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ORIGINAL ARTICLE

Incidence and risk factors for trocar site hernia following laparoscopic cholecystectomy: A long-term follow-up study

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Abstract
Background The aim of this retrospective study was to assess the incidence of trocar site hernias (TSH) following laparoscopic cholecystectomy (LC) through a long-term follow-up and to elucidate the significance of several technical and patient-related factors.
Methods A total of 313 patients submitted to LC between 2000 and 2004 were included in our study. The pneumoperitoneum was always performed by means of Hasson's technique at the umbilical site and the operative trocars were positioned using either the American technique or the French technique. Closure of the fascial defect was performed only at the umbilical site. The effects of several variables, including age, gender, size of gallstones, coexisting umbilical hernia, complexity of operation, diabetes, obesity, malnutrition, smoking, and heavy manual work on the development of TSH were assessed by univariate and multivariate models.
Results Thirteen cases of TSH (4.1 %) were detected over a mean follow-up period of 89.8 months (range: 60–128). Of these, 11 (84.6 %) developed at the umbilicus and 2 at the 10 mm subxiphoid site (15.4 %). At univariate and multivariate analysis, gallstones $\geq$2 cm ($p = 0.030$; OR = 9.95, $p = 0.01$) and obesity ($p = 0.002$; OR = 22.93, $p < 0.01$) were found to increase the likelihood of TSH development.
Conclusions After long-term follow-up, the incidence of TSH following LC was higher than expected. The insertion of large trocars at the umbilical site plays a key role in the development of TSH. Other conditions such as obesity and large gallstones can be additional risk factors since the umbilical defect must often be widened in these cases.

Keywords Trocar site hernia · Incisional hernia · Laparoscopic cholecystectomy · Open cholecystectomy

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Introduction

It is generally accepted that laparoscopic surgery is associated with a lower risk of incisional hernia compared with traditional surgery [1]. According to a recent review, the mean incidence of so-called trocar site hernias (TSH) is 0.5 % [2]. However, when reports are considered separately, the values range from an optimistic 0 % to a more worrisome 5.2 % [3–19], reaching an absolutely off-scale 22 % peak after laparoscopic ventral hernia repair [20]. Such high variability is probably attributable to non-homogeneity between the different studies in terms of types of surgical procedure, trocar size and design, and preventive measures adopted. Overall, however, TSH incidence could be higher than commonly thought, because, due to short or incomplete follow-ups, most studies tend to underestimate late-onset and pauci-symptomatic cases [11, 21], which in open surgery account for respectively one-third and two-third of the total [22].

Some of the greatest risk factors for TSH occurrence are the use of large-size trocars ($\geq$10 mm) [1, 2, 21, 23, 24], their insertion in weak areas of the abdominal wall (median

line, umbilicus, Spigelian fascia) [1, 2, 6, 8, 10, 21, 25] and the enlargement of the trocar site in order to introduce surgical devices or retrieve specimens [6, 20, 26, 27]. Controversies exist regarding prevention methods: many authors suggest systematic suture of the largest fascial defects [3, 10, 11, 18, 21, 23, 25], whereas others hold that trocar sites do not require closing up when blunt-tip trocars [12, 17, 28] or bladeless radially expanding trocars [13–16] are used.

It is evident that the onset of TSH can be strongly influenced by the specific features of each laparoscopic procedure in addition to the surgeon's personal technical choices; therefore, in this framework, it is difficult to obtain homogeneous and comparable data from the literature.

Thus, we decided to carry out a retrospective study, taking laparoscopic cholecystectomy (LC) as the only reference procedure and with a minimum follow-up of 5 years. The choice of procedure was based on the observation that although it is among the most commonly performed general surgical procedures, the studies that address the specific problem of TSH are still too few and dated [3, 6, 9, 10]. Follow-up duration was based on the fact that 27–35 % of incisional hernias occur more than 3 years after the first procedure, and therefore, follow-up should be continued for at least 4–5 years to obtain reliable data [22, 29].

The purposes of the study were to assess TSH incidence, both globally and in relation to trocar size, tip design and site, and to identify the risk factors correlated with the patients and with the main technical aspects of the procedure.

Patients and methods

The medical records of a consecutive series of 320 patients who underwent LC in the period between January 2000 and December 2004 were examined. Six of them were found to have died for reasons not correlated to the operation, whereas one refused to undergo follow-up. Consequently, 313 patients were considered for the study, mean age 51.9 years ± 14.5 SD (range: 15–82) and with a male/female ratio of 1:2.2. The main indication for surgery was symptomatic gallstones (84.3 %), followed by acute cholecystitis (11.2 %), chronic cholecystitis (3.2 %) and gallbladder polyps (1.3 %) (Table 1).

The first 173 cases were performed with the American technique, that is, by placing all operative trocars below the right costal margin, so that the 10-mm trocar was placed in the subxiphoid area, whereas the two 5-mm trocars were placed, respectively, in the midclavicular and anterior axillary lines. The subsequent 140 procedures were performed using the French technique, so that the 10-mm operating trocar was moved to the mesogastric region, left of the midline, and the two 5-mm trocars were placed, respectively, in the subxiphoid area and in the right flank.

Table 1 Indications for LC

Surgical indication	Number	%
Symptomatic cholelithiasis	264	84.3
Acute cholecystitis	35	11.2
Chronic cholecystitis	10	3.2
Gallbladder polyps	4	1.3
Total	313	100

Disposable trocars were always used, initially with a sharp tip (164 cases) and later with a blunt tip (149 cases).

Pneumoperitoneum was created always by open technique, by performing a curved skin incision just above the umbilicus and making an approximately 2 cm opening of the fascia and the peritoneum along the linea alba. The operative trocars were inserted under direct vision after transillumination of the abdominal wall in order to locate and avoid injury to the epigastric vessels.

At the end of the procedure, a drainage is routinely placed through the 5-mm right lateral port and usually removed 1 or 2 days postoperatively. The gallbladder is put into an endobag and removed through the umbilical port together with the Hasson's trocar. The Hasson's trocar is then temporarily re-inserted to enable extraction of the operating trocars under direct vision, so as to recognize and promptly treat any wall bleeding.

Fascial closure is performed routinely only at the umbilical site by conventional technique, that is, by grasping the fascial margins with Kocher clamps in order to lift it upward, and closing the defect with an interrupted absorbable suture of 2-0 Polyglactin 910 (Vicryl; Ethicon, Amersfoort, The Netherlands). At extra umbilical ports, our only indication for fascial closure is to secure hemostasis in the event of wall bleeding, but in our experience this has never been necessary.

If no complications occur, patients are discharged on the second or third postoperative day, and return for follow-up examinations 1 week and 1 month after the operation.

Between January and September 2010, all the patients included in this study were interviewed and checked clinically with respect to trocar site healing. If a TSH was suspected, they were submitted to an ultrasound examination of the abdominal wall. Mean duration of the follow-up was 89.8 months (range: 60–128).

Assessment of risk factors for TSH was carried out using univariate analysis (Student's t test and χ^2 test) and multivariate analysis with logistic regression of the following variables: age, sex, gallstone diameter $\geq$2 cm, co-existing umbilical hernia, complexity of the pathology (acute and

chronic cholecystitis), diabetes, obesity (BMI $\geq$ 30), malnutrition (BMI $<$ 18.5), smoking, heavy manual work. Data were considered significant at a p value less than 0.05.

The logistic regression function describes the relation between the development of TSH and the above-mentioned variables. We included first order interactions in the model to assess the effect of each variable for a particular level of the other covariates. Logistic regression analysis was performed through a backward procedure based on eliminating step by step first the least significant interactions and later the non-significant independent variables. The results are reported indicating the odds ratio (OR) with 95 % confidence interval and the p value for each variable. All statistical analyses were performed using SPSS® version 14.0 (SPSS, Chicago, IL, USA).

Results

The overall incidence of TSH was 4.1 % (13/313), 84.6 % (11/13) of which developed at the umbilicus, and 15.4 % (2/11) at the subxiphoid site. The only two cases of subxiphoid TSH occurred after the use of 10-mm bladed trocars. Tables 2, 3 and 4 show the incidence data stratified by trocar size, tip design and site.

Only one patient came to our center spontaneously for a symptomatic TSH. She was a 73-year-old woman that about 3 months after surgery had noticed the development of a small epigastric bulge. Over the next few days, the bulge had grown quickly, accompanied by increasingly intense pain, nausea and general sickness. The patient was examined at our center (clinical examination, blood chemistry tests, and abdominal X-ray) and was diagnosed with incarcerated subxiphoid TSH. Abdominal ultrasound confirmed the presence of the incisional hernia, which appeared to consist of preperitoneal fat, which had herniated through a defect of about 2 cm in diameter. On the same day, the patient underwent a hernia repair by means of Prolene Hernia System® (P.H.S.®) under local anesthesia and was discharged the following day in good general condition. All the other patients were examined in the course of the follow-up. Twenty of them had suspicious signs/symptoms for TSH, but abdominal ultrasound only confirmed this condition in 12 of them. Of these, 11 (91.6 %) noticed a swelling and 3 (25 %) complained of moderate and intermittent discomfort at one of the trocar site scars. Two of them have already undergone hernia repair, they too in local anesthesia and with P.H.S.® prosthesis, whereas the others are scheduled for surgery.

Table 2 TSH incidence according to trocar diameter

Trocar diameter (mm)	Incidence
12 (Hasson's trocar)	3.5 % (11/313)
10	0.6 % (2/313)
5	0.0 % (0/313)

Table 3 TSH incidence according to tip trocar design (only assessed for extraumbilical sites)

Tip trocar design	Incidence
Sharp	1.2 % (2/164)
Blunt	0.0 % (0/149)

Table 4 TSH incidence according to trocar site (only assessed for 10-mm trocars, separately for the American and French techniques)

Trocar site	Incidence
Subxiphoid (American technique)	1.1 % (2/173)
Left mesogastric (French technique)	0.0 % (0/140)

At univariate analysis, only obesity ($p = 0.002$) and gallstones $\geq$2 cm ($p = 0.030$) were found to be associated with TSH development to a statistically significant degree (Table 5).

At multivariate analysis with logistic regression, the same variables were found to be independent risk factors for TSH with an OR of 22.93 for obesity ($p < 0.01$) and of 9.95 for gallstones $\geq$2 cm ($p = 0.01$). Thus, the final logistic regression model includes these two variables and their interaction. The other variables and interactions are not significantly associated with TSH and therefore have been excluded from the model (Table 6).

As a consequence of the interaction factor, equal to 0.04 ($p = 0.02$), the presence of both variables in the same patient does not further increase the risk of developing TSH compared with when only one variable occurs.

Discussion

LC is currently the "gold standard" for the treatment of symptomatic cholelithiasis [30]. In addition to its well-known advantages over the traditional cholecystectomy, that is, better cosmetic outcome, shorter length of hospital stay and less postoperative pain, this technique offers the advantage of reducing the incidence of incisional hernias. However, although it has long been considered indisputable, to our knowledge there are no recent targeted studies supporting the last feature with a strong degree of evidence [3, 6, 9, 10].

Subcostal laparotomy, which is also that most used for open cholecystectomy, appears to be the one least likely to give rise to incisional hernia: in some case series, incidence

Table 5 Comparative univariate analysis between patients with and without TSH

Variables	Healthy patients (no. 300)		Patients with TSH (no. 13)		*p*
	No.	%	No.	%	
Male/female	94/206		4/9		0.793
Mean age ±SD	51.8 ± 14.4		52.5 ± 18.1		0.827
Gallstone diameter ≥2 cm*	66/302	22.0	6/11	45.5	0.030
Co-existing umbilical hernia*	13/302	4.3	–	0.0	0.956
Complexity of the pathology	45/300	15.0	–	0.0	0.269
Acute cholecystitis	35/300	11.7	–	0.0	0.391
Chronic cholecystitis	10/300	2.3	–	0.0	0.892
Diabetes	23/300	7.7	1/13	7.7	0.597
Obesity	36/300	12.0	6/13	46.1	0.002
Malnutrition	7/300	2.3	–	0.0	0.688
Smoking	43/300	14.3	2/13	0.7	0.766
Heavy manual work	17/300	5.6	1/13	7.7	0.763

* Parameter specific to the umbilical site

Table 6 Final logistic regression model

	p	Odds ratio	95 % C.I. for OR	
Gallstones ≥2 cm and no obesity	0.01	9.95	1.88	52.73
Gallstones ≥2 cm and obesity	0.37	0.35	0.04	3.36
Obesity and gallstones <2 cm	<0.01	22.93	4.21	124.96
Obesity and gallstones ≥2 cm	0.86	0.82	0.09	7.59

rates are almost the same as those recorded for LC (1.3–5.4 vs 0.77–5.2 %) [3, 6, 9, 10, 21, 31]. In the only study that to date has directly compared these two approaches, the incidence of incisional hernia was found to be lower for laparoscopic versus open cholecystectomy (1.6 vs 5.9 %), but this difference was not statistically significant [3].

In our series, TSH incidence was 4.1 %, a value which, while falling within the range of current literature, is markedly higher than that considered the reference standard, that is, 1.6–1.8 % [21]. However, it is likely that in most studies TSH incidence was underestimated due to short or incomplete follow-up, which almost certainly failed to include late-onset and asymptomatic cases. It is well known that in open surgery about one-third of incisional hernias develop more than 3 years after the operation and two-third of them do not display significant clinical signs [2]. Therefore, the estimate of overall incidence cannot be reliable if the follow-up lasts less than 4–5 years and fails to include clinical examination and, where necessary, instrumental examination of the abdominal wall. Among all the studies we considered, none has a minimum follow-up of more than 3 years [3–20], one only considered symptomatic patients who returned for an examination on their own initiative [10], while in others only clinical examination was performed [3, 4] and in yet others the duration [7, 19] or type of follow-up checks [5, 6, 9, 11–13, 15, 18] were not specified.

One aspect that would have also negatively affected data acquisition in our study is the difficulty of determining whether the clinical-ultrasound finding at the follow-up was compatible with a TSH or with a pre-existing umbilical hernia which had gone undetected at the first surgical procedure. In fact, according to where the incision is performed (just above or below the umbilicus), a small umbilical hernia might go undetected and not be repaired during the LC, becoming clinically evident at a later time. Thus, in addition to the timing and modality of follow-up, another factor that can distort the data on real TSH incidence is the lack of an accurate pre- or intra-operatory assessment of the umbilical region, without which it is not possible to clearly distinguish a pre-existing hernia from an incisional hernia during the subsequent follow-up [6]. As suggested by some authors, this problem can be solved by simply routinely exploring the umbilicus region from the inside, introducing a finger through the fascial defect after trocar removal [10].

Umbilical hernia is found in 10.5–18 % of LC and is considered to be a risk factor for developing TSH [6, 18, 32]. In the study by Azurin et al. [10], 90 % of patients with umbilical TSH had a hernia in the same site prior to surgery. However, there is a basic interpretative error in this regard, since a hernia that occurs at the site of a previous hernia repair, regardless of whether the site was used for inserting a trocar, should be classified more correctly as a recurrent hernia. Terminology aside, discovery of an umbilical hernia before or during surgery should induce the surgeon to follow the rules of current hernia surgery and therefore carry out a tension-free repair, preferably with prosthetic device [10, 32–34]. In our study, a co-existing umbilical hernia was found in 4.1 % of cases (13/313) and univariate and multivariate analysis showed no correlation

with TSH development. However, these data are scarcely reliable, in that they are not supported by a systematic pre- or intra-operative study of the umbilical region.

One aspect that was found to be in line with the literature is that TSH almost exclusively occurred at the umbilical site (84.6 %) and always after use of 10-12 mm trocars. Trocar size ≥10 mm has long been considered one of the main risk factors for occurrence of TSH [1, 24]. Furthermore, use of 12-mm trocars involves a 13 times higher risk than that recorded with 10-mm trocars (3.1 vs 0.23 %), showing that even small differences in trocar diameter can have a significant impact on TSH incidence [23]. Cannula insertion along the midline, especially at the umbilical site, is considered a further predisposing factor since the linea alba is a naturally weak site of the abdominal wall subjected to the greatest mechanical stresses [19, 21]. So it is not surprising that, according to a recent review, 96 % of TSHs occur after use of 10–12 mm trocars, and 82 % develop at the umbilical site [2].

There is widespread consensus that to reduce the risk of TSH all ports ≥10 mm should be closed [3, 10, 11, 18, 21, 23, 25]. However, already in 1994 Montz et al. [1] remarked that 18 % of incisional hernias occurred despite fascial closure, and explained this fact as the result of technical errors favoured by the small size of the skin incision. In the umbilical site, this problem might be linked to the technique used to insert the first trocar. Mayol et al. [5] have observed that although the incidence of umbilical TSH is lower in sutured ports (1.9 vs 3.3 %), such hernias only developed where the first trocar had been introduced using the closed technique.

Use of the open technique should facilitate closing of the fascial plane since the skin incision is usually larger, but the results of those, including ourselves, who employ this method do not appear to be better [3, 10, 15]. It is therefore likely that when the open technique is used, factors other than a hypothetical technical error in suturing may come into play. Some authors have demonstrated that enlargement of the trocar site to introduce surgical devices or retrieve specimens favors the occurrence of TSH and that subsequent fascial suturing or prosthetic repair do not provide complete prevention [6, 20, 26, 27]. In our experience, we have found that the fascial opening at the umbilical site has a larger diameter than Hasson's trocar (about 20 vs 12 mm) and may be further enlarged for the purpose of facilitating identification and opening of the peritoneum in the event of excess preperitoneal fat or to remove especially large gallbladders. It is probably not by chance that among the different variables analyzed, obesity ($p = 0.002$) and gallstones ≥2 cm ($p = 0.030$) have been found to be significantly associated with TSH occurrence, as it is exactly in those circumstances that the umbilical port has to be enlarged. At multivariate analysis, obesity and large gallstones were found to be independent risk factors for TSH, with ORs, respectively, of 22.93 ($p < 0.01$) and 9.95 ($p = 0.01$). In the specific case of obese patients, additional problems may be represented by the greater difficulty in properly closing the fascia due to the thickness of subcutaneous fat, by high intra-abdominal pressure and by higher susceptibility to infections [21]. However, in our study, the risk of TSH is not amplified by the association of the two factors and this supports our hypothesis that both cases involve the same pathogenetic mechanism, that is, enlargement of the fascial opening.

Ultimately, the risk of developing an umbilical TSH is not eliminated by fascial closure and tends to increase with the diameter of the defect, which does not necessarily coincide with trocar diameter. Enlargement of the trocar insertion site seems to be the key factor in the pathogenesis of umbilical TSH when the first trocar is introduced using Hasson's technique, especially in obese patients or patients with large gallstones.

In our study, the only two extra umbilical TSH were observed in the subxiphoid area, and in both cases, the procedure had been performed with the American technique and using bladed trocars. After we moved on to the French technique, which involves the insertion of a 10-mm operative trocar away from the midline, and on to the use of bladeless trocars, no further cases were observed of incisional hernias at extra-umbilical sites. The advantage offered by blunt-tip trocars is that they produce smaller openings since the muscle bundles are split instead of being cut and therefore tend to come together spontaneously after trocar removal [12]. This has been clearly demonstrated by an animal-model randomized trial, which showed that the opening produced by a 12-mm blunt-tip trocar is similar to that created by an 8-mm pyramidal tip trocar [35]. Most of the authors who use blunt-tip trocars report TSH incidences of or close to 0 % despite the fact that fascial closure was not performed. However, this result is linked to the insertion of the trocars away from the midline, where the abdominal wall is strengthened by the presence of muscular layers and is therefore less prone to developing incisional hernias [12, 17, 28].

Although the umbilicus is the site at highest risk of TSH, it is also that most commonly used for inserting large trocars. Consequently, some authors suggest repairing the related defect with theoretically more effective means, such as non-absorbable suture or prosthetic devices [10, 18, 36], while others suggest avoiding the midline, inserting the trocar with an angle of 40–60° to the abdominal wall [19]. Following the same principle, but paying greater attention to the cosmetic outcome, Lafullarde et al. [4] use a modified Hasson's technique, placing the cannula through a curved periumbilical skin incision, opening the anterior fascia, retracting laterally the rectus muscle and

opening the posterior fascia and the peritoneum. Following this procedure, the rectus muscle returns to its original position after trocar removal, thereby offering excellent protection to the two sutured fascial layers. All the options mentioned are associated with a TSH incidence of or close to 0 %, nevertheless these come from isolated experiences which require further studies to be confirmed.

Conclusions

After long-term follow-up, the incidence of post-LC incisional hernias was found to be worryingly close to that recorded for subcostal laparotomies.

The insertion of large trocars at the umbilicus plays a key role in the pathogenesis of TSH. Obesity and large gallstones can act as additional risk factors since the umbilical defect must often be widened in these cases, causing further weakening of the umbilical region.

While the use of blunt-tip trocars seems to be an effective means to prevent the onset of TSH away from the midline, fascial closure remains mandatory at the umbilical site, although it does not offer absolute guarantees. Repairing the umbilical defect with non-absorbable suture or prosthetic devices could be indicated at least in high-risk patients.

Before or during LC, an accurate examination of the umbilical region should be performed, since a possible co-existing hernia would require an appropriate tension-free repair, and failure to recognize it might lead to some misinterpretations during follow-up.

Conflict of interest The authors declare that they have no conflict of interest.

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