External Validation of the European Hernia Society Classification for Postoperative Complications after Incisional Hernia Repair: A Cohort Study of 2,191 Patients

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BACKGROUND: Incisional hernia is a frequent complication after midline laparotomy. Surgical hernia repair is associated with complications, but no clear predictive risk factors have been identified. The European Hernia Society (EHS) classification offers a structured framework to describe hernias and to analyze postoperative complications. Because of its structured nature, it might prove to be useful for preoperative patient or treatment classification. The objective of this study was to investigate the EHS classification as a predictor for postoperative complications after incisional hernia surgery.

STUDY DESIGN: An analysis was performed using a registry-based, large-scale, prospective cohort study, including all patients undergoing incisional hernia surgery between September 1, 2011 and February 29, 2016. Univariate analyses and multivariable logistic regression analysis were performed to identify risk factors for postoperative complications.

RESULTS: A total of 2,191 patients were included, of whom 323 (15%) had 1 or more complications. Factors associated with complications in univariate analyses ($p < 0.20$) and clinically relevant factors were included in the multivariable analysis. In the multivariable analysis, EHS width class, incarceration, open surgery, duration of surgery, Altemeier wound class, and therapeutic antibiotic treatment were independent risk factors for postoperative complications. Third recurrence and emergency surgery were associated with fewer complications.

CONCLUSIONS: Incisional hernia repair is associated with a 15% complication rate. The EHS width classification is associated with postoperative complications. To identify patients at risk for complications, the EHS classification is useful. (J Am Coll Surg 2018;226:223–229. © 2017 Published by Elsevier Inc. on behalf of the American College of Surgeons.)

Incisional hernia remains a frequent complication after abdominal surgery, with incidence rates of 10% to 30% after midline laparotomies, depending on risk factors.[1-6] This incidence leads to a high number of hernia repair operations. In the US alone, more than 300,000 repairs are performed annually. The associated costs of these hernia repairs are estimated to be US$3.2 billion per year.[7] Incisional hernias can be surgically repaired for many reasons; patients can have cosmetic concerns, pain, bowel obstruction, mechanical symptoms, or incarceration.

There is a great variety of incisional hernias with different locations, widths, and lengths. To categorize these hernias, the European Hernia Society (EHS) developed and published the "Classification of Primary and Incisional Abdominal Wall Hernias" in 2009.[8] One of the aims of this classification was to describe hernias in both scientific and clinical communication using a uniform method. It combines the location and size of the hernia. For location, differentiation is made among midline, lateral, or combined. For size, the width of the hernia is used, and is divided into 3 subgroups:

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Members of The Hernia-Club are listed in the Appendix.

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W1 (<4 cm), W2 (4 to 10 cm), and W3 (>10 cm). The classification is based partly on the estimated risk of complications and recurrences. Although published several years ago, the EHS classification has not been externally validated thoroughly.

Several studies have addressed the issue of postoperative complications after incisional hernia repair,[9-11] but these studies did not correct for any risk factors and did not use any size classification, such as the EHS classification.

The objective of this study was to evaluate the EHS classification among other factors, as a potential predictive tool for postoperative complications after incisional hernia surgery, by using a large-scale database. It was hypothesized that a higher hernia width class would lead to more postoperative complications.

METHODS

Study design

A retrospective analysis of a registry-based, large-scale, prospective cohort was performed. Using the French Hernia-Club registry, all adult patients undergoing incisional hernia surgery between September 1, 2011, and February 29, 2016 were included. The Hernia-Club registry is approved by the French *Commission Nationale de l'Informatique et des Libertés* (registration number 1993959v0). Because the study is a registry-based study, and patient data are anonymized, additional participant consent and IRB approval were not required in accordance to the French and Dutch national ethical standards.

The STROBE (Strengthening the Reporting of Observational studies in Epidemiology) recommendations for the reporting of observational studies, as well as the European Registry of Abdominal Wall Hernias recommendations were used for this study.[12,13]

Hernia-Club registry

The Hernia-Club registry is a collaborative, prospective, anonymized online database of all abdominal wall hernia surgery procedures performed by 42 French surgeons with a specific interest in abdominal wall surgery. Each participating surgeon must accept and sign the Charter of Quality, which states that, "all input must be registered in a consecutive, unselected, and exhaustive manner and in real time." Participants consent to random peer review of original medical charts. A total of 164 parameters are collected prospectively from screening, pre-, peri-, and postoperative periods. Parameters are directly collected online by the operating surgeon in real time. Postoperative outcomes are collected by the surgeon and are further checked by an independent clinical research associate during the 2-year follow-up. The clinical research associate is blinded for operative techniques used. In case of discrepancies, the medical record is checked.

All parameters collected in this database are fully compatible with the European Hernia Society (EHS) classification of primary and incisional abdominal wall hernias[8] and the European Registry of Abdominal Wall Hernias international online platform.[14]

Data collection

Data extracted from the registry included patient age, sex, and other patient characteristics (BMI, smoking habits, diabetes mellitus, corticosteroid use, preoperative radio- or chemotherapy, history of aneurysm of the abdominal aorta, connective tissue disorders, anticoagulants use or coagulopathies, previous other abdominal wall hernias, and American Society of Anesthesiologists score), hernia characteristics (location, width, length, EHS width class, primary or recurrent hernia), and surgical characteristics (open or laparoscopic, emergency surgery, mesh use and technique of mesh placement, duration of surgery, and Altemeier wound classification[15] (clean/clean contaminated/contaminated/dirty)).

Outcomes

The primary outcomes measure was the number of patients with postoperative complications within 30 days after surgery. Postoperative complications were graded using the Clavien-Dindo grading system.[16]

Statistics

SPSS, version 21.0 (IBM Corp, 2012) was used for all statistical analyses. Normal distribution of continuous variables was assessed and Levene's test for equality of variances was used. Continuous variables are presented as means with SDs or median with interquartile range. Categorical variables are presented as numbers with percentages. Mann-Whitney U (continuous data) and chi-square tests (categorical data) were used to analyze risk factors for complications after incisional hernia surgery. In case of small groups ($n < 5$), Fisher's exact test was used. Potential risk factors that were related to postoperative complications in the univariate analysis ($p < 0.20$) and clinically relevant factors often described in hernia publications were included in the multivariable logistic regression analysis. To prevent bias and to increase statistical power, multiple imputations were performed to compensate for missing data. In the multivariable analysis, p values <0.05 were considered as statistically significant.

RESULTS

A total of 2,191 patients with an incisional hernia were included in this study. Baseline patient characteristics

Table 1. Baseline Characteristics

Variable	No complication (n = 1,813)	Missing	Any complication (n = 323)	Missing	p Value
Age, y, mean (SD)	62.77 (14.01)	6 (0.3)	63.94 (14.09)	2 (0.6)	0.155
Male sex, n (%)	865 (48)	0	151 (47)	0	0.750
BMI, kg/m^2, mean (SD)	29.03 (6.85)	0	29.94 (7.92)	0	0.069
Smoking, n (%)	315 (17)	98 (5.4)	63 (20)	20 (6.2)	0.319
Diabetes mellitus, n (%)	216 (12)	39 (2.2)	46 (14)	7 (2.2)	0.239
Corticosteroid use, n (%)	63 (3.5)	39 (2.2)	12 (3.7)	7 (2.2)	0.828
Radiotherapy, n (%)	33 (1.8)	39 (2.2)	5 (1.5)	7 (2.2)	0.733
Chemotherapy, n (%)	107 (5.9)	39 (2.2)	22 (6.8)	7 (2.2)	0.527
Abdominal aortic aneurysm, n (%)	12 (0.7)	15 (0.8)	5 (1.5)	2 (0.6)	0.100
Connective tissue disorder, n (%)	6 (0.3)	15 (0.8)	1 (0.3)	1 (0.3)	0.949
Anticoagulant use or coagulopathy, n (%)	289 (16)	39 (2.2)	65 (20)	7 (2.2)	0.062
Presence of ascites, n (%)	10 (0.6)	19 (1.0)	4 (1.2)	4 (1.2)	0.249
American Society of Anesthesiologists class, n (%)					0.096
I to II	1249 (69)	—	208 (64)	—	—
III to IV	554 (31)	—	114 (35)	—	—
Missing	10 (0.6)	—	1 (0.3)	—	—
Previous other abdominal wall hernia, n (%)					
Inguinal hernia	196 (11)	—	28 (8.7)	—	0.242
Primary ventral hernia	299 (17)	—	37 (12)	—	0.021
Incisional hernia	313 (17)	—	68 (21)	—	0.105
Other abdominal wall hernia	46 (2.6)	—	8 (2.5)	—	0.945
Missing	15 (0.8)	—	2 (0.6)	—	—
Hiatal hernia, n (%)	52 (2.9)	15 (0.8)	12 (3.7)	2 (0.6)	0.414
Family history of hernia, n (%)	15 (0.8)	15 (0.8)	2 (0.6)	2 (0.6)	0.696

are presented in Table 1. Most notable, age, BMI, smoking, diabetes mellitus, and American Society of Anesthesiologists class were not statistically significantly different between patients with or without complications. Patients with a postoperative complication had statistically significantly fewer primary ventral hernias in their medical history (12% vs 17%, p = 0.021). Other factors were not statistically significantly different.

Postoperative complications

Of the 2,191 patients, 323 patients (15%) developed 1 or more postoperative complications. Of these 323 patients, most patients had a wound complication (166 patients, 51% of all complications), followed by medical complications (137 patients, 42% of all complications) and surgical complications (93 patients, 29% of all complications). All 30-day postoperative outcomes are presented in Table 2.

Hernia characteristics

Hernia characteristics are presented in Table 3. There were significant differences in EHS width classification between patients with or without postoperative complications ($p < 0.001$) with more W1 class hernias (<4 cm) in the group without complications and more W3 class hernias (>10 cm) in the group with complications. Most hernias were located in the midline. The location of hernias, the recurrences, and previous mesh placement were not significantly different between patients with or without postoperative complications.

Surgical characteristics

Surgical characteristics are presented in Table 4. Patients with complications had more incarcerated hernias (7.7% vs 3.0%; $p < 0.001$), fewer laparoscopic procedures (12% vs 29%; $p < 0.001$), and different mesh locations ($p < 0.001$). Operating time was longer in the complication group (80 minutes [interquartile range 45 to 120 minutes] vs 45 minutes [interquartile range 24 to 75 minutes] $p < 0.001$). Additionally, Altemeier wound class[15] and antibiotic treatment were also significantly different (both $p < 0.001$). Emergency surgery rates and primary suture rates were not significantly different.

Multivariable analysis

After univariate analysis, 10 imputations were performed to reduce bias caused by missing data and to increase

Table 2. Thirty-Day Postoperative Outcomes

Characteristic	Data	Missing
Admission duration, d, mean (SD)	4.3 (4.6)	0
Patients with ≥1 complication within 30 d, n (%)	323 (15)	2 (0.09)
Wound complication	166 (7.6)	—
Surgical complication	93 (4.2)	—
Medical complication	137 (6.3)	—
Clavien-Dindo grade,[16] n (%)		
<III	176 (54)	—
≥III	51 (16)	—
Unknown	96 (30)	—
30-d mortality, n (%)	2 (0.1)	—

statistical power. The imputed data were then used for logistic regression analysis. All factors with a p value <0.20 and all clinically relevant factors were used for the multivariable analysis, identifying factors significantly associated with complications. The result of the multivariable analysis is shown in Table 5.

After correcting for possible confounding variables in the multivariable logistic regression analysis, the following factors remained statistically significant: EHS width class (W2: odds ratio [OR] 1.448; 95% CI 1.064 to 1.971; p = 0.019; W3: OR 2.090; 95% CI 1.375 to 3.179; p = 0.001), third recurrence (OR 0.369; 95% CI 0.144 to 0.941; p = 0.037), emergency surgery (OR 0.207; 95% CI 0.068 to 0.631; p = 0.006), incarceration (OR 3.187; 95% CI 1.199 to 8.467; p = 0.020), open surgery (OR 2.060; 95% CI 1.408 to 3.015; p < 0.001), duration of surgery (OR 1.006; 95% CI 1.004 to 1.009; p < 0.001), Altemeier wound class (clean contaminated: OR 2.179; 95% CI 1.225 to 3.877; p = 0.008; contaminated: OR 2.855; 95% CI 1.074 to 7.585; p = 0.035; dirty: OR 6.346; 95% CI 1.442 to 27.938; p = 0.015), and therapeutic antibiotic treatment (OR 2.391; 95% CI 1.289 to 4.438; p = 0.006).

DISCUSSION

In this analysis of a large-scale prospective French database of 2,191 patients undergoing incisional hernia surgery, EHS width class, incarceration, open surgery, duration of surgery, Altemeier wound class, and therapeutic antibiotic treatment were independent risk factors for postoperative complications. Emergency surgery and the presence of a third recurrence were found to be factors leading to a lower risk of postoperative complications. The complication rate of 15% found in this study was comparable with the 2009 study by Bisgaard and colleagues[11] reporting complication rates of 10.7%.

Hernia size has been identified as a risk factor for postoperative complications previously.[10] Larger hernias mean more extensive dissection, larger meshes, and increased operating time. For ease of use, the EHS classification contains only 3 classes instead of the absolute size.

Table 3. Hernia Characteristics

Characteristic	No complication (n = 1,813)	Missing	Any complication (n = 323)	Missing	p Value
Hernia location, n (%)					0.119
Midline	1,037 (57)	—	209 (65)	—	—
Lateral	194 (11)	—	27 (8.4)	—	—
Combined	71 (3.9)	—	9 (2.8)	—	—
Missing	511 (28)	—	78 (24)	—	—
European Hernia Society width classification,[8] n (%)					<0.001
W1: <4 cm	899 (50)	—	94 (29)	—	—
W2: 4 to 10 cm	700 (39)	—	146 (45)	—	—
W3: >10 cm	168 (9.3)	—	70 (22)	—	—
Missing	46 (2.5)	—	13 (4.0)	—	—
Recurrent hernia, n (%)	366 (20)	31 (1.7)	68 (21)	6 (1.9)	0.712
Recurrences, n (%)					0.051
First recurrence	268 (15)	—	52 (16)	—	—
Second recurrence	63 (3.5)	—	7 (2.2)	—	—
Third recurrence	31 (1.7)	—	5 (1.5)	—	—
Fourth or more recurrence	4 (0.2)	—	4 (1.3)	—	—
Missing	35 (1.9)	—	10 (3.1)	—	—
Previous mesh, n (%)	610 (34)	25 (1.4)	113 (36)	6 (1.9)	0.597

Table 4. Surgical Characteristics

Characteristic	No complication (n = 1,813)	Missing	Any complication (n = 323)	Missing	p Value
Emergency procedure, n (%)	69 (3.8)	7 (0.4)	18 (5.6)	3 (0.9)	0.133
Incarceration, n (%)	53 (3.0)	57 (3.1)	24 (7.7)	1 (3.4)	<0.001
Laparoscopic procedure, n (%)	519 (29)	26 (1.4)	37 (12)	6 (1.9)	<0.001
Primary suture closure, n (%)	183 (10)	55 (3.0)	40 (13)	22 (6.8)	0.137
Mesh location, n (5)					<0.001
Intraperitoneal	1,084 (62)	—	136 (45)	—	—
Sublay	447 (26)	—	101 (34)	—	—
Onlay	37 (2.1)	—	20 (6.7)	—	—
Component separation with mesh	4 (0.2)	—	3 (1.0)	—	—
Missing	55 (3.0)	—	22 (6.8)	—	—
Duration of surgery, min, median (IQR)	45 (25–75)	23 (1.3)	80 (45–120)	7 (2.2)	<0.001
Altemeier wound classification,[15] n (%)					<0.001
Clean	1,735 (96)	—	277 (86)	—	—
Clean contaminated	57 (3.1)	—	28 (8.7)	—	—
Contaminated	12 (0.7)	—	11 (3.4)	—	—
Dirty	4 (0.2)	—	7 (2.2)	—	—
Missing	5 (0.3)	—	0	—	—
Antibiotic treatment, n (%)					<0.001
None	383 (21)	—	43 (13)	—	—
Prophylactic	1,355 (75)	—	240 (74)	—	—
Therapeutic	66 (3.6)	—	37 (12)	—	—
Missing	9 (0.5)	—	3 (0.9)	—	—

IQR, interquartile range.

The EHS classification has been studied previously as a predictor for wound complications.[17] In this 2015 study by Baucom and colleagues,[17] 538 patients were analyzed and compared based on EHS location (midline or lateral). They found that postoperative complications were more likely to occur in midline hernias than in lateral hernias. However, the EHS classification was not used in more detail. Our study uses both the location of the hernia as well as the size class. After multivariable analysis, hernia location was not a statistically significant risk factor for postoperative complications. This different finding might be explained by the fact that Baucom and colleagues performed univariate analyses only and not multivariable analysis.

The other statistically significant findings; incarceration, open surgery, duration of surgery, Altemeier wound class, and therapeutic antibiotic treatment all reflect more complicated procedures. Wound contamination is especially more likely to lead to surgical site infections in these cases. In 2016, Petro and colleagues[18] suggested including contamination in a hernia risk model. This is in line with the findings of this study.

Duration of surgery was associated with a higher risk of complications. It could be argued that duration of surgery could also be considered as a kind of an outcomes measure.

Emergency surgery was associated with fewer complications in the multivariable analysis. However, this is possibly due to adjusting for confounders related to emergency surgery (ie incarceration, open surgery, Altemeier wound classification, and antibiotic treatment).

In general, there was a nonsignificant trend of fewer complications after more recurrent hernias. The only statistically significant difference in the third recurrence is probably associated with the relatively small group size (n = 5 with third recurrences in the complications group) and does not reflect a clinically relevant finding.

This study demonstrates that there is great variance within all patients with an incisional hernia. Although this might not sound surprising, it is of paramount importance to stress that hernia research should not investigate all patients with an incisional hernia as a homogeneous group. Given the great differences in outcomes, studies should divide their patients into subgroups, based on the EHS classification, or the EHS classification should be considered when determining inclusion or exclusion criteria for new studies. Using the EHS classification in research might reduce heterogeneity in results of

Table 5. Results of Multivariable Analysis

Variable	Odds ratio	95% CI	p Value
Age	1.007	0.996–1.017	0.223
Female sex	1.138	0.870–1.488	0.345
BMI	1.013	0.994–1.033	0.168
Smoking	1.334	0.952–1.870	0.094
Diabetes	0.914	0.618–1.351	0.650
Abdominal aortic aneurysm	2.192	0.671–7.165	0.194
Anticoagulants	1.237	0.867–1.763	0.240
American Society of Anesthesiologists III and IV vs I and II	1.090	0.807–1.473	0.573
History of primary ventral hernia	0.763	0.509–1.143	0.190
History of incisional hernia	1.009	0.654–1.554	0.969
EHS location			
Midline	1.000	—	—
Lateral	0.718	0.440–1.170	0.180
Combined	0.514	0.252–1.045	0.066
EHS width class			
W1: <4 cm	1.000	—	—
W2: ≥4 to 10 cm	1.448	1.064–1.971	0.019
W3: >10 cm	2.090	1.375–3.179	0.001
No. of recurrences			
First recurrence	1.000	—	—
Second recurrence	0.831	0.530–1.303	0.420
Third recurrence	0.369	0.144–0.941	0.037
Fourth or more recurrence	0.455	0.157–1.318	0.146
Emergency procedure	0.207	0.068–0.631	0.006
Incarceration	3.187	1.199–8.467	0.020
Open vs laparoscopic procedure	2.060	1.408–3.015	<0.001
Primary suture closure	0.893	0.581–1.373	0.607
Duration of surgery	1.006	1.004–1.009	<0.001
Altemeier wound classification[15]			
Clean	1.000	—	—
Clean contaminated	2.179	1.225–3.877	0.008
Contaminated	2.855	1.074–7.585	0.035
Dirty	6.346	1.442–27.938	0.015
Antibiotic treatment			
None	1.000	—	—
Prophylactic	1.251	0.865–1.808	0.234
Therapeutic	2.391	1.289–4.438	0.006

studies on incisional hernia. It might also allow readers to appreciate results better by comparing different study populations based on the EHS classification. Although not evaluated in this study, the EHS classification might be a framework to use for tailored hernia care. An important step in this direction has recently been taken by Dietz and colleagues,[19] by adjusting treatment based on a preoperative risk assessment. In this article, risk-adjusted procedure tailoring ensured that high-risk patients did not have a higher rate of postoperative complications. This research direction is an important one to investigate. Hernia surgery, especially when conducted electively, is considered to be relatively low-risk surgery. Fortunately, this is the case for most patients, but the results found in this study show that specific subgroups can have worse outcomes.

Limitations

There are several limitations to this study. First, the results of this study are not based on randomized data. This gives

a potential risk of selection. However, the benefit of this kind of registry study is the translation to the real clinical situation: no artificial selection has been made in patient inclusion. Second, this study focuses on postoperative complications. However, this only covers part of the outcomes of hernia repair. A second, long-term analysis should study whether the EHS classification could be used to predict recurrences or reoperations as well. Such a study might require combining different large-scale cohort studies to achieve the statistical power needed.

CONCLUSIONS

The width classification of the EHS classification of incisional hernias is an independent risk factor for complications after incisional hernia repair. Therefore, the EHS classification should be used in studies reporting on incisional hernia repair. Surgeons should also use the classification for preoperative risk assessment. To achieve this, emphasis should be on the simplicity of the classification. A next step will be to analyze different treatment strategies for patients from different EHS classes in an attempt to lower the overall postoperative complication rate effectively.

Author Contributions

Study conception and design: Kroese, Kleinrensink, Lange, Gillion
Acquisition of data: Kroese, Gillion
Analysis and interpretation of data: Kroese, Kleinrensink, Lange, Gillion
Drafting of manuscript: Kroese, Kleinrensink, Lange, Gillion
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APPENDIX

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