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Predictive modeling for chronic pain after ventral hernia repair



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Abstract

BACKGROUND: Few studies predict which patients have dissolution of their postoperative discomfort or develop chronic pain after ventral hernia repair (VHR). This study develops a predictive model to determine which patients are at the greatest risk of chronic pain after VHR.

METHODS: A prospective study of VHR patients was performed via the International Hernia Mesh Registry. Anonymous, self-reported, quality of life data using the Carolinas Comfort Scale (CCS) was recorded preoperatively, and 1,6, and 12 months postoperatively. Pain was identified as a score of 2 or more (mild but bothersome to severe) for any Carolinas Comfort Scale pain-specific questions. Logistic regression analyses were performed to determine statistically significant predictors of chronic pain. Univariate analysis selected potential predictors with a P value less than .15, and a subsequent multivariable model was built using backward elimination setting retention criterion at P < .15. Goodness-of-fit of the model was tested using Hosmer-Lemeshow test. A value of greater than 70% for the area under the curve (AUC) was considered most accurate diagnostically. The final model was then internally validated with bootstrap analysis.

RESULTS: A total of 887 patients underwent VHR between 2007 and 2014. The patients had an average age of 57.2 ± 12.8 years, 52.4% were female, 17.0% were active smokers, and 13.2% used narcotics preoperatively. With 74% follow-up at 1 year, 26.0% of the patients reported chronic discomfort. After logistic regression model, independent predictors of pain at 6 months were preoperative pain score 2 or more (P < .0001), preoperative narcotic use (P = .06), and 1-month postoperative pain score 2 or more (P < .0001), AUC = .74. Baseline, 1-month, and 6-month predictors determined the final multivariate regression model for prediction of chronic pain at 1 year, AUC = .73. Older age was protective against chronic pain (odds ratio [OR] .98, 95%confidence interval [CI] = .96 to .998, P = .03), female sex increased risk with an OR of 1.7(CI = 1.1 to 2.7, P = .02); preoperative pain, and recurrent hernia repair nearly doubled the risk of developing chronic pain postoperatively (OR = 3.0, CI = 1.8 to 4.8, P < .0001 and 1.6, CI = .98 to 2.6, P = .06, respectively). Importantly, presence of pain at 1 month was a strong predictor of chronic pain at 1-year follow-up (OR = 2.6, CI = 1.7 to 4.2, P < .0001).

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CONCLUSIONS: Patients who have preoperative pain and at 1 month postoperatively are significantly more likely to have chronic pain. Both short- and long-term pain can be predicted from female sex, younger age, and repair of recurrent hernias. This predictive model may aid in preoperative counseling and when considering postoperative intervention for pain management in VHR patients. © 2016 Elsevier Inc. All rights reserved.

It is estimated that 360,000 ventral and incisional hernia repairs are performed annually in the United States, resulting in \$3.2 billion in health care costs. 1,2 Management of the VH patient has undergone significant change over the last 20 years. Mesh reinforcement during ventral hernia repair (VHR) has resulted in a 50% reduction in hernia recurrence.^{3,4} More surgeons now focus on managing patient comorbidities, such as smoking cessation or weight before elective hernia repair.^{5–10} Minimizing morbidity after hernia repair and the inclusion of patient quality of life (QOL) as measures of good hernia repair outcomes are commonly reported in contemporary surgical articles. 11-13 Current rates of chronic pain after VHR are up to 39%, demonstrating a patient-centered outcome that warrants study, understanding, and planned strategy for improvement.4,13-15

Our institution has previously investigated factors affecting QOL for VHRs, including technique, ¹³ the hernia defect size itself, ¹⁶ number of mesh fixation tacks, ¹⁷ adjunct techniques such as components separation as an additive factor of pain after open VHR, ¹⁸ and mesh type. ¹⁹ Ways to proactively treat pain with local anesthetics such as suture site injections to mitigate the short-term complication of pain have been explored, ²⁰ but there is still much to learn. The ability to predict patients' postoperative pain could have a significant impact on preoperative counseling, patient satisfaction and, perhaps, direct different or more aggressive pain management techniques before, during, and after the surgery.

We have previously demonstrated that preoperative pain predicts postoperative pain in VHR within our own prospective data. Herein, this study was designed to explore this finding in an international, multi-institution, hernia-specific registry. Our intent was to identify individual or combinations of factors, including patient demographics and comorbidities, hernia-related characteristics, operative details, and early postoperative outcomes, to develop a comprehensive evaluation tool as a predictive model to identify those patients at greatest risk to develop chronic pain.

Methods

Data collection

The International Hernia Mesh Registry (IHMR), a prospective multi-institutional database with more than 30 participating sites worldwide from the United States, Europe, Australia, and Canada was queried for all VHRs

performed in patients 18 years old or more from 2007 to 2014. IHMR is an established registry by Ethicon, Inc. (Somerville, NJ); however, data collection, storage, statistical and scientific evaluation, and presentation are completely independent from any corporate entity. Complete list of inclusion and exclusion criteria for the IHMR is listed in Table 1. The IHMR is a registered clinical trial with ClinicalTrials.gov, study NCT00622583 found at http://www.clinicaltrials.gov/ct2/show/study/NCT00622583. Patients were included if they underwent a ventral or incisional hernia with either an open or laparoscopic approach for analysis. Any patients with missing data from any time points for follow-up at 1 month, 6 months, or 1 year were excluded from the analysis. Patient demographics, comorbidities, and hernia-specific data were collected. Perioperative characteristics such as surgeon specialty, type of anesthesia, type of mesh used, operative time, and length of stay were collected. Postoperative outcomes including pneumonia, venous thromboembolic event, stroke, myocardial infarction, sepsis, and 30-day mortality, as well as outcomes specific to the repair such as hematoma, seroma, wound complications, superficial surgical site infection, deep surgical site infection, 30-day return to the operating room, and recurrence were collected.

QOL assessment

The Carolinas Comfort Scale was used to survey and compare outcomes of QOL preoperatively and at 1, 6, and 12 months postoperatively. The CCS has been previously validated,²¹ is currently used worldwide in more than 48 countries, has been translated into 25 languages and is accessible online or completed by mail. Mesh sensation, severity of pain, and movement limitation were collected as continuous measurements on a 6-point scale within the following functional actions: lying down, bending over, sitting, activities of daily living, coughing or deep breathing, walking, walking upstairs, and exercise. CCS scores of 0 (none) or 1 (minimal and not bothersome) were considered asymptomatic whereby patients were defined as symptomatic with CCS scores of 2 (mild, but bothersome) or higher. Patients reported their own data and were guaranteed anonymity in an attempt to eliminate collection bias.

Statistical analysis

Patient characteristics are described by means and standard deviations for continuous variables, mean with standard deviation or median and inter-quartile range for

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