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

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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

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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

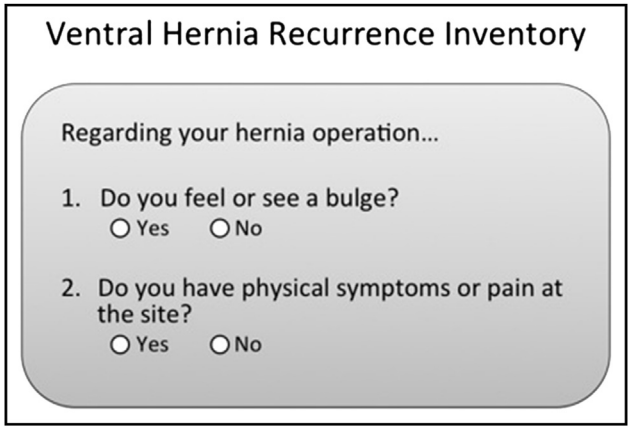

Figure 1 The two-item VHRI.