia are measured on a long-term basis.[1–3] Accurately assessing recurrence has significant implications for value as each 1% change in recurrence translates into at least $32 million consumed by the health system.[4] Placed in context of 350,000

The authors declare no conflicts of interest.

* Corresponding author. Tel.: +1-615-343-5613; fax: +1-615-343-9485.
E-mail address: rebeccah.baucom@vanderbilt.edu

Manuscript received March 26, 2015; revised manuscript May 29, 2015

0002-9610/$ - see front matter © 2015 Elsevier Inc. All rights reserved.
http://dx.doi.org/10.1016/j.amjsurg.2015.06.007

ventral hernia repairs performed each year in the United States, with long-term recurrence rates of up to 32%, this represents an area for significant value improvement.[4,5]

The standard method used in most studies evaluating long-term incisional hernia recurrence relies on physical examination with or without adjunct imaging.[5–8] Most studies do not include routine imaging because of high cost and logistical hurdles; as such, physical examination remains the mainstay for the evaluation of recurrence. Our previous work has demonstrated that reliance on physical examination alone can miss 23% to 31% of recurrent hernias seen on computed tomography, with worse performance in obese patients.[9] Ultrasound evaluation via dynamic abdominal sonography for hernia (DASH) has been prospectively shown to be superior to both computed tomography and physical examination for detection of incisional hernia.[10] However, all of these methods require a clinical encounter and can be biased if the original surgical team is performing the evaluation. These barriers make routine, objective long-term assessment of hernia recurrence difficult.

Patient reported outcomes (PROs) present a novel method to evaluate therapies with an emphasis on outcomes that matter to patients.[11,12] The assessment of long-term incisional hernia recurrence may be particularly suited for PROs as recurrence often results in bulges or discomfort experienced by patients at the operative site. A study by Luijendijk et al,[1] suggested that patient perception of recurrence was highly sensitive for detecting recurrences. If this concept could be precisely validated by defining and testing exact wording offered to patients, decoupling the assessment of hernia recurrence from a physical clinical visit would be feasible. This would have immense implications for reliability, completeness, and efficiency in the long-term assessment of incisional hernia patients, both for clinical quality improvement efforts and research. The purpose of this study was to determine the performance of condition-specific PROs in detecting incisional hernia recurrence compared to a gold standard.

Methods

Study design and overview

A prospective, comparative study was performed, involving adult patients with a history of incisional hernia repair performed 1 to 5 years before enrollment. The Institutional Review Board at Vanderbilt University approved the study procedures. Patients were asked to answer the items being considered for the Ventral Hernia Recurrence Inventory (VHRI). The questions, placed in context of their hernia operation, assessed the patients' own perception of recurrence, bulge, or pain. Using DASH as the gold standard for diagnosis of hernia recurrence, testing characteristics and real-world performance for the PROs were determined. Multivariable logistic regression was used to determine the independent associations of responses on the PROs with long-term incisional hernia recurrence, adjusting for quality of life and follow-up time.

Development of patient-reported outcomes

To determine the questions for the VHRI, patients and surgeons were engaged. Focus groups were conducted at bimonthly sessions of the Vanderbilt Surgical Health Services Research conference over a 2-month period. On the basis of the study performed by Luijendijk et al,[1] we developed a screening question:

"Regarding your hernia operation, do you feel your hernia has come back?"

[] Yes [] No.

To develop hernia-specific questions, patients with incisional hernias, seen at the Vanderbilt Hernia Center during routine care, were asked about symptoms. The 2 main themes were recurrence of a bulge and pain at the hernia site. An iterative process was used to refine the PROs, and the PROs developed as potential items for the VHRI are shown in Fig. 1.

Patient population and study procedures

Patients with a history of an incisional hernia repair performed at Vanderbilt University Medical Center between 1 and 5 years before enrollment were contacted. Patients were recruited via telephone and through secure patient portal messaging, known as My Health at Vanderbilt. Verbal consent was obtained during telephone contact, or initial consent was given if patients agreed to complete the PROs electronically. Patients were excluded if they were pregnant or if the original hernia repair was performed emergently. In addition to the PROs, patients were asked whether a physician or other health care provider had diagnosed a recurrence, whether a recurrence had been noted on an imaging test, and about interval abdominal

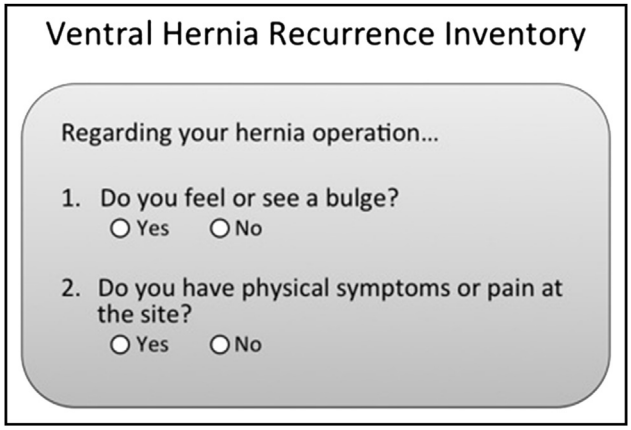

Figure 1 The two-item VHRI.

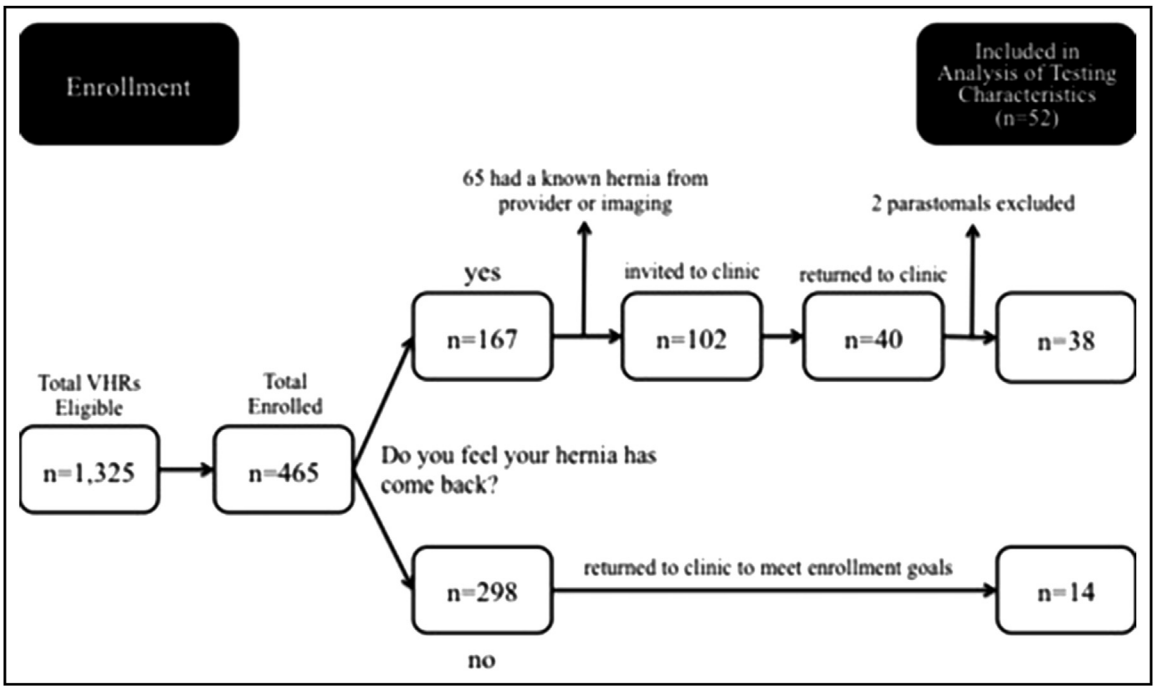

Figure 2 Flow diagram of patient enrollment and follow-up. The patients who believed their hernia had come back were invited for a clinical visit. Patients who felt they did not have a recurrence were then invited to return until enrollment goals were met. The overall enrollment goal, based on the power calculation, was 25 patients with a recurrence and 25 without recurrence. Of the 52 patients who returned for a clinical visit, there were 26 with a recurrence and 26 without. VHRs = Ventral hernia repairs.

operations. If patients reported an interval hernia repair or had been told of a recurrence by a provider or imaging study, they were excluded. In addition, patients with parastomal hernias were excluded, as questions about pain, symptoms, and a bulge were not clearly directed at the parastomal component of the hernia versus a concurrent incisional hernia. For patients who had undergone multiple hernia repairs at Vanderbilt University Medical Center, the most recent repair was considered the index hernia operation.

All patients who felt that their hernia had recurred were invited for a clinical visit, provided they had not been told by a physician or imaging examination that they had a recurrence. A comparable number of patients with no perception of recurrence were also invited, with an enrollment goal based on the study's power calculation. We aimed for balanced groups, resulting in 50% with recurrent hernias and 50% without recurrences based on the DASH gold standard. During the clinic visits, written informed consent was obtained, and patients completed the Likert pain scale, EQ-5D (The EuroQol Group, The Netherlands), HerQLes (hernia-related quality of life survey), a physical examination, and a DASH examination. The Likert pain scale asked patients to rate their current pain on a scale from 0 to 10.[13] The EQ-5D included a visual analog scale, which asked patients to rate their overall health state and also queried about health status in 5 dimensions: mobility, self-care, usual activities, pain and/or discomfort, and anxiety and/or depression.[14] HerQLes is a 12-question assessment evaluating abdominal wall function with responses to each question presented in a Likert-style questionnaire.[3] Finally, information about patients' index hernia operation and comorbidities was collected.

Power calculation and statistical analysis

The method for estimating the number of true-positive and true-negative patients follows that described by Beck et al.[10] The percent correlation for outcome between DASH and PROs was assumed to be similar to that for DASH and physical examination (latter with sensitivity and specificity of 77% and 95%, respectively[15]). To estimate the minimum number of true-positive and true-negative patients required for this prospective study, we calculated 95% confidence intervals (CIs) using Wilson's method to estimate error rates assuming DASH to be the gold standard. Power curves were then plotted for a given number of true-positive or true-negative patients, and the accompanying 95% CI widths evaluated. On the basis of this information, a minimum 25 true-positive and 25 true-negative patients were recruited for this study. Patients who felt they had experienced a recurrence were invited for a clinical visit, followed by patients who were more likely not to have a recurrence, until enrollment goals were attained.

Descriptive statistics for the study population were calculated. Testing characteristics (sensitivity and specificity) were determined for the individual PROs and combinations of PROs. Real-world performance was

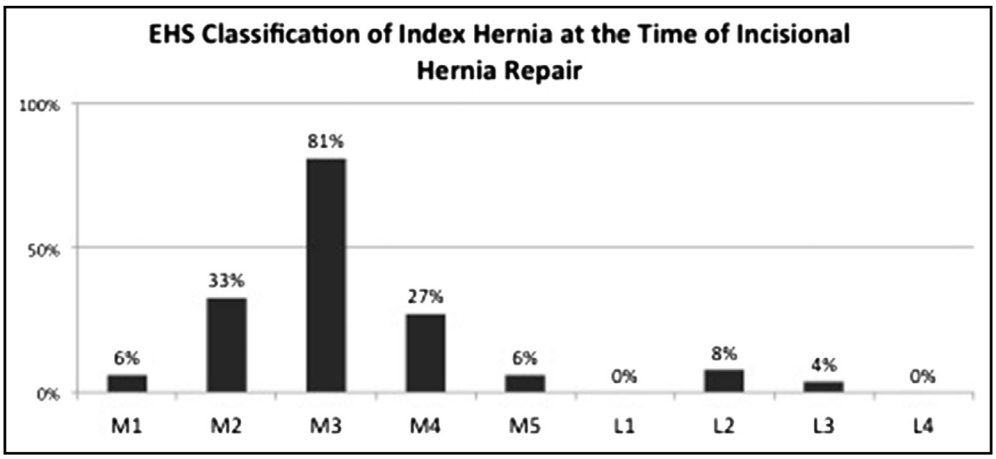

Figure 3 EHS classification of incisional hernias. The EHS classification divides incisional hernias into midline (M) and lateral (L) hernias. Groups are numbered from cranial to caudal location along the M hernias as follows: subxiphoid (M1), epigastric (M2), umbilical (M3), infraumbilical (M4), and suprapubic (M5). L hernias are classified as subcostal (L1), flank (L2), iliac (L3), and lumbar (L4). Most patients had midline hernias, with M3 (periumbilical) hernias being the most common. A hernia can span more than 1 classification, depending on its craniocaudal dimension; thus, the sum of the percentages is not 100. EHS = European Hernia Society.

estimated by the calculation of positive predictive value (PPV) and negative predictive value (NPV), with 95% CIs computed for each statistic. Logistic regression was used to construct receiver operating characteristic curves for each of the questions and combinations of questions to determine the utility of each for detection of recurrence.[16] The higher the area under the receiver operating characteristic curve, that is, the closer to 1, the greater the overall accuracy of the test. The CIs for the areas were compared, and in cases where CIs overlapped, the PRO with the highest area under the curve was selected for inclusion in the final model. Responses to the 5 EQ-5D items were converted to health preference weights using the model by Shaw et al.[17] Principal component analysis was used to compute a weighted composite measure of health-related quality of life (HRQOL) that represented the Likert pain scale, HerQLes score, EQ-5D visual analog scale, and EQ-5D health preference weight. Finally, a multivariable logistic regression model was constructed to evaluate whether the responses on the PROs were independently associated with the likelihood of recurrence after adjusting for HRQOL and follow-up time. Stata, version 13.1 (StataCorp, College Station, TX), and IBM SPSS Statistics, version 22 (IBM Corporation, Armonk, NY), were used for statistical analysis.

Table 1 Frequency of responses to the PROs and results of DASH examination

	Hernia on DASH examination		
PRO responses	Yes	No	Total
"Do you feel your hernia has come back?"			
Yes	25	13	38
No	1	13	14
Total	26	26	52
"Do you feel or see a bulge?"			
Yes	22	5	27
No	4	21	25
Total	26	26	52
"Do you have physical symptoms or pain at the site?"			
Yes	22	14	36
No	4	12	16
Total	26	26	52

Table entries are number of patients with given response.
DASH = dynamic abdominal sonography for hernia; PRO = patient reported outcome.

Results

Study enrollment and demographics

Overall, 1,325 patients were eligible for the study. Of those, 465 patients completed initial enrollment questions (35% response rate); 74 enrolled electronically through My Health at Vanderbilt, and 391 completed the PROs by telephone. Of the 465 respondents, 167 (36%) believed they had a hernia recurrence. After excluding patients who had been told of their hernia recurrence by a health care provider or imaging study, 102 patients who believed they had a recurrence were eligible to return for a clinical visit. A flow diagram of study enrollment can be found in Fig. 2.

A total of 52 patients returned for a clinical visit. This included 38 patients who believed they had a recurrence, along with 14 patients who did not feel they had a recurrence. There were 26 patients who actually had a hernia recurrence (true positives) and 26 who did not (true negatives) as determined by the gold standard DASH. The population consisted of 29 females (56%) with mean age of 52 ± 12 years and mean body mass index (BMI) of 33 ± 6.5 kg/m^2. A total of 47 patients (90%) were white and 5 (10%) African American and/or black. Eight patients

Table 2 Diagnostic characteristics of components of the PRO for incisional hernia recurrence

Diagnostic characteristic	"Do you feel your hernia has come back?"	"Do you feel or see a bulge?"	"Do you have pain or symptoms at the site?"
Sensitivity	.96 (.78-1.0)	.85 (.64-.95)	.85 (.64-.95)
Specificity	.50 (.30-.70)	.81 (.60-.93)	.46 (.27-.66)
PPV	.66 (.49-.80)	.81 (.61-.93)	.61 (.44-.76)
NPV	.93 (.64-1.0)	.84 (.63-.95)	.75 (.47-.92)

Prevalence of hernia in the sample was 50%. The 95% confidence intervals for each characteristic are noted in parentheses.
NPV = negative predictive value; PPV = positive predictive value; PRO = patient reported outcome.

(15%) were current smokers and 21 (40%) former smokers. For 34 patients (67%), the index hernia repair was their only prior repair, and the mean number of prior hernia repairs was 1.6 ± 1.0 (range, 1 to 5). The mean time of patient evaluation after index hernia repair was 46 ± 13 months. The European Hernia Society classification[18] of the index hernias at the time of the hernia repair is shown in Fig. 3. The mean width of the original hernias was 6.0 ± 4.5 cm (range, 1 to 20 cm).

All but 2 patients had undergone open hernia repair; 7 (13%) underwent primary suture repair, 30 (58%) mesh repair with fascial closure, and 15 (29%) mesh repair without fascial closure. Of those who underwent mesh repair, 34 (76%) had permanent prosthetic mesh placed, 10 (22%) biologic, and 1 (2%) absorbable prosthetic. A high proportion of patients (48%, n = 25) reported current pain at the site of the hernia repair; the mean pain level for the group overall was 2.0 (range, 0 to 10).

Contingency tables summarizing responses to the each of PROs along with the results of the DASH examination are presented in Table 1. Overall, 27 patients (52%) reported a bulge, and 36 (69%) reported experiencing pain or symptoms at the site of the hernia operation. Of note, only 11 of the 26 patients (42%) who had a recurrence by DASH examination had a hernia palpable on surgeon physical examination. The mean width of the hernia recurrences was 6.4 cm (range, 1 to 20 cm). There were 7 patients whose recurrence was 1 cm wide. After the study visit, 1 patient underwent repair of their recurrence, 1 patient was scheduled for repair, 3 patients were seen by surgeons but were not felt to be operative candidates, and 1 patient was referred for evaluation.

The testing characteristics for the PROs are summarized in Table 2. Patient-perceived recurrence had a sensitivity of .96, with a false negative rate of .07. Although less sensitive than the question about recurrence, the question about a bulge had the best overall performance, with sensitivity .85, specificity .81, PPV .81, and NPV .84. Areas under the receiver operating characteristic curves were .73 (95% CI, .63 to .84) for the question regarding recurrence, .83 (95% CI, .72 to .93) for the question about a bulge, and .65 (95% CI, .53 to .77) for the question about pain were determined. The high area under the curve for the bulge question (.83) indicated this PRO to be the best single-question–discriminating recurrence. In multivariable analysis including the 3 PROs and follow-up time, only a patient-reported bulge was significantly associated with recurrence (odds ratio, 11.9; 95% CI, 2.18 to 65.5, $P = .004$).

Given that a question about a bulge was the single best discriminating question, we sought to determine whether a combination or sequence of questions offered additional benefit. A negative response to both bulge and pain virtually ruled out the presence of a hernia (NPV, 1.0; 95% CI, .70 to 1.0), but came at the expense of many false positives (sensitivity, .46; 95% CI, .27 to .66). If positive responses to the recurrence question were followed by the bulge question, this offered few improvements over the testing characteristics of the bulge question alone (sensitivity, .88; specificity, .62; PPV, .81; NPV, .73). No other sequences or combinations offered improvement over the bulge question alone using area under the curve analyses.

Principal component analysis demonstrated that the Likert pain scale, HerQLes score, EQ-5D visual analog scale, and EQ-5D health preference weight were associated with a single HRQOL component that represented a substantial proportion (73%) of the total covariance among the 4 measures. The absolute values of the 4 HRQOL or pain scale

Table 3 Multivariable logistic regression model of the likelihood of incisional hernia recurrence with the single PRO "do you feel or see a bulge?"

Covariate	Odds ratio	95% Confidence interval	*P* value
Do you feel or see a bulge?	18.1*	3.7-90.0	<.001
HRQOL composite score	1.1	.5-2.2	.882
Follow-up time (months since hernia repair)	1.0	.9-1.0	.976

HRQOL = health-related quality of life; PRO = patient reported outcome.
*Results adjusted for the computed HRQOL composite score and follow-up time.

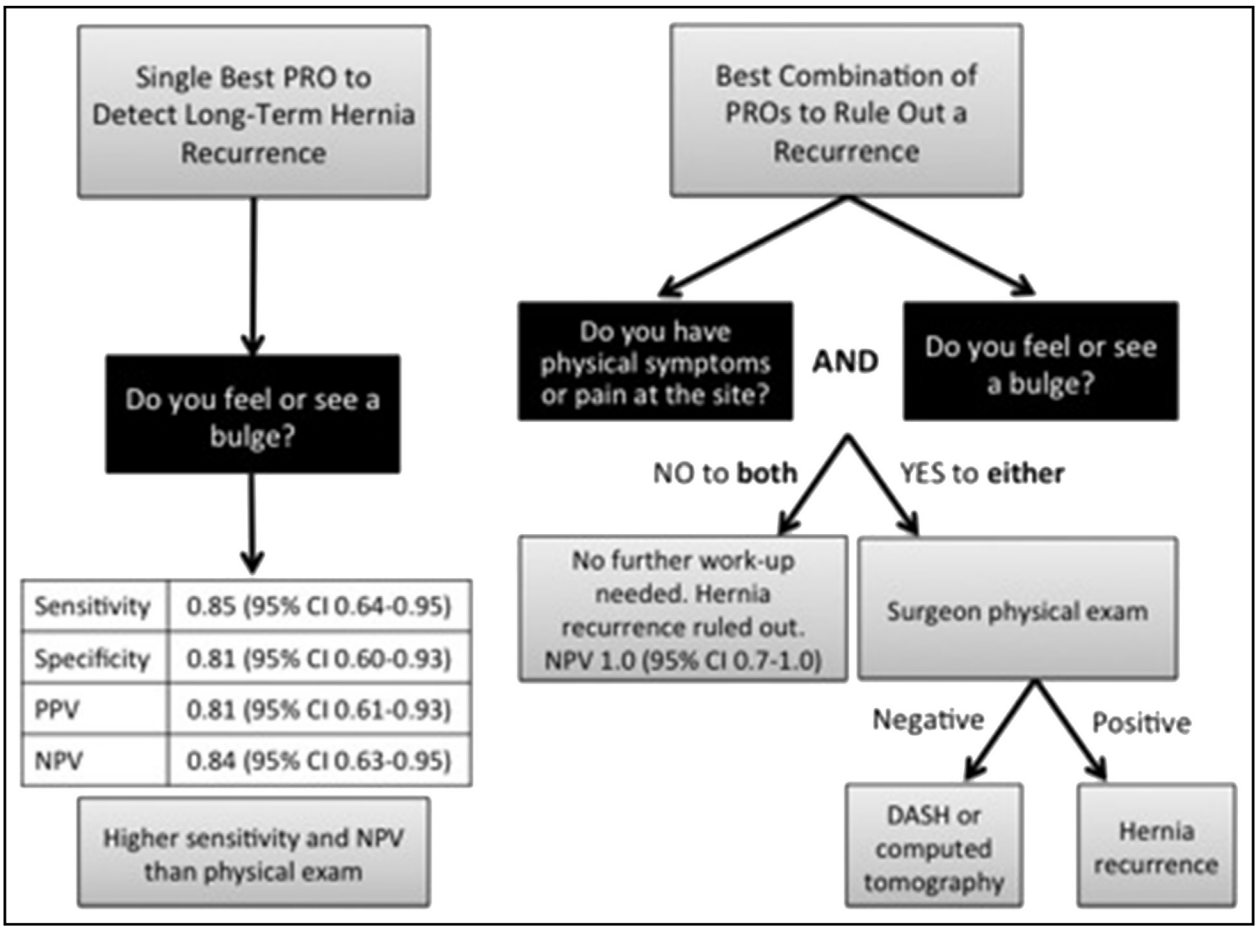

Figure 4 VHRI-based algorithm to assess long-term recurrence after incisional hernia repair. The minimum time before assessment is 1 year after incisional hernia repair. The single best discriminatory PRO is whether a patient notices a bulge (area under the receiver operating characteristic curve, .83). This outperforms physical examination as a screening test and is more specific than the questions about pain and recurrence. If a patient does not notice a bulge and does not experience pain or symptoms at the site of the operation, the probability of a recurrence is essentially 0. If the response to either question is yes, physical examination should be performed by an experienced hernia surgeon to determine the need for ancillary testing. Additional radiographic testing options include DASH or computed tomography for confirmation, but a positive bulge question alone gives reasonable certainty of hernia recurrence.

loadings were consistently high ($\geq .8$) and were used to compute a standardized HRQOL composite score for each participant. The final multivariable logistic regression model is presented in Table 3. "Do you feel or see a bulge?" was significantly associated with an increased likelihood of recurrence ($P < .001$), after adjusting for HRQOL and follow-up time. Persons having a positive response to that question were, overall, 18 times more likely to have a recurrence (odds ratio, 18; 95% CI, 3.7 to 90.0).

Comments

This preliminary evaluation of PROs shows that the VHRI offers a promising method of detecting recurrence in the long-term follow-up of patients after incisional hernia repair. This study is the 1st to quantify the utility of two PROs that are commonly asked during follow-up visits after incisional hernia repair. Importantly, these PROs were effective for detecting recurrence outside of a clinical visit, and testing was performed using a validated gold standard for comparison. On the basis of these results, we propose an algorithm (Fig. 4) that incorporates the VHRI as the potential means to assess long-term recurrence beginning 1 year after incisional hernia repair.

Given that recurrence likely increases with time, this approach offers a robust means of long-term follow-up without requiring a physical clinical visit. All patients should be asked about bulge and pain. If a patient does not notice a bulge and does not experience pain or symptoms at the site of the operation, the probability of a recurrence is essentially 0. Importantly, a patient-reported bulge outperforms physical examination as a screening test for detection of a recurrence. Patient-reported pain or a patient-reported bulge warrants further clinical follow-up to determine recurrence status. This algorithm, even taking into account the use of confirmatory radiographic testing, would greatly improve the feasibility and efficiency of

long-term follow-up in quality improvement efforts and research.

Our findings concerning patient-perceived recurrence correlate well with those from the study by Luijendijk et al.[1] Our study adds value by defining the precise questions to ask patients and by using a standard and validated method of ultrasound assessment of the abdominal wall (DASH) in all patients. In addition, these questions were validated in a U.S. population, an important factor for the generalizability of PROs. The VHRI was superior to physical examination as a screening test for recurrence, the latter of which is the most used assessment during long-term follow-up. In this prospective study, only 11 out of 26 patients who had a hernia confirmed on DASH examination had a hernia detected on physical examination. This is in line with our prior work demonstrating that surgeon physical examination has a sensitivity of only .77 and false negative rate of .33 for detecting incisional hernias.[9] However, surgeon physical examination is useful when positive, with a specificity and PPV of .95.[9] Although not 100% sensitive, the VHRI can still be useful as a tool to evaluate recurrence without the logistics, cost, or potential inconvenience of a clinical visit.

One notable finding in this study is the large proportion of patients who reported experiencing pain or symptoms at the site of their operation at least some of the time (69%) and the number of patients who were actively experiencing pain at the time of the clinical visit (48%). This is higher than the 20% to 23% of patients who reported pain at the scar and 20% to 36% who reported abdominal pain in the long-term follow-up study performed in The Netherlands.[5] The patients in our study also rated their pain higher than those in the study by Burger et al.[5] We postulate that this is a result of several factors. First, patients' experience of pain can vary between cultures. In addition, there was likely an element of selection bias because patients with chronic symptoms were more likely to desire evaluation by a physician.

On the basis of our experience long-term follow-up of incisional hernia patients should include a measure of recurrence, an assessment of pain, and quality-of-life metrics. This study evaluated a simple Likert scale for pain intensity, but other more robust measures could also be used such as the PROMIS (Patient Reported Outcome Measurement Information System, National Institutes of Health, PROMIS Network Center, Chapel Hill, NC) pain intensity scale or a PROMIS pain interference short form.[11] The addition of HRQOL metrics is important, as not all recurrences may impact quality of life. Several patients were evaluated for repair once the recurrences were diagnosed during this study, but not all recurrences were symptomatic. Hence, although a robust measure of recurrence is important in evaluating outcomes, assessment of pain and quality-of-life metrics should also be used. We evaluated 2 HRQOL instruments including the EQ-5D, a generic measure, and HerQLes, a disease-specific instrument. EQ-5D was selected over other global assessment instruments because the US health preference weights allow for the use of EQ-5D in health utility analyses. Other potential generic instruments include versions of the Short Form Health Surveys. HerQLes was chosen as a validated disease-specific measurement designed to assess the abdominal wall function, independent of the use of prosthetics. Another hernia-specific measure that could be used would be the Carolinas Comfort Scale.[19]

The results of this study should be considered in light of several limitations. The number of patients included in the study was relatively low although based on the a priori power calculation and previous work evaluating recurrence assessment, this number was sufficient to establish reasonably narrow CIs. There may be factors that made some patients more likely than others to enroll in the study, leading to selection bias. Typically, patients who have recurrent hernias and symptoms tend to be those seeking medical attention and may have been overrepresented in the final study population. We attempted to minimize this bias by inviting patients with and without symptoms as part of the initial screening process. In addition, DASH was performed on all patients, regardless of symptoms. Future prospective studies will further clarify the testing characteristics of the VHRI components.

The prevalence of hernia recurrence in the eligible population was not known, and prevalence of recurrence will impact the PPV and NPV of the PROs. For instance, if the prevalence of recurrence in a population is 25%, the NPV of the question about a bulge will increase to .94, increasing the reliability of a negative response and improving the clinician's certainty that no recurrence is present. The specificity of simply asking the patients whether they had experienced a recurrence was lower than anticipated based on prior studies. Ultimately, this resulted in unbalanced groups of patients who felt they had or had not experienced a recurrence, but this should not have impacted the testing characteristics of the PROs. Our primary goal of recruitment was achieved, which was balanced groups of true positives and true negatives on DASH examination. Because PROs are most valid in the population that is similar to the one tested and 90% of the study population was white/Caucasian, the generalizability of our findings to other populations is not known. Obesity might make a bulge more difficult to discern, limiting the accuracy of a patient-reported bulge. The mean BMI in our population was 33 kg/m^2, so we would expect the testing characteristics of the VHRI would improve in a population of patients with normal BMI, but more studies are needed.

The PROs evaluated here have not been tested in other aspects of abdominal wall disease such as parastomal hernia repair and inguinal hernia repair. As such, their utility in these scenarios is unknown. Considering the PRO wording focuses on the concept of recurrence without mention of incisional hernia, the algorithm can likely be

used to assess recurrence after primary abdominal wall hernia repair (ie, epigastric or umbilical hernias). However, this should ideally be tested in a population of patients with primary hernias. Finally, potential observer bias was introduced during the DASH examination because the examiner knew the results of the PROs. However, one of the advantages of DASH over computed tomography is that it is a real-time examination in which interaction with the patient is used to facilitate the examination. Because it was not feasible to blind the person performing the DASH examination to the PRO results, we felt that it would introduce less bias by asking the PROs before the DASH examination rather than performing them in the reverse order.

Conclusions

In summary, this study presents a novel use of PROs in the incisional hernia patient population. Asking patients "Do you feel or see a bulge?" demonstrated 85% sensitivity and 81% specificity and was shown to be the best single question to assess for incisional hernia recurrence. If patients answered "No" to this question and also "No" to the question "Do you have physical symptoms or pain at the site?" a recurrent incisional hernia was essentially ruled out. The VHRI can be used to help facilitate long-term follow-up after incisional hernia repair, and it can be integrated into practices in the form of e-mail, telephone, or written surveys. The PROs are particularly valuable when responses to the questions are negative and can help to rule out the presence of a recurrence. The VHRI can offer a simple yet effective method in research studies and quality improvement efforts to detect the end point of recurrence. Finally, this highlights a potential area for cost-savings in both research and clinical settings by decreasing the need for some long-term clinical visits and imaging after incisional hernia repair.

Acknowledgments

Data were collected and managed using REDCap electronic data capture tool, which is supported by the UL1 TR000445 grant from NCATS/NIH and hosted at the Vanderbilt University Medical Center. The authors acknowledge William Dupont, Ph.D., for assistance with the study power calculation, Stephen Deppen, Ph.D., and Marie Griffin, M.D., M.P.H., for assistance with calculating testing characteristics of the novel patient-reported outcomes.

References

1. Luijendijk RW, Hop WC, van den Tol MP, et al. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med 2000;343:392–8.
2. Colavita PD, Tsirline VB, Belyansky I, et al. Prospective, long-term comparison of quality of life in laparoscopic versus open ventral hernia repair. Ann Surg 2012;256:714–23.
3. Krpata DM, Schmotzer BJ, Flocke S, et al. Design and initial implementation of HerQLes: a hernia-related quality-of-life survey to assess abdominal wall function. J Am Coll Surg 2012;215:635–42.
4. Poulose BK, Shelton J, Phillips S, et al. Epidemiology and cost of ventral hernia repair: making the case for hernia research. Hernia 2012;16:179–83.
5. Burger JW, Luijendijk RW, Hop WC, et al. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. Ann Surg 2004;240:578–83; discussion 583–5.
6. Heniford BT, Park A, Ramshaw BJ, et al. Laparoscopic ventral and incisional hernia repair in 407 patients. J Am Coll Surg 2000;190:645–50.
7. Novitsky YW, Porter JR, Rucho ZC, et al. Open preperitoneal retrofascial mesh repair for multiply recurrent ventral incisional hernias. J Am Coll Surg 2006;203:283–9.
8. Itani KM, Rosen M, Vargo D, et al. Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: the RICH study. Surgery 2012;152:498–505.
9. Baucom RB, Beck WC, Holzman MD, et al. Prospective evaluation of surgeon physical examination for detection of incisional hernias. J Am Coll Surg 2014;218:363–6.
10. Beck WC, Holzman MD, Sharp KW, et al. Comparative effectiveness of dynamic abdominal sonography for hernia vs computed tomography in the diagnosis of incisional hernia. J Am Coll Surg 2013;216:447–53.
11. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. J Clin Epidemiol 2010;63:1179–94.
12. Bevans M, Ross A, Cella D. Patient-Reported Outcomes Measurement Information System (PROMIS): efficient, standardized tools to measure self-reported health and quality of life. Nurs Outlook 2014;62:339–45.
13. McCaffery M, Beebe A. Pain: Clinical Manual for Nursing Practice. Baltimore, MD: V. V. Mosby Company; 1993.
14. Brooks R. EuroQol: the current state of play. Health Policy 1996;37:53–72.
15. Baucom R, Beck W, Holzman M, et al. Prospective evaluation of surgeon physical exam for detection of incisional hernias. J Am Coll Surgeons 2013;218:363–6.
16. Cleves MA. From the help desk: comparing areas under receiver operating characteristic curves from two or more probit or logit models. Stata J 2002;2:301–13.
17. Shaw JW, Johnson JA, Coons SJ. US valuation of the EQ-5D health states: development and testing of the D1 valuation model. Med Care 2005;43:203–20.
18. Breuing K, Butler CE, Ferzoco S, et al. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. Surgery 2010;148:544–58.
19. Heniford BT, Walters AL, Lincourt AE, et al. Comparison of generic versus specific quality-of-life scales for mesh hernia repairs. J Am Coll Surg 2008;206:638–44.