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RISK FACTORS FOR TROCAR SITE INCISIONAL HERNIA IN LAPAROSCOPIC CHOLECYSTECTOMY: A PROSPECTIVE ANALYSIS

Brief title: Trocar site incisional hernia in laparoscopic cholecystectomy

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ABSTRACT

Background: Trocar site incisional hernia (TSIH) is the most common of laparoscopic surgery complications and is frequently underdiagnosed This study evaluate the prevalence of and analyze the influence of several risk factors for this complication in a prospective series. Information on which patients will be at risk for TSIH could be useful to introduce preventive measures.

Study design: From 2007 to 2008, a population-based prospective observational study was performed including all consecutive patients with cholelithiasis that underwent elective laparoscopic cholecystectomy. The following variables were analyzed: age, gender, diabetes mellitus, body mass index (BMI) > 30 kg/m^2, fascial incision enlargement and the pre-existence of an umbilical hernia. Multivariate regression analysis was performed to identify risk factors of TSIH in laparoscopic cholecistectomy.

Results: A total of 241 patients were included. During a median follow-up of 46.8 months, 57 patients (25.9%) were diagnosed with TSIH. In the univariate analysis, age > 70 years, diabetes mellitus, BMI > 30 kg/m^2, fascial incision enlargement and wound infection were statistically significant risk factors for the development of a TSIH. The multivariable analysis revealed that diabetes mellitus (adjusted odds ratio [AOR]= 2.79, 95% confidence interval CI 1.05-7.37), obesity (AOR: 2.71, 95%CI: 1.28-5.75), incision enlargement (AOR: 5.62, 95% CI: 2.35-13.42) and wound infection (AOR: 14.17, 95% CI: 3.61-55.51) contributed to the risk of developing a TSIH.

Conclusions: TSIH is highly prevalent. We identified several factors that could be useful to introduce preventive measures such as mesh closure in high-risk patients.

INTRODUCTION

The introduction of laparoscopic surgery in 1987 and its widespread use in the last 20 years has dramatically increased the number of patients undergoing this surgical approach. Any new technique is associated with the development of new complications and trocar site incisional hernia (TSIH) is possibly the most common in laparoscopic surgery.[1]

Although this complication can cause significant morbidity, it is frequently underdiagnosed. To date, the prevalence of TSIH was believed to range from 1.50% to 1.80% [1-4] but it is commonly accepted[1, 5] that without a medium-long term follow-up, most cases will remain undiagnosed. Therefore, the true prevalence may be higher.

There are few recommendations in the literature on how TSIH should be avoided or minimized and the real impact of TSIH and its causal factors should be determined by prospective studies. Identifying which patients will be at risk of TSIH could be of paramount importance to establish preventive measures or a special follow-up schedule. However, to date, there have been insufficient prospective series with a long-term follow-up to allow the impact of this complication to be analyzed.

The aim of the present study was to evaluate the prevalence of TSIH and to analyze the influence of several risk factors for this complication in a prospective series.

METHODS

Inclusion and Exclusion Criteria

A population-based prospective observational study was performed including all consecutive patients with cholelithiasis that underwent elective laparoscopic cholecystectomy from 2007 to 2008 in our institution. Exclusion criteria consisted of conversion from laparoscopy to an open procedure and the finding of an unexpected acute cholecystitis during the intervention.

Surgical Technique

Six experienced surgeons participated in the study and all performed the same technical procedure to enter the abdomen and the same closure technique. At the beginning of surgery, a supraumbilical transverse skin incision followed by an open technique with a vertical incision along the midline were performed. Next, a 12-mm Hasson trocar was inserted and an additional 2 or 3 more bladeless trocars (5 mm at the lower right quadrant, 10 mm at the upper left quadrant and 5 mm, if required, at the epigastrium) were introduced.

Only the umbilicus incision was always closed with handsewn interrupted suture of medium-term absorbable synthetic polyglycolic acid polymer (size 0), using a 30-mm atraumatic hook needle.

No antimicrobial prophylaxis was used. In all patients, the gallbladder was removed through the umbilical incision without a protection bag.

Study Variables

The following variables were recruited prospectively: age, gender, diabetes mellitus, obesity considered as body mass index (BMI) > 30 kg/m^2, fascial incision enlargement to remove the gallbladder from the abdomen and the pre-existence of an umbilical hernia. In addition, trocar location, trocar size and the occurrence of postoperative port site wound infection were registered prospectively.

Wound infection was defined according to the internationally accepted definition of the Centers for Disease Control[6] and attending to two criteria: a positive culture and / or a finding of infection in the surgeon's opinion.

Follow-up

The main endpoint of the study was a postoperative diagnosis of TSIH. In all patients, a thorough physical examination was performed checking specifically for signs suggestive of a TSIH at day 7, 1 month, 1 year and 3 years after the intervention. The diagnosis was performed clinically but if the examiner suspected a TSIH but could not confirm it by physical examination, an abdominal ultrasound was carried out.

All patients received instructions on the clinical signs of TSIH and were told to contact the team if they developed these signs outside the follow-up schedule described.

Statistical Analysis

All results and variables were introduced in a specially designed database. Continous variables are presented as mean and range and categorical variables with absolute numbers or percentages. The Chi square test was used to compare differences in categorical variables (Fisher's Exact test was performed when needed), and Student's T-test was used for continuous variables. Univariate analysis and multivariable logistic regression analysis were performed to identify independent predictive causal factors for the development of TSIH. Adjusted dds ratios (AORs) were calculated using logistic regression. Variables achieving statistical significance in the univariate analysis were considered for multivariable analysis. AORs with 95% confidence intervals (CI) were calculated. Differences were considered to be significant at the 5% level. All p-values reported were two-sided. Statistical analyses were performed using the SPSS 17.0 statistical package (SPSS™, Chicago, Illinois).

RESULTS

Patients Included

From January 2007 to December 2008, a total of 276 patients with cholelithiasis were considered eligible for the study. All of them underwent laparoscopic cholecystectomy but 35 were excluded during the intervention for the following reasons: conversion to laparotomy was required in 26 due to technical difficulties and acute cholecystitis was unexpectedly found in nine patients. Of the remaining 241 patients, 21 patients were lost-to-follow-up (9 deaths and 12 missing patients) and subsequently were excluded from the study (Figure 1).

The final sample analyzed consisted of 156 women and 64 men, with a mean age of 55.12 years (range: 21 to 88). The patients' characteristics are shown in Figure 1: 26 patients (11.8%) had a diagnosis of diabetes mellitus, 72 patients (32.7%) had a BMI > 30 kg/m^{2,}, 21 patients (9.5%) required incision enlargement to remove the gallbladder from the abdomen, 15 patients (6.8%) had a previous umbilical hernia and 39 (17.7%) developed a postoperative wound infection at the umbilical port during the short-term follow-up.

Prevalence of TSIH

During a median follow-up of 46.8 months (range: 2.3 to 60.6), 57 patients (25.9%) were diagnosed with a TSIH. All of them were located at the umbilical port site. The TSIH was asymptomatic in 27 patients (47. 4% of all TSIH) and was detected only by a careful clinical examination. In table are presented the percentages of TSIH of series according to studied variables.

Risk Factors for TSIH

In the univariate analysis, age > 70 years, diabetes mellitus, BMI > 30 kg/m^2, fascial incision enlargement and wound infection were statistically significant risk factors for the development of a TSIH. The remaining variables were not significant.

Finally, the multivariable analysis revealed that diabetes mellitus (p=0.038), obesity (p=0.009), incision enlargement (p<0.001) and wound infection (p<0.001) contributed to the risk of developing a TSIH (Table 2).

DISCUSSION

TSIH is considered an uncommon complication after laparoscopic surgery and in the largest published series since 1995 the incidence ranges from 0.65% to 2.8%.[1-3, 7-10] However, these series were composed by retrospective or prospective studies with a short or incomplete follow-up. Our study reports a large series of patients, who were thoroughly and repeatedly screened in a prospective follow-up and confirms that the real impact of TSIH is higher than expected, since it is frequently underdiagnosed (47.4% in our series). In addition, this study identifies several risk factors for TSIH, which may help clinicians to implement preventive measures.

In agreement with other studies with multivariable analysis published to date,[2, 11] we found no significant association between gender and TSIH. In addition, because age over 60 years was a significant factor in a multivariable analysis performed by Uslu et al,[11] we investigated age as a risk factor for TSIH. In our series, there was no significant association between age over 70 years and TSIH in multivariable analysis, although a higher risk was hypothesized in older people because of a weaker fascia and a less muscular abdominal wall.

Obesity, defined as a BMI > 30 kg/m^2, was a significant risk factor in both univariate and multivariable analysis. Our hypothesis, supported by other authors,[12-19] is that higher intra-abdominal pressure and the difficulty of achieving full-thickness closure plays a role in the genesis of TSIH. Also, the well-kown technical difficulties in obese patients could be contributed to our

results. The importance of this finding is supported by experience in obesity surgery. The dramatic increase in obesity in recent years has led to the adoption of technical preventive measures in this population.

We also analyzed whether the pre-existence of an umbilical hernia could predispose to the development a TSIH, as suggested by Azurin et al[7] and Ahmad et al,[10] but no association was found by univariate or multivariable analysis. In contrast, infection rates were high in our series and, as suggested in several studies,[2, 3, 7, 20-22] wound infection was associated with the development of TSIH, as confirmed by multivariable analyses. Although antibiotic prophylaxis could be expected to decrease the incidence of infection in elective laparoscopic cholecystectomy, recent studies[23-25] with large numbers of patients have concluded there are no significant differences between patients who receive antibiotic prophylaxis in elective surgery and those who do not. This finding prompted us to start an ongoing randomized controlled trial to try to reduce the number of wound infections in laparoscopic cholecystectomy by using a protective bag for the gallbladder.

Surprisingly, a significant association between diabetes mellitus and TSIH was found in our results. Apart from the well-known effect of diabetes on tissue healing, it is difficult to explain this association. A similar association was found between the rate of incisional[26, 27] hernias and diabetes.

Many authors have shown that most hernias occur at the site of midline trocars, and of these, umbilical sites are the most common.[7-9, 14, 28] Several explanations

have been put forward to elucidate the pathogenesis of TSIH based on the anatomical and inherent weakness of the paraumbilical region. Nassar et al[3] found an incidence of umbilical or paraumbilical fascial defects of 12% of patients who had preoperative laparoscopic cholecystectomy. Duron et al[28] reported that the lateral wall is composed of two fascial planes and muscle, theoretically making it less prone to dehiscence. However, two other hypotheses have also been proposed. First, the frequent use of a large trocar in this area may lead to a trocar site hernia in the paraumbilical region,[1] and second, the small intestine may less often be in contact with a lateral trocar site.[28] In our series all the TSIH occurred at the umbilical port site (Hasson) and none in the left upper quadrant port (10 mm). Therefore, we believe that umbilical location plays a more important role than trocar size or fascial closure, especially if associated with other risk factors such as obesity, diabetes mellitus and enlargement of the fascial wound.

Technically, in our series, bladeless trocars were used in all patients, which may explain the non-occurrence of TSIH in the left upper quadrant port, as indicated by Schmedt et al.[29] The need to enlarge the fascial wound to remove the gallbladder also plays an important role since there were significant differences both in the univariate and in the multivariable analyses, probably due to the difficulty of achieving full-thickness closure without enlarging the skin wound.[4]

From the technical point of view, the present results suggest that bladeless trocars should be used to prevent TISH. In addition, all planes of an umbilical

fascial incision should always be closed (full-thickness), enlarging the skin wound if necessary. The use of a prophylactic mesh at the umbilical port site can also be considered to prevent TSIH when the patient has one or more risk factors. Some authors have proposed the use of mesh use in large trocar orifices in bariatric surgery[30] or always in the umbilical trocar orifice.[31]

The strengths of this study lie in the finding of risk factors for TSIH in a homogenous sample of patients with a thorough follow-up in a prospective schedule. Our study also has several limitations. One limitation is that we decided do not to perform a radiological test in all patients. Consequently, some asymptomatic patients could be underdiagnosed. We decided to do a clinical basis protocol in order to perform a realistic follow-up plan.

In conclusion, in our series with a long follow-up, TSIH were highly prevalent. We also identified several factors that could be of use in introducing preventive measu res such as mesh closure in high-risk patients. A prospective randomized clinical trial to evaluate the indication of preventive mesh in these patients is warranted.

REFERENCES

1. Coda A, B.M., Ferri F, et al. Incisional hernia and fascial defect following laparoscopic surgery. . Surg Laparosc Endosc Percutan Tech, 2000. **10**: p. 34-38.
2. Mayol J, G.-A.J., Ortiz-Oshiro E, De-Diego Carmona JA, Fernandez-Represa. JA Risks of the minimal access approach for laparoscopic surgery: multivariate analysis of morbidity related to umbilical trocar insertion. World J Surg, 1997. **21**: p. 529-533.
3. Nassar AH, A.K., Rashed AA, Abdulmoneum MG. Laparoscopic cholecystectomy and the umbilicus. Br J Surg, 1997. **84**: p. 630-633.
4. Tonouchi H, O.Y., Kobayashi M, Kusunoki M. Trocar Site Hernia. Arch Surg, 2004. **139**: p. 1248-1256.
5. H. A. Swank, I.M.M., C. F. la Chapelle, J. B. Reitsma, J. F. Lange and W. A. Bemelman. Systematic review of trocar-site hernia. British Journal of Surgery, 2012. **99**: p. 315-323.
6. Mangram AJ, H.T., Pearson M, Silver L, et al. Guidelines for prevention of surgical site infection. Infection control and hospital, 1999. **20**: p. 247-278.
7. Azurin DJ, G.L., Arroyo LR, Kirkland ML. Trocar site herniation following laparoscopic cholecystectomy and the significance of an incidental preexisting umbilical hernia. Am Surg, 1995. **61**: p. 718-720.
8. Sanz-Lopez R, M.-R.C., Nunez-Pena JR, Ruiz de Gopegui M, et al. Incisional hernias after laparoscopic vs open cholecystectomy. . Surg Endosc., 1999. **13**: p. 922-924.

9. Bowrey DJ, B.D., Crookes PF, et al. Risk factors and the prevalence of trocar site herniation after laparoscopic fundoplication. . Surg Endosc., 2001. **15**: p. 663-666.

10. Ahmad SA, S.A., Azurin DJ, et al. Complications of laparoscopic cholecystectomy: the experience of a university-affiliated teaching hospital. J Laparoendosc Adv Surg Tech A. , 1997. **7**: p. 29-35.

11. Uslu HY, E.A., Cakmak A, Kepenekci I, et al. and 600–603., Trocar site hernia after laparoscopic cholecystectomy. J Laparoendosc Adv Surg Tech A, 2007. **17**: p. 600-603.

12. Hussain A, M.H., Singhal T, Balakrishnan S, et al. Long-term study of port-site incisional hernia after laparoscopic procedures. JSLS, 2009. **13**: p. 346-349.

13. Chiong E, H.P., Davis JW, Kamat AM, Pisters LL, Matin SF. Port-site hernias occurring after the use of bladeless radially expanding trocars. Urology, 2010. **75**: p. 574-580.

14. PlausWJ., Laparoscopic trocar site hernias. J Laparoendosc Surg, 1993. **3**: p. 567-570.

15. Yahchouchy-Chouillard E, A.T., Picone O, Etienne JC, Fingerhut A. Incisional hernias. I. Related risk factors. . Dig Surg, 2003. **20**: p. 3-9.

16. Hesselink VJ, L.R., de Wilt JH, Heide R, Jeekel J. An evaluation of risk factors in incisional hernia recurrence. Surg Gynecol Obstet 1993. **176**: p. 228-234.

17. Burcharth J, R.J., Hernias as medical disease. Ugeskr Laeger, 2008. **170**: p. 3314-3318.

18. White B, O.C., Gletsu N, Jeansonne L, et al. , Abnormal primary tissue collagen composition in the skin of recurrent incisional hernia patients. . Am Surg, 2007. **73**: p. 1254-1258.

19. Cottam DR, G.P., Curvelo M,Weltman D, Angus LD, Shaftan G., Preperitoneal herniation into a laparoscopic port site without a fascial defect. Obes Surg, 2002. **12**: p. 121-123.

20. Wirkowski A, P.W.T.o.l.c.o.e., Wideochirurgia I Inne Techniki Maloinwazyjne, 2008. **3**: p. 179-185.

21. Crist DW, G.T., Complications of laparoscopic surgery. Surg Clin North Am., 1993. **73**: p. 265-289.

22. Ramachandran CS, Umbilical hernial defects encountered before and after abdominal laparoscopic procedures. Int Surg., 1998. **83**: p. 171-173.

23. Chang WT, L.K., Chuang SC, Wang SN, et al. The impact of the role of prophylactic antibiotics in elective laparoscopic cholecystectomy: a prospective randomized study. Am J Surg, 2006. **191**: p. 721-725.

24. Choudhary A, B.M., Puli SR, Othman MO, Roy PK, Role of prophylactic antibiotics in laparoscopic cholecystectomy: a meta-analysis. J Gastrointest Surg, 2008. **12**: p. 1847-53.

25. Kuthe SA, K.L., Verma GR, Singh R, Evaluation of the role of prophylactic antibiotics in elective laparoscopic cholecystectomy: a propective randomized trial. Trop Gastroenterol. , 2006. **191**: p. 721-725.

26. Beltrán MA, C.K., Incisional hernia after McBurney incision: retrospective case-control study of risk factors and surgical treatment. World J Surg, 2008. **32**: p. 596-601.

27. Guzmán-Valdivia G, Incisional hernia at the site of a stoma. Hernia, 2008. **12**: p. 471-474.

28. Duron JJ, H.J., Msika S, et al. , Prevalence and mechanisms of small intestinal obstruction following laparoscopic abdominal surgery: a retrospective multicenter study. Arch Surg., 2000. **135**: p. 208-212.

29. Schmedt C-G, L.B., D¨aubler P, Bittner JG. , Access-related complications – an analysis of 6023 consecutive laparoscopic hernia repairs. Minim Invasive. Ther Allied Technol, 2001. **10**: p. 23-29.

30. Sánchez-Pernaute A, P.-A.E., García Botella A, Rodríguez L, Antona EM, Cabeza J, Valladolid DJ, Rubio MA, Delgado I, Torres A., Prophylactic closure of trocar orifices with an intraperitoneal mesh (ventralex) in laparoscopic bariatric surgery. Obes Surg., 2008. **18**: p. 1489-91.

31. Moreno-Sanz C, P.-Y.J., Manzanera-Díaz M, Herrero-Bogajo ML, Cortina-Oliva J, Tadeo-Ruiz G. Prevention of trocar site hernias: description of the safe port plug technique and preliminary results. Surg Innov, 2008. **15**: p. 100-104.

Table 1. Results of percentages of TSIH in the series.

	No. of patients	TSIH*	p
Sex			
Female	156	43 (27.5)	0.382
Male	64	14 (21.9)	
Age > 70 years	45	20 (44.4)	0.004
Diabetes Mellitus	26	12 (46.1)	0.012
BMI > 30 kg/m^2	72	32 (44.4)	< 0.001
Fascial incision enlargement	21	18 (85.7)	< 0.001
Wound Infection	39	25 (64.1)	< 0.001

Values in parentheses are *percentages

BMI= Body Mass Index

Table 2. Results of a multivariate logistic regression analysis for development of TSIH in the series.

	Adjusted Odds ratio	95 cent confidence intervals		p
Diabetes Mellitus	2.795	1.059	7.377	0.038
BMI > 30 kg/m2	2.717	1.283	5.752	0.009
Wound infection	5.620	2.352	13.427	< 0.001
Fascial incision enlargement	14.172	3.617	55.519	< 0.001

BMI= Body Mass Index