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ORIGINAL ARTICLE

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Bleeding remains a major complication during laparoscopic surgery: analysis of the SALTS database

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Abstract *Background and aims:* The aim of this study was to determine the incidence of bleeding complications from various laparoscopic procedures in a nationwide prospective multicentre study in Switzerland from 1995 to 2001 following an initial learning curve. *Patients and methods:* Since 1989, the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SALTS) has prospectively collected data from patients undergoing laparoscopic or thoracoscopic surgery at 114 surgical institutions (university, county and district hospitals, private practice). More than 130 items of data, including indication for surgery, intraoperative course, local as well as general postoperative complications, mortality and follow-up were recorded on a computerised data sheet. *Results:* Some 43,028 procedures were assessed and analysed. Local morbidity (e.g. wound infections) occurred in 0.05% of the whole patient group, whereas 3.3% developed general postoperative complications. The overall mortality rate was 0.2%. In 1.7% of the cases, the intraoperative course was complicated by internal bleeding or haematoma of the abdominal wall. In the postoperative course, 1.5% of the patients presented with internal bleeding or bleeding of the abdominal wall. Major vascular injury occurred in 0.09%. This patient group with bleeding complications was analysed in the context of the operator's experience, instrumental lesions (Veress needle or trocar) and conversion incidence. Furthermore, a trend analysis of the complication rate from 1995 to 2001 was performed. *Conclusion:* Although the initial learning curve of laparoscopic procedures is probably finished, the rate of bleeding complications is still substantial. These results demonstrate that the collection of data in the form of multicentre studies is essential for quality control. It permits recognition and understanding of the current problems in laparoscopic surgery in order to improve the quality of daily surgical practice. The fact that the operator's experience seems to play an important role shows that improvement in learning and teaching programmes is still necessary and should be coordinated on a national basis.

Keywords Laparoscopy · Bleeding complication · Major vascular injury · Teaching · Learning curve

Introduction

The performance of laparoscopic procedures in general surgery has become increasingly common since its introduction in the early 1990s. Nevertheless, the need to assess complications is still substantial after the initial learning curve, particularly because the access-related complications, e.g. bleeding complications, do not occur during

conventional surgery. Furthermore, bleeding complications remain one of the most frequent reasons for conversion [1]. Overall, the incidence of bleeding complications ranges from 0.05% to 4% in the literature [1–16] but is probably under-reported. The reason for this probable under documentation may include publication bias or differences in the patient cohort relating to the procedures performed. Another problem is the definition of a bleeding complication; some groups describe the incidence of haematomas in the abdominal wall, whereas others describe the incidence of major injuries to retroperitoneal vessels [3]. In addition, the cited series, particularly for major vascular injuries, are mostly retrospective case series with a small sample size.

The objective of this study was, therefore, to determine the number and consequences of bleeding complications during 43,028 standard laparoscopic procedures from a prospective, nationwide, database in Switzerland from 1995 to 2001.

Patients and methods

Since 1989, the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SALTS) has prospectively collected data from patients undergoing laparoscopic surgery at 114 surgical institutions (university, county and district hospitals, private practice). Data from more than 65% of all laparoscopic procedures in Switzerland have been documented. More than 130 items of data, including personal records, indication for surgery, intraoperative course, local as well as general complications, mortality and follow-up were recorded. Furthermore, the duration of the operation and the hospital stay, the operator's experience, the reason for conversion and other factors were recorded. 'Conversion' for postoperative bleeding is defined as open re-intervention for haemorrhage after surgery, in comparison to re-laparoscopic management of bleeding complication. These computerised data sheets were transferred into a database program (Qualicare) by one person qualified to verify the data entered and prove completeness of the data. If incomplete operation reports, medical records and follow-up was found, an additional questionnaire was demanded from the surgeon responsible. If necessary, the institution was visited by one of the investigators, who would collect the missing data.

In this study, 43,028 laparoscopic operations were performed from 1995 to 2001. The most frequent intervention was cholecystectomy (52%), followed by groin hernia repair (18%), appendicectomy (12%), colorectal resection (4%) and 4% others, such as fundoplication or bariatric surgery (see patients' characteristics, Table 1).

Bleeding complications were divided into intraoperative bleeding and postoperative bleeding with either an abdominal wall bleeding or internal (peritoneal cavity or retroperitoneal space) bleeding source. Haematomas were subsumed under the term "abdominal wall bleeding", whereas internal bleeding was defined as a bleeding complication caused by a blood loss of >500 ml. The time point for postoperative bleeding was limited to 24 h after surgery, and the indication for blood transfusion was a decrease of haemoglobin <10 g/dl or haemodynamic instability. Major vascular injuries were defined as a lesion of one of the following vessels: aorta, vena cava, iliac vessels, mesenteric vessels and other major intra- or retroperitoneal vessels such as mesenteric or portal vein. The analysis of postoperative morbidity was focused on local postoperative problems, such as wound infections or anastomotic leakage, and on general postoperative morbidity, such as pulmonary or cardiac disorders.

Table 1 Patients' characteristics. Data are given as medians and ranges

Characteristic	Absolute number
Patients (*n*)	43,028
Gender (male:female)	19,115:23,913; ratio 0.8
Age (years)	53 (range 1–101)
ASA classification I/II:III/IV	37,865/5163; ratio 88%, ASA I/II
Hospital stay (days)	5 (range 1–300)
Local postoperative morbidity	1,882 (0.05%)
General postoperative morbidity	1,538 (3.6%)
Bleeding complication	1,425 (3.3%)
Mortality	107 (0.2%)

Statistical analysis Data are given as absolute numbers or as medians and ranges, if indicated. Associations between various predictor factors and outcome variables, such as transfusion and bleeding complications, were examined with chi^2 tests. To test for a time trend across calendar years, the Cochran–Armitage trend test was used. A P value <0.05 was considered statistically significant.

Results

The overall bleeding rate was 3.3%. Intraoperative bleeding complications occurred in 1.7% of all patients, of whom 99 (14%) had an abdominal wall and 623 (86%) an internal bleeding source. Nine percent of patients with internal bleeding and 3% with an abdominal wall haematoma needed transfusion, with a significant difference for internal bleedings (P=0.05). For the group of patients with postoperative bleeding (1.5%), 7% with abdominal wall bleeding needed transfusion and a higher (P<0.0001) use of transfusion was found for the patients with internal bleeding; nearly half the patients received transfusion (47%). When the need for blood transfusion was compared between the groups of intraoperative bleeding and postoperative bleeding, haemorrhage after the operation was more often the reason for transfusion (P<0.0001).

Major vascular injuries occurred in 0.09% of cases (n=42), of which 7% needed blood substitution. The major vessels injured were the abdominal aorta (n=1), the common iliac artery (n=2), the external iliac artery (n=2), the splenic vein (n=2), mesenteric vessels (n=3), omental vessels (n=3), vessels in the liver (n=2) and others. Thirty-three percent of the major vascular injuries occurred during the set-up phase of pneumoperitoneum because of the insertion of the first trocar (n=10) or establishment of the pneumoperitoneum by the Veress needle (n=4). In all cases the entry site of trocar or Veress needle was near the umbilicus. The operator's experience was, in all these cases, >100 performed laparoscopies. Another reason for major vascular injury was the inattentive handling of the hook electrocautery or other instruments (e.g. grasping forceps). In two other cases the major vascular injury was caused by the blade of the scalpel that was used to cut the skin at the trocar entry site.

In 3% of intraoperative bleeding, insertion of the first trocar caused the haemorrhage, and in 1% it was caused by insertion of the Veress needle. With postoperative bleeding, only 0.5% suffered from internal or abdominal wall bleeding because of problems that had occurred during the set-up phase of the pneumoperitoneum and were recognised only in the postoperative period. However, for the total number of injuries caused by trocar insertion (n=63), a bleeding complication (either intraoperative bleeding, postoperative bleeding or major vascular injury) occurred in 57%. On the other hand, 40% of all Veress needle lesions (total number n=25) led to either intraoperative bleeding or major vascular injury. These complications during laparoscopy led to conversion in 31% of intraoperative bleeding cases, 32% of the internal bleeding cases and 16% of the abdominal wall bleeding cases. Altogether, 91% of all internal bleeding during operation had to be ameliorated surgically (open or laparoscopic management) and 77% of all intraoperative abdominal wall bleeding. In 13% of postoperative haemorrhages, an open re-intervention was mandatory (17% with internal bleeding and 10% with abdominal wall bleeding). In the statistical analysis, the conversion rate of intraoperative versus postoperative bleeding was higher (P<0.0001). Patients with a major vascular injury (45.2%) underwent conversion procedure. Analysis of the significance level shows that postoperative bleeding was terminated significantly more often laparoscopically (P<0.0001).

In order to determine the influence of the surgeon's experience we compared the number of bleeds during interventions, between surgeons who had undertaken fewer than 100 laparoscopic interventions and those who had undertaken more. For intraoperative bleeding, the experience of the surgeon was a contributing factor (P<0.0001), whereas for postoperative bleeding, the surgeon's experience was not an important risk factor (P=0.65), as was the case for major vascular injuries (P=0.6).

In addition to the individual learning curve, a trend analysis over the investigated time period (1995–2001) was performed. Figure 1 shows the significant decrease in internal bleeding over the years investigated (P<0.0001), as was also observed for the postoperative internal bleeding rate (P=0.007) and the development of intraoperative (P<0.0001) and postoperative (P=0.007) haematoma at the abdominal wall (Fig. 2).

The analysis of postoperative complications shows that the highest rate (99%) of local morbidity (wound and urinary infection, anastomotic leakage) occurred in the patient group with postoperative bleeding. In contrast, only 15% of patients with intraoperative bleeding and 16.7% of patients with major vascular injuries developed postoperative local complications. These differences are highly statistically significant (P<0.0001). Patients with major vascular injuries developed the highest rate of general postoperative complication (pulmonary and cardiac), 16.7%, followed by patients with postoperative bleeding (15.4%). A significantly lower rate of general complications was observed in the group of intraoperative bleeding (8.7%).

The highest mortality rate, 2.4%, occurred after major vascular injuries, followed by the patient group with intraoperative bleeding (1.5%). 0.6% of patients with postop-

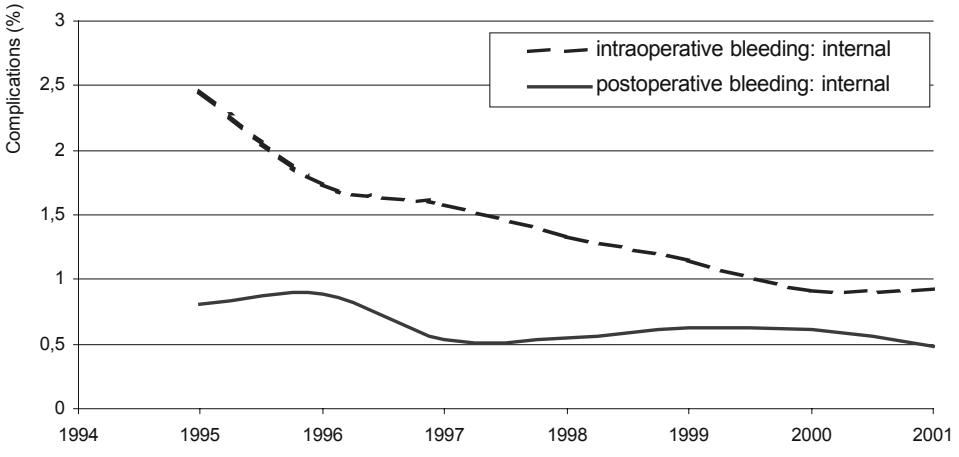

Fig. 1 Trend analysis of the development of intra-abdominal bleeding (intraoperative and postoperative) from 1995 and 2001; Cochrane–Armitage test

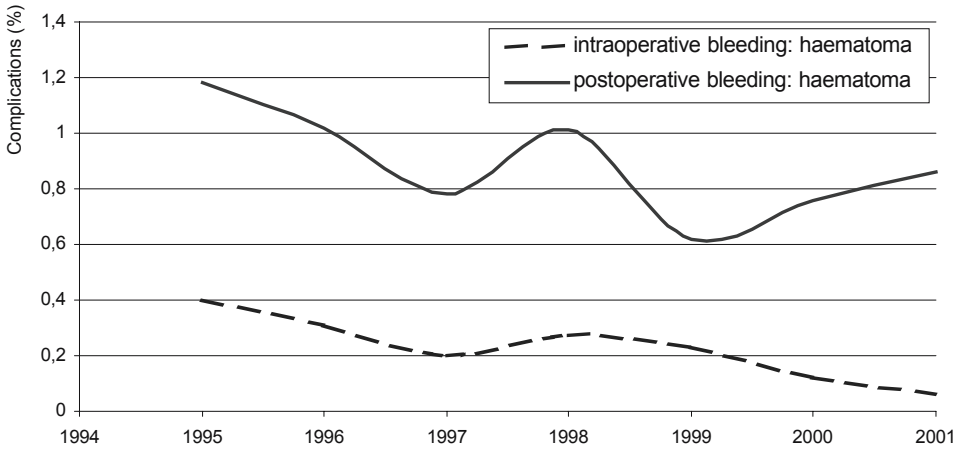

Fig. 2 Trend analysis of the development of abdominal wall haematoma (intraoperative and postoperative) from 1995 to 2001; Cochrane–Armitage test

erative bleeding died. However, these differences are not statistically significant.

Discussion

The overall bleeding rate of 3.3% investigated in the present study on 43,028 laparoscopic interventions is comparable to the results in the literature, which range from 0.005% to 8.6% [1–16] and shows that bleeding remains a major problem during laparoscopic surgery.

These differences can be explained partly by publication bias, since many reports of complications are not cited in *Index Medicus* and are consequently not represented in the reviews. Furthermore, there is always a tendency for publication of rather positive experiences. Another critical point is the evidence base level of the current literature, which consists mostly of retrospective small case series. However, even in large cross-sectional surveys such as SALTS, which already includes 65% of all hospitals in Switzerland, the results never represent the complication rate of a whole nation.

Apart from this issue, the problem of how to define a bleeding complication has led to different results because some authors assessed only major vascular injuries, while others documented less important intraoperative or postoperative bleeding. Therefore, in our study, we have distinguished between intraoperative and postoperative bleeding, on the one hand, and internal or abdominal wall haemorrhage, on the other. Major vascular injuries were analysed separately. This precise, preoperative, definition of possible bleeding complication during laparoscopic surgery makes the current study unique. The bleeding rates of the various groups (1.7% intraoperative bleeding, 1.5% postoperative bleeding, and major vascular injuries of 0.09%) come very close to the lower limit of the ranges reported in the literature [3, 4, 6, 8, 9, 11, 12].

The importance of distinguishing between the various bleeding sources is underlined by the fact that the highest transfusion rate was observed in patients with postoperative bleeding (24%). This is probably due to the fact that intraoperative bleeding was successfully managed during the intervention whereas postoperative bleeding was first treated conservatively. Therefore, the rate of conversion was significantly higher for intraoperative haemorrhage than the rate of open re-intervention in postoperative bleeding. However, the highest rate of conversion, 45%, was observed in the group of patients with major vascular injuries, which fits the data reported in the literature [3]. It is obvious that immediate laparotomy is the best method to control massive bleeding, as most fatal results are observed if diagnosis is delayed. We also observed the highest morbidity and mortality rate in patients with major vascular injuries.

On the other hand, patients with postoperative abdominal wall haematomas also develop a high local complication rate. In our series local postoperative morbidity, mostly wound infections (5%), was significantly higher in patients with postoperative bleeding than in the others. As this was also found in other series [17, 18], accurate haemostasis of the trocar sites is strongly recommended. Besides bleeding control by either compression or internal or external ligation/coagulation, an alternative method might be short-term tamponade with a balloon catheter.

Looking closely at the origin of these bleeding complications, we found that one third of major vascular injuries occurred during the set-up phase; 23% during the insertion of the first trocar and 10% during establishment of the pneumoperitoneum by the Veress needle. The major vascular injury rate reported in the literature during the set-up phase of laparoscopy is even higher; more than 75% of major vascular injuries occur during insertion of the Veress needle or the first trocars [2, 3, 19, 20].

The discussion on how to establish pneumoperitoneum either by open (Hasson) or closed (Veress needle) technique is still ongoing, as is the use of Bachaus forceps during the insertion of the Veress needle with a 45° angle. The invention of new technical devices, such as blunt-tipped or ‘optical’ trocars that allow recognition of each layer of the abdominal wall during the access to the peri-

toneal cavity, have not eliminated the risk of bleeding complications [7]. The advantage of the Hasson technique is, obviously, the better view, but results the in literature are controversial. Bonjer et al. [21] described a significant difference between the open and closed technique, for the rate of vascular and visceral injuries, that favoured the Hasson technique, when they analysed personal experiences in 1,293 patients and reviewed the literature. In this series, 40% of all bleeding complications were produced by inserting the Veress needle, with a mortality rate of 0.8%. An Australian group's systematic review of the safety of methods to establish the pneumoperitoneum showed that the evidence in the literature is not clear [14]. This meta-analysis of 14 studies (four randomised controlled trials, prospective and retrospective cohort studies) comparing open with closed (needle/trocar) access indicated a trend during open access towards a reduced risk of major complications (e.g. bleeding complication and organ injury) with a relative risk of 0.3. Vascular injury occurred rarely with the open technique (0%–0.03%) and ranged from 0.003% to 1.33% with the needle/trocar technique. The authors concluded that the incidence is too low in both groups to demonstrate a difference without an exceptionally large sample size. However, they prefer the open technique, since any injury can be recognised and repaired immediately.

In addition to the establishment of the pneumoperitoneum, further trocar insertion also plays an important role in the incidence of bleeding complications, as in our series that showed haemorrhage in 57% of further trocar insertions. An anatomical study of 21 cadavers, in which the course of the inferior epigastric arteries and the ascending branches of the deep circumflex iliac artery was pursued, showed that half of the 36 trocar insertion sites recommended in the common literature imply the risk of injury to these arteries. Therefore, the authors suggested the following insertion sites: ventral midline, and in a zone of 5-cm width lateral to the lateral border of the rectus sheath [22]. Another important anatomical relationship is the distance between the skin and the retroperitoneal vascular structures at the level of the umbilicus, which can be reduced to less than 2 cm, particularly in thin anaesthetised patients with muscle relaxation [23]. Another risk factor for the development of intraoperative bleeding complications is the surgeon's experience. In the current series, surgeons who had performed fewer than 100 laparoscopies had significantly more intraoperative bleeds ($P<0.0001$), while the incidence of postoperative bleeding complication and major vascular injuries showed no statistical difference. From the historical point of view, bleeding complications seem to have decreased over the learning curve of laparoscopy from the early 1990s, which is confirmed in our series. A slight increase in 1999 and 2000 for postoperative internal bleeding can be explained by the fact that laparoscopy was beginning to be used for more complex operations such as colorectal procedures. In accordance with this finding, the complication rate in an American survey also increased when more complex laparoscopic procedures were performed [24, 25]. The tendency for a general learning curve has also been observed by other groups [2, 8] and can be explained by the ongoing refinement of the operating technique, particularly when new and more demanding procedures are introduced.

In conclusion, bleeding complications in laparoscopic surgery remain a major problem that results in substantial morbidity and mortality. Based on our nationwide experience, and the fact that the operator's experience seems to play an important role, we believe that the learning and teaching of laparoscopic skills is still necessary and should be coordinated on a local (teaching programs) and national (societies) basis.

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