Female gender and diabetes mellitus increase the risk of recurrence after laparoscopic incisional hernia repair

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ABSTRACT

BACKGROUND Laparoscopic hernia repair is used widely for the repair of incisional hernias. Few case studies have focussed on purely 'incisional' hernias. This multicentre series represents a collaborative effort and employed statistical analyses to provide insight into the factors predisposing to recurrence of incisional hernia after laparoscopic repair. A specific hypothesis (ie, laterality of hernias as well as proximity to the xyphoid process and pubic symphysis predisposes to recurrence) was also tested.

METHODS This was a retrospective study of all laparoscopic incisional hernias undertaken in six centres from 1 January 2004 to 31 December 2010. It comprised a comprehensive review of case notes and a follow-up using a structured telephone questionnaire. Patient demographics, previous medical/surgical history, surgical procedure, postoperative recovery, and perceived effect on quality of life were recorded. Repairs undertaken for primary ventral hernias were excluded. A logistic regression analysis was then fitted with recurrence as the primary outcome.

RESULTS A total of 186 cases (91 females) were identified. Median follow-up was 42 months. Telephone interviews were answered by 115/186 (62%) of subjects. Logistic regression analyses suggested that only female sex (odds ratio (OR) 3.53; 95% confidence interval (CI) 1.39–8.97) and diabetes mellitus (3.54; 1–12.56) significantly increased the risk of recurrence. Position of the defect had no statistical effect.

CONCLUSIONS These data suggest an increased risk of recurrence after laparoscopic incisional hernia repair in females and subjects with diabetes mellitus. These data will help inform surgeons and patients when considering laparoscopic management of incisional hernias. We recommend a centrally hosted, prospectively maintained national/international database to carry out additional research.

KEYWORDS

Laparoscopic hernia – Incisional hernia repair – Hernia recurrence – Hernia

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Incisional hernias are a considerable surgical problem that have been estimated to occur in 2–11% of incisions after abdominal surgery (though this prevalence is probably underestimated).¹ Risk factors for incisional hernias include: chronic lung disease; obesity; use of corticosteroids; diabetes mellitus (DM); malnutrition; jaundice; chemoradiotherapy; use of oral anticoagulants.^{1,2} Since Karl LeBlanc published the first series of laparoscopic incisional hernia repairs (LIHRs) in 1993, the role of LIHR compared with open repair has been controversial.³ Case series from all over the world have displayed heterogeneity in terms of methodology and patient groups. Several randomised trials

comparing laparoscopic and open methods have shown LIHR to be at least comparable (and possibly superior) to open methods in selected patient groups.^{4–6} LIHR has been advocated as the procedure of choice in the clinically obese.⁷

Several studies have compared open with laparoscopic repair for 'ventral' hernias, but there is a paucity of literature reporting solely on LIHR. The Prospective Randomized Study of Midline Incisional Hernia Treatment (ProLOVE) trial published their results recently. They demonstrated a lower prevalence of surgical-site infection (SSI) and lower physical function after laparoscopic midline incisional

hernia repair but no difference in pain scores.⁸ A Cochrane review from 2011 compared open with laparoscopic ventral and incisional hernia repairs.⁶ The authors concluded that short-term outcomes were promising but that the lack of long-term results and low numbers of study subjects from included studies necessitated caution before laparoscopic surgery could be endorsed fully. In addition to the limited data in this arena, there are a lack of statistical analyses to determine risk factors predisposing patients to hernia recurrence.

Research collaborations have become increasingly popular in the last five years following formation of the West Midlands Research Collaborative (<http://www.wmresearch.org.uk>). They initiated and completed a national multi-centre randomised control trial that became the first surgical trial to stay ahead of projected recruitment from start to finish.⁹ Undertaking high-quality research as a trainee can be challenging because trainees tend to move between hospitals each year. The registrar-led Severn and Peninsula Audit and Research Collaborative for Surgeons (SPARCS; www.sparcs.org.uk) was formed in 2010 with the aim of producing high-quality research.

We wished to determine, from a multicentre regional retrospective review, which factors in a patient's history or surgical procedure increased the risk of hernia recurrence. A second hypothesis, ie, that hernias that are off the midline or closer to the xiphoid process or pubic symphysis are more likely to recur, was also tested.

Methods

SPARCS identified lead investigators at six centres across the Southwest Peninsula region. All collaborators signed up to the SPARCS constitution regarding authorship and data protection.¹⁰ Ethical approval was gained from audit departments at the six sites. Investigators undertook a coordinated retrospective review of all LIHR procedures undertaken from 1 January 2004 to 31 December 2010. Data were anonymised and stored on hospital-approved encrypted memory sticks.

Primary endpoints were the prevalence of recurrence and infection. A standardised spreadsheet was used to record: patient demographics; symptoms; size of the hernia defect (clinically and at the surgical procedure); the procedure preceding incisional hernia; method used (type, size, overlap and anatomical placement of the mesh); postoperative complications; recurrence. A standardised telephone interview focusing on patient satisfaction was undertaken based upon questions used in the Swedish Hernia Register (Appendix).⁷

Recurrence was deemed to have occurred if it was recorded in the medical notes or if the patient confirmed in the telephone follow-up that a medical professional had examined and diagnosed the recurrence.

Statistical analyses

Fisher's exact test was used to compare categorical data. $p < 0.05$ was deemed significant. A logistic regression model was applied with terms for: centre; sex; age; body mass

index (BMI); sector (on-midline or off-midline); previous hernia repair; DM; duration of surgery; number of ports; suture; Protack auto suture; length of hospital stay; 30-day re-admission to hospital; infection. Location of the initial incisional hernia was classified into one of conventional nine segments of the abdomen and as on-midline or off-midline.

Results

A total of 186 patients (91 females, 95 males) were identified. The median age was 62.2 (range, 27–91) years and the BMI 30.3 (19–48) kg/m². The most common procedure preceding incisional herniation in order of prevalence was emergency laparotomy, open left-sided colonic resections, laparoscopic cholecystectomy and open cholecystectomy (Table 1). Out of 186 patients, 25 (13.4%) suffered an infection after the primary procedure, 120 (64.5%) did not, and this information was not recorded in 41 patients. Thirty-six cases had the size of the hernia measured in centimetres whereas, in nine subjects, the hernia was described qualitatively, such as 'lemon/orange' or 'large'. Measurements were not taken in 141 subjects. Forty-six patients had the hernia defect measured in the clinic, and 140 did not. Out of those 46 patients, the median size of the hernia defect in clinic was 18 (range, 4–144) cm². Loss of domain was

Table 1 Most common primary procedures resulting in incisional hernia

Procedure	Number
Emergency laparotomy	21
Open left-sided colonic resection	17
Laparoscopic cholecystectomy	16
Open cholecystectomy	16
Hysterectomy	14
Caesarean section	8
Appendectomy	7
Laparoscopic left-sided colon resection	6
Perforated duodenal ulcer	6
Incisional hernia	6
Formation of stoma	5
Incisional hernia	5
Right hemicolectomy	5
Nephrectomy	4
Defunctioning Ileostomy	4
Repair of abdominal aortic aneurysm	4
Other	38
Not recorded	4
Total	186

Table 2 Procedure details, complications and recurrence in all patients, midline and off-midline hernias (ranges in parenthesis)

Procedure details	Whole series	Midline hernias	Off-midline	Not recorded
Number	186	111	69	6
Median duration of procedure (min)	88.5 (13–300)	90 (15–300)	85 (13–160)	
Median size of hernia defect at surgery (cm ²)	30 (2–600)	16 (4–600)	50 (2–400)	
Median mesh size used (cm ²)	264 (9–864)	225 (12–864)	300 (9–858)	
Complications				
Enterotomies	2 (1.1%)	2	0	
Bleeding	3 (1.6%)	1	2	
Recurrence	31 (16.7%)	22 (19.8%)	9 (13%)	

documented in only 13/186 subjects. Thirty-eight subjects had a history of incisional hernia repair. At the time of assessment, 34 patients were classified as ‘current smokers’, 18 as ‘ex-smokers’, 118 did not smoke, and this information was not recorded in 16 subjects. Nineteen patients had DM. Procedure details and complication rates are seen in Table 2.

Median duration of stay in hospital was 1.1 (range, 1–19) days. There were seven hospital readmissions due to pain (five), vomiting (one) and not recorded (one). Five patients underwent reoperation within 30 days of surgery: hernia recurrence (two), enterotomy (one), internal hernia (one) and no abnormality identified (one).

Recurrence was said to have occurred if there was a record in the case notes of such an event or if the patient reported in the telephone follow-up that a medical professional had confirmed recurrence.

The overall prevalence of recurrence was 31/186 patients (16.6%). There was a higher prevalence of recurrence in midline hernias but this was not significant (Fisher’s exact test, $p=0.31$).

Telephone interview

A total of 114/186 (61.2%) patients agreed to partake in a telephone interview. Median follow-up was 42 months (Table 3).

Logistic regression analyses

The intercept was the expected odds ratio (OR) for a patient: from centre 1; male; aged 60 years; normal BMI; midline sector; no previous hernia repair; non-DM; duration of surgery of 90 min; ≤ 3 ports; no suture; no Protack auto suture; duration of hospital stay of 0 days; no re-admission to hospital within 30 days; and no previous or current infection.

The remaining effects were multiplicative: being female increased the OR by 3.5 times; being overweight increased the OR by 1.4 times; being female and overweight increased the OR by $3.5 \times 1.4 = 4.9$ times.

There was little evidence that the probability of hernia recurrence was affected significantly by age or duration of surgery. For a ten-year increase in age, the OR was

Table 3 Results from telephone interviews on patient satisfaction and symptoms (%)

Question	Yes	No	Unsure
Ongoing pain?	29 (25)	85 (75)	
Ongoing bulge?	45 (39)	60 (53)	9 (8)
Recurrence in patient's opinion?	21 (18)	74 (65)	19 (17)
If yes, confirmed by a medical professional?	10		
Wound infection?	10 (9)	99 (87)	6 (4)
Bowel obstruction?	5 (4)	101 (89)	8 (7)
Happy with cosmetic effect?	88 (77)	17 (15)	9 (8)
Was your quality of life impaired by the incisional hernia before surgery?	72 (63)	34 (30)	8 (7)
Has the surgery improved your quality of life?	82 (72)	20 (18)	12 (10)
Would you recommend the procedure to a friend in a similar position?	99 (87)	6 (5)	9 (8)

expected to increase by 1.11 (ie, an 11% increase; 95% confidence interval (CI), 0.82–1.52). For a 30-min increase in the duration of surgery, the OR was expected to increase by 1.23 (ie, a 23% increase; 95% CI, 0.88–1.73).

The effects of BMI, off-midline hernia, previous repair, number of ports, suture, Protack auto suture, 30-day re-admission to hospital, previous infection and current infection were all >1 . This finding suggested an expected increase in the probability of recurrence, but the effects were not significant.

For a one-day increase in the duration of hospital stay, the OR was expected to decrease by 0.89 (ie, an 11% decrease; 95% CI, 0.73–1.09) but the effect was not significant (Table 4).

Table 4 Estimated odds ratios with 95% confidence intervals for risk factors associated with recurrence

Parameter	OR estimate (95% CI)
Intercept	0.02 (0–0.24)
Centre: 2	0.35 (0.07–1.84)
Centre: 3	1.22 (0.2–7.6)
Centre: 4	0.59 (0.18–2.00)
Centre: 5	0.49 (0.08–3.12)
Centre: 6	0.55 (0.1–3.09)
Female	3.53 (1.39–8.97)
Age >60	1.01 (0.98–1.04)
BMI: overweight	1.39 (0.42–4.65)
BMI: obese	1.91 (0.75–4.84)
Sector off-midline	1.88 (0.67–5.26)
Previous repair	1.37 (0.51–3.7)
Smoking	1.10 (0.37–3.3)
Diabetes mellitus	3.54 (1–12.56)
DUR >90	1.01 (1–1.02)
>3 ports	1.68 (0.65–4.33)
Suture	1.38 (0.49–3.85)
Protack auto suture	4.42 (0.81–24.16)
LOS	0.89 (0.73–1.09)
30-day re-admission to hospital	2.03 (0.3–13.88)
Previous infection	1.12 (0.36–3.48)
Current infection	13.67 (0.62–303.96)

BMI = body mass index; DUR >90 = duration >90 min; LOS = length of stay in hospital in days

Discussion

Practising evidence-based medicine (EBM) is an integral part of a physician's job. EBM forms one of the 'pillars' of good medical practice as outlined by the General Medical Council. Trainees can find completing good-quality research challenging while in full-time training and staying in placements for an average of one year at a time. Research collaborations are novel ideas that use the 'migratory' nature of trainees to produce large-volume, high-quality research. Such collaborations rely upon a clear constitution with regard to authorship and data protection. The present study and research from other collaborations prove that this approach can be successful.⁹

LIHRs are relatively uncommon in comparison with open repair. However, in a recent prospective study from Denmark with >3,000 patients, 54.1% of cases underwent a laparoscopic procedure and 7.1% of patients converted to open repair. Using a multicentre design gave us the largest series of pure LIHRs in the UK. Several studies published

on this topic have been a combination of laparoscopic primary and incisional hernias, thereby making the drawing of meaningful conclusions very difficult.

This is the first study to demonstrate a difference in recurrence after LIHR according to incision site. There was a prevalence of recurrence of 13% in off-midline LIHR versus 19% in midline repairs, but the difference was not significant. Logistical regression analyses identified two independent risk factors for recurrence after LIHR: being female and having DM.

DM patients carry a higher risk of SSI in open and laparoscopic hernia repairs.¹¹ Infection is a risk factor for the development of incisional hernia, so having DM should increase the risk of recurrence. However, in our series, DM patients who had a recurrence did not have documented evidence of infection. Being female was also identified as a risk factor for recurrence; this finding contradicts a retrospective study that found being male to be associated with incisional hernias.¹² Again, no factors from our data could explain this finding. BMI was not different between the sexes, and females were no more likely to have an infection than males. One theory may be based on exposure to the ligamentous-relaxing hormones of pregnancy. It is widely known that femoral hernias are more common in women, and it is possible that a similar association exists. However, obstetric history was not available for the patients in our study.

Recurrence is a major issue in terms of symptoms and potential complications. Several of the recurrences from this series were on the basis of the telephone interview but patients were asked to confirm that a medical professional had corroborated that a recurrence had occurred. Some recurrences may have been missed or misdiagnosed. This raises another issue of the variation in methods across only one region. For example, some surgeons advocate closure of the defect before mesh placement. Wide variation in the meshes and fixation methods used was also noted. Good evidence to support which method is superior is lacking.

The benefit of research collaborations is the large volume of patient data that can be accrued. Unfortunately, owing to the multicentre design of our study and data collection from several investigators, data gaps occurred. To reduce the risk of such data gaps, lead investigators were posted at each site and the questionnaires and databases standardised. The telephone interview questionnaire was not validated but the questions were based on the respected Swedish Hernia Register.¹⁵ These missing data introduce errors but reinforce the need for better documentation and standardisation in hospital records for hernia assessments in the clinic, peri-operative care and follow-up. Derriford Hospital now uses the validated Carolina Comfort Scale.¹⁴

We suggest the formation of a national hernia registry to document management of these complex and potentially morbid surgical procedures. In our series of 186 patients, there was wide variation in the methods employed in just one region. A national (or international) registry would allow elucidation of the most effective methods and aid patient selection.

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