Risk factors of incisional hernia after single-incision cholecystectomy and safety of barbed suture material for wound closure

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Purpose: Single-incision cholecystectomy is a surgical method that offers comparable results to conventional laparoscopic cholecystectomy. However, a high risk of postoperative incisional hernia is an issue in single-incision cholecystectomy. This study evaluated the risk factors and incidences of incisional hernia after single-incision cholecystectomy and the advantage issue of using barbed suture material during wound closures.

Methods: A total of 1,111 patients underwent laparoscopic or robotic single-incision cholecystectomy between March 2014 and February 2020 at our institution at CHA Bundang Medical Center. During this period, there were 693 patients who underwent wound closure with monofilament suture material (Monosyn 2-0; B. Braun) and the other 418 patients used barbed suture material (Stratafix 2-0; Ethicon).

Results: The two patient groups were comparable in age, body mass index, and diagnosis. The total incidence of incisional hernia after single-incision cholecystectomy was 0.5% (five cases). All patients who developed incisional hernia were in the monofilament suture material group (0.7% vs. 0%, \( p = 0.021 \)). The influence of predictive and possible risk factors on incisional hernia rate was analyzed. Among these factors, only old age was an independent predictive risk factor of incisional hernia.

Conclusion: Our study showed a low incidence of incisional hernia, all of which occurred in the monofilament suture material group. If technically appropriate, single-incision cholecystectomy does not appear to present a high incidence of hernia. Barbed suture material can be safely applied in wound closure showing comparable incisional hernia incidence to monofilament suture material.

Keywords: Incisional hernia, Laparoscopy, Cholecystectomy, Minimally invasive surgery

INTRODUCTION

Conventional laparoscopic cholecystectomy (CLC) with a four-port technique has become the gold standard for management of symptomatic gallbladder disease [1]. To minimize surgical wounds, single-incision surgery including cholecystectomy has been increasing. Single-incision surgery has benefits of fewer surgical wounds that allow faster recovery by reducing surgical stress and pain, leading to better cosmesis [2]. Despite these advantages, single-incision cholecystectomy has no advantages in operation time, the average length of stay in a hospital, return to normal activities, or postoperative quality of life compared to CLC [3,4].

A recent meta-analysis by Haueter et al. [5] found that single-
incision laparoscopic cholecystectomy (SILC) has advantages in cosmesis, body image, and postoperative pain compared with CLC, but the incidence of incisional hernia is higher. SILC and robotic single-site cholecystectomy require a larger fascia incision at the umbilicus than that in CLC, increasing the possibility of incisional hernia [6,7]. It is important that single-incision cholecystectomy has a cosmetic advantage over CLC; however, incisional hernia is not only a cosmetic issue but also can cause intestinal obstruction and ischemia, leading to a potentially life-threatening condition that could necessitate emergency surgery [8].

Surgical technique failures such as suture material loosening, or breakage of a surgical knot can result in incisional hernia. Single-site cholecystectomy requires a larger fascia incision than CLC, and there is a greater possibility of surgical failure. Barbed suture materials, which were patented in 1964, are growing in popularity [9]. They have been reintroduced for several surgical applications such as digestive surgery [10,11] and fascia closure [12,13]. We hypothesized that barbed suture materials can help prevent these surgical failures and reduce the incidence of incisional hernia. This study evaluated the incidence of incisional hernia after single-incision cholecystectomy, the influence of risk factors on incisional hernia rate, and demonstrated the safety of barbed suture materials for fascia closure.

METHODS

Patients and study design

A total of 1,111 patients underwent laparoscopic or robotic single-incision cholecystectomy between March 2014 and February 2020 by three surgeons in CHA Bundang Medical Center. We analyzed the data for 693 patients who underwent wound closure with monofilament suture material (Monosyn 2-0; B. Braun, Melsungen, Germany) and 418 patients with barbed suture material (Stratafix 2-0; Ethicon, Raritan, NJ, USA).

Demographic variables, operative parameters, and postoperative outcome data were obtained and evaluated from a prospective database with additional retrospective medical record review and patient contact. Operation time was dichotomized according to the median (47.3 minutes), old age was defined over 60 years, and obesity was defined as body mass index (BMI) of >25 kg/m². American Society of Anesthesiologists (ASA) physical status (PS) classification was divided as I and ≥II. A postoperative complication was defined as any complication of Clavien-Dindo classification ≥II during the follow-up period [14,15]. Postoperatively, patients visited the outpatient clinic at 1 week and 1 month following the procedure. After that, patients who complained of a bulging at the umbilicus were reexamined at the outpatient clinic, and abdomen-pelvis computed tomography was performed when required.

Surgical procedure

Because of the three surgeons in our hepatobiliary division, we standardize the procedure which is as follows.

We used Gloveport (Nelis, Bucheon, Korea) with four channels for all single-incision cholecystectomy procedures. A 2.5-cm vertical transumbilical skin incision was made, the fascia was opened about 3 cm, and the glove port was installed. Then, a laparoscopic instrument was inserted, or the robotic arm was docked, and cholecystectomy was conducted. At the end of surgery, fascia closure was achieved with running sutures of monofilament suture material (Monosyn 2-0) or barbed suture material (Stratafix 2-0) with each bite of 5-mm interval.

Statistical methods

Statistical analysis was performed using R version R 4.0.0 (R Foundation for Statistical Computing, Vienna, Austria). Categorical variables were compared with the chi-square or Fisher exact test. Equality of variances in continuous variables was tested by the Levene test. Continuous variables with symmetrical distribution were compared using the independent t test. Continuous data with asymmetrical distribution were compared using Mann-Whitney U test. As for risk analysis of incisional hernia, logistic regression was performed. Two-tailed analyses were performed, and a p value of <0.05 was considered significant.

RESULTS

Demographics of patient and perioperative outcomes

There were differences in sex (female rate for monofilament vs. barbed, 65.7% vs. 56.9%; p = 0.004) and ASA PS classification (classification I rate for monofilament vs. barbed, 61.5% vs. 45.7%; p ≤ 0.001) in the two groups. Age (45.8 ± 13.1 years vs. 47.1 ± 12.5 years, p = 0.119), BMI (24.4 ± 3.7 kg/m² vs. 24.6 ± 3.6 kg/m², p = 0.369), and previous surgical history (23.2% vs. 23.9%; p = 0.374) were comparable in the monofilament vs. barbed groups, as was acute cholecystitis rate (11.0% vs. 11.5%, p = 0.812) (Table 1).

The total incidence of incisional hernia after single-incision cholecystectomy was 0.5% (5 of 1,111 patients). All patients who developed incisional hernia were in the monofilament suture material group. Total operation time was slightly longer in the barbed suture material group (46.5 ± 15.2 minutes vs. 48.6 ± 17.3 minutes, p = 0.045), intraoperative bile spillage rate was higher in the barbed suture material group (15.9% vs. 25.4%, p ≤ 0.001), while total complication rate was higher in the monofilament suture material group (2.9% vs. 0.5%, p = 0.010) (Table 1).
Table 1. Patients’ demographics and perioperative outcomes

| Variable                        | Monofilament suture material group | Barbed suture material group | p value |
|---------------------------------|-----------------------------------|-------------------------------|---------|
| No. of patients                 | 693                               | 418                           |         |
| Sex                             |                                   |                               | 0.004*  |
| Male                            | 238 (34.3)                        | 180 (43.1)                    |         |
| Female                          | 455 (65.7)                        | 238 (56.9)                    |         |
| Age (yr)                        | 45.8 ± 13.1                       | 47.1 ± 12.5                   | 0.119   |
| Body mass index (kg/m²)         | 24.4 ± 3.7                        | 24.6 ± 3.6                    | 0.369   |
| ASA PS classification           |                                   |                               | <0.001* |
| I                               | 426 (61.5)                        | 191 (45.7)                    |         |
| II                              | 256 (36.9)                        | 217 (51.9)                    |         |
| III                             | 11 (1.6)                          | 10 (2.4)                      |         |
| Previous surgery history        |                                   |                               | 0.374*  |
| No                              | 532 (76.8)                        | 318 (76.1)                    |         |
| Yes                             | 161 (23.2)                        | 100 (23.9)                    |         |
| Diagnosis                       |                                   |                               | 0.812   |
| Chronic cholecystitis           | 587 (84.9)                        | 355 (84.9)                    |         |
| Gallbladder polyp               | 30 (4.3)                          | 15 (3.6)                      |         |
| Acute cholecystitis             | 76 (11.0)                         | 48 (11.5)                     |         |
| Operation time (min)            | 46.5 ± 15.2                       | 48.6 ± 17.3                   | 0.045*  |
| Bile spillage                   |                                   |                               | <0.001* |
| No                              | 583 (84.1)                        | 312 (74.6)                    |         |
| Yes                             | 110 (15.9)                        | 106 (25.4)                    |         |
| Postoperative complication      | 20 (2.9)                          | 2 (0.5)                       | 0.010*  |
| Complication type related to SS |                                   |                               | 0.021*  |
| Incisional hernia               | 5 (0.7)                           | 0 (0)                         |         |
| Wound infection                 | 0 (0)                             | 1 (0.2)                       |         |

Values are presented as number (%) or mean ± standard deviation.
ASA, American Society of Anesthesiologists; PS, physical status; SS, surgical site.
*p < 0.05.

Postoperative complications included persistent abdominal pain after postoperative day 7 (seven cases), severe constipation (four cases), postoperative ileus (five cases), incisional hernia (five cases), and wound infection (one case).

Influence of perioperative factors on incisional hernia rate

The influence of perioperative factors on incisional hernia is reported in Table 2. Incidence of incisional hernia was observed higher in females (0.6%), those with a BMI less than 25 kg/m² (0.5%); however, there was no statistical significance. The patients older than 60 years (2.6%, p < 0.001) and those with ASA PS classification lower than II (1.0%, p = 0.040) showed a significantly higher incidence of incisional hernia. The influence of additional factors related to disease and operation on the incisional hernia are reported in Table 3. Higher incidences of incisional hernia were observed in patients with acute cholecystitis (1.6%), intraoperative bile spillage (0.5%), and longer operation time (1.0%) and with the use of monofilament suture material (0.7%); however, there was no statistical significance. For logistic regression, we selected variables such as sex, age, and BMI which were well-known patients’ risk factors of incisional hernia [16]. In addition, disease and operation-related factors that might affect incidence of incisional hernia such as diagnosis of acute cholecystitis, bile spillage during operation, and long operation time were also included in the analysis [17]. Multiple logistic regression analysis also yielded similar results, showing that age was positively associated incisional hernia (odds ratio [OR], 27.35; 95% confidence interval [CI], 3.67–567.82; p = 0.004) (Table 4).

Table 2. Preoperative characteristics of the patients with and without incisional hernia

| Variable                        | No Incisional hernia | Incisional hernia | p value |
|---------------------------------|----------------------|-------------------|---------|
| Sex                             | 417 (99.8)           | 1 (0.2)           | 0.724   |
| Male                            | 689 (99.4)           | 4 (0.6)           |         |
| Age (yr)                        | 953 (99.9)           | 1 (0.1)           | ≤0.001* |
| ≤60                             | 153 (97.5)           | 4 (2.5)           |         |
| >60                             | 425 (99.5)           | 2 (0.5)           | >0.999  |
| BMI (kg/m²)                     | 681 (99.6)           | 3 (0.4)           |         |
| ≤25                             | 425 (99.9)           | 2 (0.5)           |         |
| >25                             | 489 (99.0)           | 5 (1.0)           |         |
| ASA PS classification           | 617 (100)            | 0 (0)             | 0.040*  |
| I                               | 489 (99.0)           | 5 (1.0)           |         |
| ≥II                             | 111 (100)            | 0 (0)             | 0.001*  |
| No. of risk factors             | 435 (100)            | 0 (0)             |         |
| 2                               | 382 (99.7)           | 1 (0.3)           |         |
| ≥3                              | 178 (97.8)           | 4 (2.2)           |         |
| Values are presented as number (%). BMI, body mass index; ASA, American Society of Anesthesiologists; PS, physical status.  
*If the patient is over 60 years old, BMI higher than 25 kg/m², or ASA PS classification higher than I, we count each of variables as a risk factor.  
*p < 0.05.
DISCUSSION

Incisional hernia after laparoscopic surgery has been researched in many institutions. Recently, several systematic reviews and meta-analyses of randomized clinical trials comparing single-incision cholecystectomy and CLC have been published. SILC was associated with a better cosmetic result but a higher incisional hernia rate [16]. Previously reported incidences of incisional hernia after CLC and SILC occur across a broad range. Nassar et al. [18] reported that incisional hernia rate after CLC was 1.8% over a follow-up duration of up to 18 months. In a more recent randomized prospective trial with a 12-month follow-up, the incisional hernia rate after CLC was 1.2% [19]. Gangl et al. [20] observed incisional hernia after SILC in 53 cases with complete follow-up, an incisional hernia rate of 1.9%, like that of CLC. Marks et al. [19] reported a much higher incisional hernia rate of 8.4% for SILC patients. In our study, the overall postoperative incisional hernia rate was 0.5%, much lower than that previously reported after SILC and ever lower than that of CLC.

Previous studies have shown several risk factors of incisional hernia. In a review of the literature on incisional hernia after CLC, it has been suggested that old age, high BMI, and long operation time increase the risk of incisional hernia [21]. Erdas et al. [22] reported variables related to incisional hernia over a mean follow-up period of 89 months, noted that obesity and gallstones larger than 2 cm were significantly associated with the increased rate. Another study reported that elevated BMI, preexisting umbilical hernia, old age, high ASA PS classification, and sex were risk factors for incisional hernia after single-incision cholecystectomy [23]. According to a comprehensive literature review, the predictive risk factors of incisional hernia after single-incision cholecystectomy were sex, old age, high BMI, high ASA PS classification, and long operation time. Incidence of incisional hernia was observed in patients with the age older than 60 years (2.6%, \( p \leq 0.001 \)), high BMI over 25 kg/m\(^2\) (0.5%, \( p > 0.999 \)), and ASA

| Variable | No incisional hernia | Incisional hernia | \( p \) value |
|----------|----------------------|-------------------|--------------|
| Acute cholecystitis | 122 (98.4) | 2 (1.6) | 0.180 |
| Yes | 984 (99.7) | 3 (0.3) | |
| Bile spillage | >0.999 | |
| Yes | 215 (99.5) | 1 (0.5) | |
| No | 891 (99.6) | 4 (0.45) | |
| Operation time (min) | 0.125 | |
| \( \leq 47.3 \) | 699 (99.9) | 1 (0.1) | |
| >47.3 | 407 (99.0) | 4 (1.0) | |
| Suture material | 0.201 | |
| Monofilament | 688 (99.3) | 5 (0.7) | |
| Barbed | 418 (100) | 0 (0) | |
| No. of risk factors\( ^a \) | 0.002* | |
| 0 | 189 (100) | 0 (0) | |
| 1 | 530 (99.8) | 1 (0.2) | |
| 2 | 272 (99.3) | 2 (0.7) | |
| \( \geq 3 \) | 115 (98.3) | 2 (1.7) | |

Values are presented as number (%).

\( ^a \)If the patient had acute cholecystitis, bile spillage occurred during operation, longer operation time than 47.3 minutes, or suture material with monofilament, we count each of variables as a risk factor.

\( ^* \)\( p < 0.05 \).

| Variable | Univariable | Multivariable |
|----------|-------------|---------------|
| | OR (95% CI) | \( p \) value | OR (95% CI) | \( p \) value |
| Sex | | | | |
| Male | 1.0 | | 1.0 | |
| Female | 2.42 (0.35–47.44) | 0.437 | 3.96 (0.51–84.94) | 0.246 |
| Age (yr) | | | | |
| \( \leq 60 \) | 1.0 | | 1.0 | |
| >60 | 24.30 (3.56–477.13) | 0.002* | 27.35 (3.67–567.82) | 0.004* |
| BMI (kg/m\(^2\)) | | | | |
| \( \leq 25 \) | 1.0 | | 1.0 | |
| >25 | 1.07 (0.14–6.47) | 0.943 | 1.10 (0.13–7.32) | 0.924 |
| Diagnosis | | | | |
| Others | 1.0 | | 1.0 | |
| Acute cholecystitis | 5.37 (0.44–47.26) | 0.098 | 5.68 (0.62–48.70) | 0.100 |
| Bile spillage | | | | |
| No | 1.0 | | 1.0 | |
| Yes | 1.04 (0.05–7.05) | 0.972 | 4.12 (0.47–96.89) | 0.262 |
| Operation time (min) | | | | |
| \( \leq 47.3 \) | 1.0 | | 1.0 | |
| >47.3 | 6.87 (1.01–134.60) | 0.085 | 5.10 (0.63–106.25) | 0.168 |

OR, odds ratio; CI, confidence interval; BMI, body mass index.

\( ^* \)\( p < 0.05 \).
PS classification of ≥II (1.0%, \( p = 0.040 \)). Next, we investigated whether there is a greater probability of developing incisional hernia with increased number of the preoperative patients’ risk factors (sex, age, high BMI, and high ASA PS classification). Statistical analysis showed that having a greater number of those risk factors was associated with a higher incidence of incisional hernia as seen in (Table 2).

Other studies have reported additional possible risk factors of incisional hernia. Patients with acute cholecystitis and intraoperative bile spillage tended to be more affected by wound infection, which can lead to incisional hernia [24]. Long operation time could modify the trocar site abdominal wall structure, increasing the possibility of incisional hernia [13]. In addition, incisional hernia developed only in the multifilament suture material group in our study.

Considering the additional risk factors related to disease and operation (acute cholecystitis, bile spillage during operation, and long operation time), the incidence of incisional hernia was 0.2% in patients with one factor, 0.7% in patients with two factors, and up to 1.7% in patients with three or more risk factors (\( p = 0.002 \)), implying that the more risk factors the patients have, the more possibility of developing incisional hernia the patients might get (Table 3). Among the variables of sex, age, acute cholecystitis, bile spillage during operation, and operation time, only old age was revealed as an independent risk factor of incisional hernia (OR, 27.35; 95% CI, 3.67–567.82; \( p = 0.004 \)) in the multiple logistic analysis. Regarding ASA PS classification, there was no one with ≥III in the patients who developed incisional hernia. In general, clinical difference between ASA PS classification I designating normal healthy status and ASA PS classification II designating mild diseases without substantive functional limitations is not regarded as significant; and univariable analysis could not calculate OR even when we dichotomized ASA PS classification to I and ≥II. When conducting risk factor analysis using logistic regression, therefore, we decided not to include ASA PS classification as a variable.

Extending the camera port site to facilitate extraction of the gallbladder was a previous important predictive factor of incisional hernia after CLC [21]. Single-site cholecystectomy usually requires a larger fascia incision than CLC and is regarded as a higher risk for incisional hernia. Although, Krajinovic et al. [6] mentioned, creating a larger incision of the fascia gives the operator better control of the abdominal wall layers during closure. It may also cause a higher risk of developing incisional hernia. Therefore, surgical failures such as suture material loosening or breakage in the surgical knot are important risk factors of incisional hernia.

Barbed suture materials have a unique characteristic in that they allow easier closure of the abdominal fascia because of their own one-way direction. In addition, use of a loop-style surgical knot or stanchion at the starting point eliminates the need to create a surgical knot during fascia closure. For these reasons, barbed suture materials can be safely applied for fascia closure after single-incision cholecystectomy, with minimized surgical failures and a lower risk of incisional hernia. Surprisingly, there was no case of incisional hernia after single-incision cholecystectomy in the barbed suture material group, despite the presence of a larger number of predictive or possible risk factors including older age, which was the only independent risk factor of incisional hernia in our study. Therefore, barbed suture materials can be a reasonable option for fascia closure after single-site cholecystectomy to reduce the likelihood of incisional hernia.

There are several limitations of our study. First, this study had a retrospective design. Second, the postoperative follow-up period was relatively short compared to previous studies. According to one previous report, to confirm the precise risk of postoperative incisional hernia, the duration of follow-up should be extended to 3 years [25]. In our study, postoperative routine outpatient clinic follow-up was set at postoperative day 7 and 30. At that time, postoperative follow-up was terminated if there were no complications. If the patient had problems after postoperative 30 days, they visited until their symptoms such as steatorrhea, surgical wound pain, and dyspepsia became tolerable.

As a result, our median follow-up period was 24.8 ± 7.8 months in the multifilament suture material group and 12.2 ± 5.2 months in the barbed suture material group. With a longer follow-up period, more patients might have been experienced incisional hernia. Thus, there is a possibility of underestimated incidence of incisional hernia in our study. However, two-thirds of postoperative incisional hernia typically are diagnosed within 1 year after surgery [25]. Similarly, all incisional hernia patients were diagnosed within 1 year after surgery in our study. Though our incisional hernia incidence of about 0.5% was limited, considering a median follow-up period longer than 1 year in both groups, it was not likely much underestimated. Based on the literature, our adjusted incisional hernia rate is 0.7%. The third limitation is that choice of suture material was not randomly selected. Despite these limitations, this single-center, large-volume study is the first that compared incisional hernia rate based on suture materials.

The incisional hernia rate after single-incision cholecystectomy was lower here than in previous studies. The only independent risk factor of incisional hernia was old age. Fascia closure with barbed suture material demonstrated no further increase of incisional hernia incidence compared to fascia closure with multifilament suture material in this study. Therefore, barbed suture material can be safely applied as an alternate suture material for wound closure after SILC.
NOTES

Ethical statements

This study was approved by the Institutional Review Board and Ethics Committees of CHA Bundang Medical Center with the waiver of the informed consent (No. 2020-06-041). This study was conducted according to the principles of the Declaration of Helsinki.

Authors’ contributions

Conceptualization: YK, SJ, SC
Data curation: YK, SJ, SL
Formal analysis: YK, SJ, SL
Funding acquisition: SJ, IK, JJ
Investigation: YK, SJ
Methodology: SC
Project administration: SC, SL
Visualization: YK, SJ
Writing–original draft: YK, SJ
Writing–review & editing: YK
All authors read and approved the final manuscript.

Conflict of interest

All authors have no conflicts of interest to declare.

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