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Medical liability insurance claims on entry-related complications in laparoscopy

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Abstract

Introduction
Installation of the pneumoperitoneum is an essential part of laparoscopic surgery. Creation can be performed by either the open or a closed technique. The aim of this study was to assess the number of, and contributing factors to entry-related complications in medical liability insurance claims in the Netherlands.

Methods
A retrospective chart review was performed including all malpractice claims filed at MediRisk, which is presently the largest medical liability mutual insurance company for institutions, mainly hospitals in health care in the Netherlands.

Results
From January 1993 to December 2005, 41 claims were identified as entry-related complications which comprised 18% of all laparoscopy-related complications leading to claims. Most were young (median age 35 years) female patients who had routine, non-advanced laparoscopic procedures planned as short-stay or day-care procedures. The claims were equally divided between general surgery (n=20) and gynaecology (n=21). A total of 51 structures were injured. There were 18 vascular structure injuries, 30 bowel injuries and three other injuries. An open-entry technique was used in only two (5%) patients. Vascular injury was exclusively associated with the closed-entry technique. In only 19 (46%) patients the entry-related complication was diagnosed peroperatively, consisting of 70% of the vascular and 25% of the bowel injuries. Twenty-six patients (64%) were admitted to the Intensive Care Unit for a median of five days. There was no mortality. Besides conversion, the majority of the patients filed a claim to compensate for a longer hospital stay and related costs. A payment was made in 17 (57%) of the 30 settled claims.

Conclusion
Medical liability claims concerning laparoscopic entry-related complications comprised one fifth of all laparoscopy-related claims. Claims concerning entry-related complications occurred in young patients who had routine, non-advanced procedures. In the investigated cases most claims involved the closed-entry technique.
Introduction

Despite the ongoing technological advances in laparoscopic surgery, the creation of a pneumoperitoneum and the additional introduction of surgical instruments remains a potential dangerous first step that can result in serious injuries to the visceras and major intra- and retroperitoneal vessels. The reported incidence of vascular and bowel injuries varies and is between approximately 0.05–0.5 complications per 100 laparoscopic procedures.\(^1\)–\(^4\) Although the incidence of entry-related complications is rare, the result of major vascular and unrecognized bowel injuries is serious, often leading to severe morbidity and even mortality. The overall mortality rate is reported to be about 4% increasing to 21% for unrecognized bowel injury.\(^5\)–\(^7\) In several reports the fatalities result from about 75% vascular injuries and the remaining 25% from unrecognized bowel injuries.\(^4\);\(^5\);\(^8\) Furthermore, it has been calculated that one half of all laparoscopic complications can be blamed on the entry technique.\(^9\)–\(^11\)

In general, there are two techniques to establish the pneumoperitoneum and to enter the abdominal cavity. The first is the closed (blind) entry, which is performed by using a Veress needle to establish the pneumoperitoneum followed by trocar insertion or, less frequently, direct trocar insertion without previously establishing a pneumoperitoneum. The second method is the open technique, in which a small laparotomy is performed. Successively, skin, rectus fascia, and peritoneum are incised under direct vision, followed by blunt (Hasson’s) trocar insertion. Subsequently the pneumoperitoneum is created.\(^1\);\(^12\)

With respect to the prevention of entry-related complications, neither of these two techniques is supported by solid evidence and there is an ongoing debate, mainly between gynaecologists who favour the closed-entry technique, and surgeons who favour the open-entry technique, about which technique is better.\(^1\);\(^10\) Many general surgeons suggest that the open-entry technique results in the same number of visceral lesions as does the closed-entry technique, but significantly fewer vascular lesions.\(^1\);\(^13\) Furthermore, it could be hypothesized that another advantage of the open-entry is that at least part of the bowel injuries is immediately seen under direct vision. Because of the lack of evidence, the European Association for Endoscopic Surgery (E.A.E.S.) practical clinical guideline on the pneumoperitoneum could not state which of the entry techniques is preferred.\(^9\)

To answer this questions with a high level of evidence a randomised comparison of the open and closed access techniques with a sample size of over 200,000 patients would be required to detect a reduction of major complications from one per 1000 to 0.5 per 1000.\(^14\) Therefore, it is important to continue to report on this topic because one has to rely on accumulating evidence of a lower level. In this study medical liability data sources were used to provide evidence on entry-related injuries.

The aim of this study was to assess the number of entry-related complications that provoked medical liability insurance claims for laparoscopic surgery at the largest medical liability mutual insurance company for institutions in health care in the Netherlands. Furthermore, the used entry technique (i.e. open vs. closed), distribution of injured organs, and predictive factors for litigation were assessed.
Methods

Data source
A retrospective chart review was performed which included all malpractice claims filed at MediRisk concerning entry-related complications in the period January 1993 to December 2005. MediRisk was founded in 1993 and is presently the largest medical liability mutual insurance company for institutions, mainly hospitals in the healthcare industry in the Netherlands. In 1993 MediRisk insured 21 hospitals. At the end of 2005 the number of insured hospitals included 80 of the 101 Dutch hospitals (Figure 1). The insured institutes are broadly representative of the Dutch teaching and non-teaching hospitals, with the exception of all eight academic hospitals in the Netherlands, none of which are insured at MediRisk.

Figure 1. The number of hospitals insured and the amount of claims that were filed between 1993 and 2005

Definitions and inclusion and exclusion criteria
An entry-related complication was defined as a direct injury related to the insertion of either the Veress needle or the first trocar, including preperitoneal insufflations and injuries to epigastric vessels, intraperitoneal viscera and vessels, and retroperitoneal viscera and vessels. Port-site hernias were excluded from this analysis. Claims, in which the aetiology of the injury was not clear and other causes than insertion (e.g. coagulation injury or other procedure-related complications) could not be ruled out, based on operative reports and/or histological examination, were excluded. Furthermore, injuries caused by second-trocar insertion were also excluded.

Claim characteristics
All included claims were reviewed and the following data were extracted using a preformatted sheet; age, gender, co-morbidity, prior abdominal surgery and/or
previous intra-abdominal infectious events, body mass index (BMI, kg/m²), specialty (i.e. gynaecology or general surgery), urgency, experience (i.e. resident or consultant), informed consent, indication for surgery, entry technique (i.e. open or closed), type of entry-related complication, moment of diagnosis of the entry-related complication, postoperative recovery including data such as reoperations, Intensive Care Unit (ICU) admission, postoperative morbidity and mortality. The entry-related complications were classified as ‘bowel’, ‘vascular’ or ‘other’. The gastrointestinal tract was divided into three parts: stomach, small intestine and large intestine. Vascular injuries were divided into retroperitoneal, intraperitoneal, and abdominal wall (epigastric vessels). Furthermore, the vascular injuries were subdivided into arterial, venous, or vascular not specified.

Statistics
Data were calculated as median values with ranges for continuous and discrete data, unless otherwise specified. Categorical data are presented as frequencies or percentages. Analysis was done using the SPSS v.12.0 package (SPSS, Chicago, Illinois, USA).

Results

Filed claims concerning laparoscopic procedures and entry-related complications
In the study period, a total of 10552 claims were filed at MediRisk (Figure 1) of which 229 (2%) involved gynaecological and surgical laparoscopic procedures. Of these 229

Figure 2. The relation between laparoscopy-related claims in total and entry-related injuries between 1993 and 2005

1. number of laparoscopy-related claims
2. entry-related injuries
claims, 50 were identified as an entry-related complication. Subsequently, seven claims were excluded because the aetiology of the injury was not clear and causes other than Veress needle or trocar insertion could not be ruled out. Furthermore, two claims were excluded because the injury was caused by insertion of the second-trocar. The final analysis comprised 41 claims, which is 18% of all laparoscopy-related claims filed at MediRisk. Figure 2 shows the relationship between all laparoscopy-related claims and the number of entry-related complications. The yearly number of filed claims concerning entry-related complications remained stable during the study period.

**Characteristics of the entry-related complications**

The median age of the 41 patients included in this study was 35 years (range 14-81). Median BMI was 24.0 kg/m² (range 18.6-55.9 kg/m²). Sixteen (39%) patients had a high (> 25.0 kg/m²), and six (15%) had a low (< 20 kg/m²) BMI. Twenty-one patients (51%) had a history of prior abdominal surgery (range 1-3 procedures). The ratio between general surgery and gynaecology was 20:21. The surgical patients consisted of 17 (85%) females and three (15%) males. Residents were involved in six (15%) claims. In both surgical and gynaecological patients the planned procedures were routine and non-advanced and in 37 (90%) patients they were elective (Table 1).

**Table 1. Planned operative procedures in the 41 patients with an entry-related complication**

<table>
<thead>
<tr>
<th>Planned procedure</th>
<th>Number of patients (n=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gynaecology</strong></td>
<td></td>
</tr>
<tr>
<td>sterilization</td>
<td>11</td>
</tr>
<tr>
<td>diagnostic laparoscopy</td>
<td>4</td>
</tr>
<tr>
<td>ovarian cystectomy</td>
<td>2</td>
</tr>
<tr>
<td>adhesiolysis</td>
<td>2</td>
</tr>
<tr>
<td>ectopic pregnancy</td>
<td>1</td>
</tr>
<tr>
<td>adnex extirpation</td>
<td>1</td>
</tr>
<tr>
<td><strong>Surgery</strong></td>
<td></td>
</tr>
<tr>
<td>cholecystectomy</td>
<td>10‡</td>
</tr>
<tr>
<td>diagnostic laparoscopy</td>
<td>3</td>
</tr>
<tr>
<td>appendectomy</td>
<td>3</td>
</tr>
<tr>
<td>hernia repair</td>
<td>2</td>
</tr>
<tr>
<td>gastric banding</td>
<td>1</td>
</tr>
<tr>
<td>gastric perforation</td>
<td>1</td>
</tr>
</tbody>
</table>

‡Including two open-entry techniques; in all other patients a closed-entry technique was used.

A total of 51 structures were injured (Table 2). There were 18 vascular structure injuries consisting mainly of retroperitoneal vessels (n=13, 72%) of arterial origin (n=10, 77%), 30 bowel injuries and three other injuries. Thirty-six patients had one injury, five (12%) patients had a combination of entry-related complications (range 2-3). The injured retroperitoneal arteries included the right iliac artery (n=2, 20%), the left iliac artery (n=2, 20%), and the abdominal aorta (n=3, 30%); in the remaining three (30%) cases the injured artery was not reported. The large bowel injuries comprised mainly the transverse (n=4, 40%) and left sided colon (n=4, 40%). Two (5%) patients had an open entry-related complication.
Both patients had a history of a previous laparotomy. In one patient the exact type of entry technique was not mentioned. A closed-entry technique was used in the remaining 38 (93%) patients. All vascular entry-related complications were seen after the closed-entry technique. In 15 (39%) cases in which the closed-entry technique was used it could not be determined whether the Veress needle or the primary trocar was responsible for the injury. In the remaining closed-entry cases, the Veress needle was responsible in 12 (32%) and the first trocar in 11 (29%) cases. In only five of the latter cases the design of the trocar was reported; four shielded trocars and one optical trocar.

Table 2. Type of entry-related complications (n=51) in the 41 patients included in this study

<table>
<thead>
<tr>
<th>Type of entry-related complication</th>
<th>Gynaecology (n=21)</th>
<th>Surgery (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vascular</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>epigastric vessels</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>retroperitoneal vessels</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>intraperitoneal vessels*</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Bowel</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>stomach</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>small intestine</td>
<td>9</td>
<td>9†</td>
</tr>
<tr>
<td>large intestine</td>
<td>6</td>
<td>4†</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>uterus</td>
<td>0</td>
<td>2†</td>
</tr>
<tr>
<td>preperitoneal insufflation</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

*mesenterial artery or omental artery; †One patient was 22 weeks pregnant; ‡including one open-entry technique

Thirteen (32%) claims provided additional narrative comments by the surgeon on the cause of the injury, citing various factors that contributed to the injury. These comments included adhesions (n=4), “overshoot” with the trocar (n=2), distended intestine (n=2), very thin patient (n=2), pregnancy (n=1), post partum (n=1), obesity (n=1), and device problems during introduction (n=1).

Time of diagnosis and postoperative course

In 19 (46%) cases the entry-related complication was diagnosed peroperatively resulting in 16 conversions. In the remaining 22 (54%) cases the injury was diagnosed at median postoperative day two (range 0-5), resulting in one or more reoperations and a complicated postoperative course (Table 3). Eighty percent of the combined injuries and 70% of the vascular injuries were diagnosed peroperatively, the remaining vascular and combined injuries were diagnosed on the same day. Only 25% of the bowel injuries were diagnosed peroperatively, the remainder were diagnosed at median postoperative day two. Twenty-six patients (64%) were admitted to the ICU for a median of five days (range 1-60). Seventy percent of the patients with a vascular injury were admitted to the ICU for a median of two days (range 1-34). Fifty-eight percent of patients with a bowel injury were admitted to the ICU for a median of eight days (range 1-60). There were no claims for fatal injuries. Nine (22%) patients suffered permanent harm (> 1 year). The latter consisted of post
traumatic stress disorder (n=3), neuropathy (n=2), post ventilation lung damage (n=1), premature childbirth due to uterus perforation (n=1), permanent enterocutaneous fistula (n=1), and intermittent claudication (n=1).

Table 3. Time of diagnosis (no delay vs. delayed diagnosis) and postoperative course of the 41 patients included in this study

<table>
<thead>
<tr>
<th></th>
<th>No delay (n=19)</th>
<th>Delayed diagnosis (n=22)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU stay</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- number of patients (%)</td>
<td>8 (42%)</td>
<td>18 (82%)</td>
</tr>
<tr>
<td>- median days (range)</td>
<td>1 (1-18)</td>
<td>8 (1-60)</td>
</tr>
<tr>
<td>Patients with postoperative morbidity (%)</td>
<td>6 (32%)</td>
<td>17 (77%)</td>
</tr>
<tr>
<td>Permanent harm</td>
<td>5 (26%)</td>
<td>4 (18%)</td>
</tr>
</tbody>
</table>

From patient records only in 13 (32%) claims, informed consent was properly established, *i.e.*, documented and understood by the patient. In the remaining claims informed consent was not documented or not given at all. In 48% of the claims complications such as bowel injury or the chance of conversion to laparotomy were discussed preoperatively. According to the records a postoperative meeting between surgeon and patient, in which the complications that occurred were discussed, had taken place in only 16 (39%) cases. The majority of the patients claimed financial compensation for the prolonged hospital stay, related costs such as travelling expenses and domestic care and the midline laparotomy scar. Thirty (73%) claims were settled at the end of the study period and a payment was made in 17 (57%) of the settled claims.

**Discussion**

Several randomised controlled trials and meta-analyses have demonstrated that laparoscopic surgery is superior to laparotomy in terms of morbidity, postoperative recovery, and length of hospital stay.\(^{15,16}\) Having achieved broad acceptance, minimally invasive surgery is a fast-expanding surgical discipline. Nevertheless, the initiation of laparoscopy, *i.e.* the creation of a pneumoperitoneum followed by the introduction of the surgical instruments remains a potentially dangerous first step, which is exclusively associated with the laparoscopic approach.

The present study demonstrates that medical liability claims involving entry-related injuries comprised about one fifth of all laparoscopic surgery-related claims filed at MediRisk. The claims were equally distributed between general surgery and gynaecologic procedures. However, this distribution does not implicate that the incidences of entry-related complications are comparable because the number of laparoscopic procedures of both specialities performed during the study period is not known.

In both the general surgery and gynaecology cases the planned procedure was generally a routine one and elective in nature. Furthermore, these procedures involved mostly young
female patients who planned to be operated on in a day-care setting or in short stay surgery. The consequences of an entry-related complication in these young patients who underwent a routine procedure are striking, however. The entry-related complication resulted in one or more laparotomies, stay in the ICU, and prolonged hospitalisation. Furthermore, 22% of the patients suffered from permanent harm.

Since the first reports on entry-related complications many articles have been published on this subject and trocars have been introduced with new design features, including retractable shields and optical trocars to allow direct viewing during insertion.5,17 Furthermore, to avoid entry-related complications it is important to identify patients at risk, e.g. those with adhesions from previous laparotomy and obese and very thin patients. However, despite this identification entry-related complications still occur at a constant rate.1,2,8 In a recent survey of the U.S. Food and Drug Administration (FDA) Fuller et al., who reviewed all reports from January 1997 to June 2002, identified 31 fatal and 1353 nonfatal trocar injuries. Most fatalities involved vascular injuries.5

In our study most claims were provoked by injuries caused by the closed-entry technique, and vascular injury was exclusively caused by the closed-entry technique. However, this does not mean that the incidence of entry-related complications for the closed-entry technique is much higher compared with that of the open-entry technique because the numbers of performed closed- and open-entry techniques are unclear. However, retroperitoneal vascular injury is associated with “overshoot” of the introduction of the Veress needle or the first trocar. Theoretically, this can be avoided by using an open introduction. It is known that an open introduction might reduce the incidence of this serious complication. On the other hand, bowel injuries are not fully avoided by the open-entry technique.

Historically, gynaecologists have been trained in the closed-entry technique. Although the technique of open laparoscopy was first described by the gynaecologist Hasson in 1971,12 only a few gynaecologists use the open-entry technique.1,18 Some have reported comparable or even higher complication rates with the open-entry technique in gynaecologic case series.1 However, in these studies gynaecologists did not use the open-entry technique frequently; it was used mainly in selected patients who had prior abdominal surgery. Consequently these patients already were at a higher risk for entry-related complications. This explains why in a systematic review by Merlin et al. the risk of major complications initially appeared to be higher for the open-entry technique.19 When only prospective series were taken into account the opposite was shown; a relative risk of 0.30 (95% confidence interval 0.09-1.03) in favour of the open-entry technique. It was noted that retrospective studies compared a high-risk with a low-risk patient population, while the prospective studies investigated an unselected patient population.19 Furthermore, in a Japanese survey of laparoscopic surgeons, Hashizume et al. reported that during the study period 96.6% of the surgeons changed their method of establishing a pneumoperitoneum from the closed-entry technique to the open-entry technique to increase patient safety. The rate of complications related to needle and/or trocar insertion subsequently decreased as the surgeon’s experience performing laparoscopic surgery using the open-entry technique increased.13
Our study also consists of a selected series of patients, because 51% percent of them had a history of surgery, and only 46% of the patients had a normal BMI (20-25 kg/m²). It is well recognized that the introduction of a pneumoperitoneum and trocars in obese patients is difficult because of the lack of feeling the instruments penetrate the fascia or the insertion is too deep. However, most patients at risk are lean. In these patients the distance between the abdominal wall and the underlying structures is short so that a Veress needle or trocar penetrating the abdominal fascia and peritoneum with a little too much force puts these structures at risk. Furthermore, the risk of bowel injury is increased in patients who had previous abdominal surgery because of adhesions of the small bowel to the abdominal wall. Nevertheless, in the present series of patients a closed-entry technique was used despite the increased risk of complications caused by an abnormal BMI and the risk of adhesions after previous surgery.

It is remarkable that in only one third of the claims informed consent was properly given and documented, and in only 48%, were complications discussed with the patient preoperatively. An unexpected negative outcome, that is neither discussed preoperatively nor explained postoperatively, is probably the most important trigger for litigation. A properly informed patient is less likely to file a claim. This group of patients consisted of young patients who underwent routine nonadvanced surgical procedures and both surgeon and patient did not expect such a serious complication. Another factor that may have provoked litigation is that more than half of the entry-related complications were diagnosed with a delay and that several of these patients had already been discharged. Therefore, it is important to discuss with the patient the risk of conversion to open surgery and the risk of vascular and bowel injuries in general, and to point out that not all of these injuries are diagnosed immediately. This conversation, including the informed consent of the patient, must be documented and patients at risk (e.g. lean or obese patients or those who had previous abdominal surgery) should be identified. Furthermore, it is important to keep in mind that entry-related complications still occur at a constant rate, even in routine procedures.

This study has several limitations. First, it probably represents only a part of all entry-related complications that occur. Furthermore, the study consists of a small, retrospectively collected, and selected population of patients, probably representing the most dramatic cases. During the study period a (growing) fraction of the hospitals in the Netherlands were insured at MediRisk. Because of insufficient record-keeping, we were unable to clearly identify risk factors or specific trocar devices at risk. In general, this study does not present any data on the total population who had a laparoscopic procedure by the same surgeons responsible for the claims analysed. Therefore, the definite relationship between several factors associated with entry-related injuries could no be established.

In conclusion, entry-related complications provoking litigation probably comprise one fifth of all laparoscopy-related claims. Patients that filed a claim were mostly young females with a history of abdominal surgery who were operated on in a day-care setting or had short-stay surgery with severe consequences of the entry-related complication. Most claims involved the closed-entry technique.
Reference List


