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**Title:** Towards safety in minimally invasive surgery: patient safety, tissue handling and training aspects  
**Issue Date:** 2014-12-17
CHAPTER 4

RISK FACTORS OF PATIENT SAFETY: MINIMALLY INVASIVE SURGERY VERSUS CONVENTIONAL SURGERY
ABSTRACT

Background

To identify the frequency of events of the different patient safety risk domains during minimally invasive surgery (MIS) and conventional surgery (CS).

Methods

A convenience sample of gynaecological MIS and CS was observed. Events were observed and categorized in one of the predefined patient safety risk domains.

Results

A total of 53 procedures were observed, 26 CS and 27 MIS procedures. General characteristics were comparable. A large amount of environment events were observed (on average one every 2.5 minutes). Technical events and events of organizational nature occurred more often in MIS than in CS (p <0.01 and p <0.01). The relative risk for the occurrence of one or more technical events in MIS compared to CS was 1.7, and 4.1 for two or more technical events. There was no relation between time out according to protocol and the occurrence of the different types of patient safety related events.

Conclusion

The technological complexity inherent in MIS makes this type of surgery more prone to technology related problems than CS, even in a specially designed minimally invasive surgical suite. A regular time out procedure developed for CS lacks the necessary attention for the complex technology used in MIS and is therefore insufficient for briefing MIS procedures. Incorporating a specially designed technology checklist in a regular briefing protocol could be a solution to decrease the number of events in MIS.
INTRODUCTION

Ever since the Harvard Medical Practice study and the report by the Institute of Medicine (IOM) “To Err Is Human: Building a Safer Health System” that followed it, patient safety (PS) has become a major focus of improvement in healthcare. It is widely known that the IOM report stated that an estimate 44,000 to 98,000 patients in the US die every year due to medical errors. In the Netherlands the results of a national study assessing the number of hospital adverse events were presented in 2007. This study showed that 5.7% of 1.3 million patients admitted in 2004 encounter an adverse event. In 40% of these patients the adverse event could probably have been prevented. This high percentage of preventability is confirmed in a systematic review, including eight studies with a total of 74,485 patients. This study showed a median incidence of hospital adverse events of 9.2% with a median percentage of preventability of 43.5%. Of these hospital adverse events 39.6% were OR-related.

In 2007 the report by the Dutch inspectorate of healthcare emphasized that the complexity of minimally invasive surgery (MIS) further increases risks in PS. However, the mechanism through which PS in MIS is more compromised compared to conventional surgery (CS) remains unclear. In order to understand this mechanism, differences in PS between the two types of surgery should be investigated according to the systems approach. This approach to quality and safety in surgery is required to obtain insight on causes of errors and has a much larger effect on PS than the person approach. A number of important studies have suggested frameworks of factors that influence PS based on the systems approach. These frameworks were adapted to explain PS in surgery in several risk domains and measurable quality outcome parameters (Figure 1). With this observational study we aim to identify differences in PS risk factors between MIS and CS according to the systems approach.

METHODS

Case selection

A convenience sample of gynaecological MIS and CS performed at the Leiden University Medical Center, the Netherlands, was observed. CS performed in an operating room (OR) with regular OR settings were observed. MIS procedures performed only in a minimally invasive surgical suite especially designed for laparoscopy (in this case OR-1, Karl Storz) were included because these suites were especially designed to facilitate MIS. In this study MIS only comprised laparoscopies. MIS was stratified based on the level of difficulty according to the guidelines of the Royal College of Obstetricians...
and Gynaecologists. RCOG levels range from level one procedures, which are basic laparoscopic procedures (e.g. diagnostic laparoscopy and sterilization), to level three, which are advanced laparoscopic procedures (e.g. total laparoscopic hysterectomy). The procedures that could not be classified as MIS were classified as CS.

**Categorization system**

The adapted framework that explains PS in several risk domains and measurable quality outcome parameters (Figure 1) was the basis for the observations in this study. In order to objectively assess the risk domains in the framework, every risk domain should be quantified. This quantification and further categorization of the observations is explained in Table 1.

The categorization was tested in a pilot study during a period of three weeks. During this pilot random gynaecological surgical procedures were observed according to the categorization. After every procedure individual surgical team members evaluated the procedure with the researcher to determine the feasibility of the categorization. Next the categorization was critically reviewed on clinical relevance and completeness by a board of three independent experts (all authorities in the field of PS and MIS representing the department of surgery, gynaecology and PS in general). The final categorization system is shown in Table 1; it consists of a number of risk domains that have to be quantified during the observations (e.g. social interaction, technology, safeguarding system, organization and environment). This was achieved by observing the number of events that can be categorized in those risk domains.

**Events**

Events were defined as occurrences that potentially increase risks and therefore compromise PS, either directly or indirectly.

**Observations**

Observation of events during a surgical procedure started with the time out and ended when the last suture was placed. The total observational time (from time out till the last suture) as well as total procedure time (from first incisions till last suture) was recorded. Furthermore the risk domains that were not quantified by events and the other outcome parameters of the procedure were recorded as defined in Table 1.
Data collection

Data collection was performed by an independent observer that had not been involved in the development of the categorization to ensure objective assessment of the risk domains. This observer was required to have ample knowledge of medical processes, however without knowledge of the specific procedures that had to be observed. Therefore a medical student with 4 years of medical training was selected to be the observer. The observer attended gynaecological surgical procedures during a training period of three weeks prior to the study to obtain familiarity with these procedures. In this period the observer learned to recognize deviations from standard procedure as events and to code events according to the categorization.

Data analysis

All data was analysed with SPSS 16.0 software package (SPSS, Chicago, IL, USA). Differences in frequency of events, experience of surgical team members and length of surgery between MIS and CS were assessed with the independent samples t-test. Differences in categorical data (e.g. patient characteristics) were assessed with chi-square test.

Figure 1. Framework of risk domains explaining patient safety in surgery according to a systems approach.
| Risk domain | Influencing factor | Observation (quantity) |
|-------------|-------------------|-----------------------|
| **Input**   |                   |                       |
| Surgical team | Knowledge and experience of individual team member | Experience of every individual team member defined as an estimation of the number of similar procedures previously performed |
| Social interaction | Verbal and nonverbal communication | Events concerning verbal miscommunication |
| Teamwork | | Events concerning teamwork |
| Technology | The availability and functioning of equipment and instruments | Events concerning the presence or correct positioning of instruments or equipment |
| Organization | Staffing and planning | Adequate scheduling |
| | | Adequate staffing |
| | Availability of recourses | Availability of supplies |
| | | Availability of technological items |
| Safeguarding system | Compliance of policies adapted for patient safety | Correct execution of the time out procedure |
| Environment | Case irrelevant disturbing factors | Door movements |
| | | Telephone calls |
| | | Pager calls |
| | | Radio use |
| | | Case irrelevant conversation |
| Patient characteristics | Condition of the patient | ASA score |
| | | Body mass index (BMI) |
| Complexity of surgery | Level of difficulty of the surgery | MIS: type of procedure which can be categorized in RCOG levels |
| | | CS: type of procedure |
| **Output**  |                   |                       |
| Performed procedure | | Was the procedure performed as intended? |
| Intraoperative complication | | Intraoperative complications? |
| Postoperative complication | | Postoperative complications up to 6 weeks postoperative. |
| Blood loss | | Amount of blood loss |
| Procedure time | | Total observational AND intraoperative procedure time |

ASA, American Society of Anaesthesiologists Physical Status Scores.; BMI, body mass index; MIS, minimally invasive surgery; RCOG, Royal college of obstetricians and gynaecologists; CS, conventional surgery.
RESULTS

General characteristics

A total of 53 procedures were observed, 26 CS and 27 MIS procedures. The CS comprised 5 laparotomies for benign indication, 5 laparotomies for malign indication, 9 vaginal hysterectomies of which 4 were combined with prolapse surgery, 6 vulva surgeries and 1 cervical procedure. The MIS comprised of 10 RCOG level one procedures, 11 level two procedures and 6 level three procedures.

The mean total observational time, as well as the mean total procedure time were comparable for MIS and CS (1h29 vs. 1h52 and 1h19 vs. 1h44 respectively). The mean experience of the surgical team members did not differ between MIS and CS. Patients BMI and ASA score were both comparable between MIS and CS (Table 2).

Events

Total counts of observed events are displayed in Table 2. Between 75% and 100% of events occurred intra-operatively as illustrated in Figure 2. The greatest part of observed events was categorized under environment (MIS vs. CS respectively 90% vs. 97%). Of these events door movements were observed most, respectively 81% in MIS (n = 925) and 80% in CS (n= 1275). All observed events were checked for a correlation with the length of surgery, which was found in telephone calls and door movements (R² = 0.71 and 0.74 respectively). There was one door movement every 154 sec in MIS and one every 140 sec in CS and one telephone call every 20 minutes in both MIS and CS. When all environment events are combined, on average one event was observed every 125 sec during MIS and every 111 sec during CS. Of these observed environment events 8.8% are noted as disturbing by the surgeon in MIS and 17.6% in CS.

MIS vs. CS

When comparing the frequency of the different types of events in MIS to CS, there was no difference found between environment and social events. Except for disturbance of the radio, this was noted more often during CS (p < 0.01). Technical events and events of organizational nature occurred more often in MIS than in CS (p < 0.01 and p <0.01) (Table 2).

Of all events with a technical nature observed during MIS, 49% (n = 34) were problems with the positioning of equipment or instruments. Problems with the functioning of
equipment or instruments accounted for 28% (n = 19). In CS 33% (n = 6) of the observed events of technical nature were positional and 28% (n = 5) were problems with functioning. Of the 13 problems of organizational nature that were observed during MIS, 8 involved the unavailability of instruments at the time of surgery. The other organizational problems were a result of inadequate staffing.

**Relative risk**

The relative risk calculated for the occurrence of one or more events of technical nature in MIS compared to CS was 1.7. The relative risk of having 2 or more technical problems during MIS compared to CS was 4.1. For organizational problems the relative risk could not be calculated because none occurred during CS.

**Time out**

The time out protocol used in the observed clinic is similar to the time out protocol developed by the world health organization (WHO). In 74% of the MIS procedures the time out proceeded according to this protocol vs. 50% in CS. In one MIS procedure and in 5 CS procedures, there was no time out at all. However no relation between a time out procedure according to the protocol and the occurrence of different types of PS related events was observed.

![Figure 2. Total counts of observed events in minimally invasive surgery (MIS) and conventional surgery (CS). The striped part represents the share of events that occurred pre- or postoperatively, and the white part represents the share of events that occurred intraoperative.](image-url)
Table 2. Count of events during the total observational time.

| Risk domain                      | MIS (n = 27) | CS (n = 26) | MIS vs CS |
|----------------------------------|-------------|-------------|-----------|
|                                  | Count | Max count | Mean | Count | Max count | Mean | Total | P value |
| Environment                      |       |           |      |       |           |      |       |         |
| Total                            | 1145  | 114       | 0.48*| 1594  | 208       | 0.54*| 2739  | NS      |
| Door movements                   | 925   | 90        | 0.39*| 1275  | 174       | 0.43*| 1812  | NS      |
| Telephone                        | 112   | 11        | 0.05*| 165   | 28        | 0.05*| 268   | NS      |
| Beeper                           | 41    | 8         | 1.52 | 77    | 13        | 2.96 | 118   | NS      |
| Radio                            | 9     | 2         | 0.33 | 20    | 2         | 0.77 | 29    | p = < 0.01 |
| Case irrelevant conversation     | 58    | 11        | 2.15 | 57    | 9         | 2.19 | 115   | NS      |
| Technical                        |       |           |      |       |           |      |       |         |
| Total                            | 69    | 8         | 2.56 | 18    | 3         | 0.69 | 87    | p = < 0.01 |
| Equipment                        | 45    | 6         | 1.67 | 11    | 2         | 0.42 | 56    | p = < 0.01 |
| Instruments                      | 24    | 2         | 0.89 | 7     | 3         | 0.12 | 31    | p = < 0.01 |
| Social                           |       |           |      |       |           |      |       |         |
| Total                            | 43    | 9         | 1.59 | 27    | 8         | 1.04 | 70    | NS      |
| Communication                    | 34    | 7         | 1.26 | 22    | 7         | 0.85 | 56    | NS      |
| Teamwork                         | 9     | 2         | 0.33 | 5     | 1         | 0.19 | 14    | NS      |
| Organizational                   | 13    | 3         | 0.48 | 0     | 0         | 0.00 | 13    | p = < 0.01 |

MIS, minimally invasive surgery; CS, conventional surgery; Count; total count of all procedures, Max count; highest count reached during one procedure. Mean, per procedure (count divided by number of procedures) if there was no correlation between count and procedure time; *per minute if there was a correlation between count and procedure time (count divided by procedure time).
DISCUSSION

Differences in PS related events between conventional surgery and minimally invasive surgery can be explained by the use of advanced technology as an essential part of MIS. This is in line with the statement made by the Dutch Inspectorate of healthcare, that the (technical) complexity of MIS further increases risks in PS compared to CS. A previous study has already shown that a great amount of technical events tend to occur during laparoscopic procedures. In fact, in 87% (26 out of 30) of the observed laparoscopic procedures, one or more incidents with technical equipment (N = 46) or instruments (N = 9) occurred. Surgeons might be aware of the implications of new technology on PS. However, to our knowledge a detailed description of the consequences of technology on events that occur in the OR has never been made. Our data show that the majority of the organizational events (62%) were also technology related; more specifically, they were related to the preparation of the technological aspect of MIS (missing instruments or equipment). Altogether, it appears to be the advanced technology added to surgery that in particular hinders PS in MIS when this surgical approach is compared to the conventional approach.

Although general briefing checklists have been proven to reduce morbidity and mortality in surgery, the results of this study suggest that in MIS a different approach is required. The fact that a time out according to protocol is not correlated to a lower frequency of events leads us to speculate that a general briefing procedure such as the checklist of the WHO is insufficient for the preparation of MIS. Since the most important difference in events between MIS and CS is the frequency of technology related events, indicates that more attention is needed for technology during the briefing. An adequate solution which has already been proven to reduce the number of technical events in MIS, is the use of a standardized checklist especially designed for MIS. Such a checklist could be incorporated in the general WHO briefing in case of MIS.

This study reports an astonishing amount of environment events occurring around every 2 minutes in both MIS and CS. Consisting mostly of door movements (one very 2.5 min), with the potential risk of surgical site infections. High frequencies of door movements have been reported before, namely 13 till 316 times per surgery (5 to 87 per recorded hour). Similar to what we have seen in the present study, the observed door movements increased in direct proportion to the length of surgery and were also related to the number of persons in the OR. It is remarkable that the bulk of environment events are not observed to be disturbing or distracting to the senior surgeon, as 8.8% of all observed environment events combined are disturbing in MIS and 17.6% in CS. The
reason for this could be that experienced surgeons learned to block distracting events and remain concentrated\textsuperscript{17} combined with the fact that most environment events do not occur during critical moments. However the effect of environment events should not be underestimated. Especially the performance of inexperienced surgeons or residents could be influenced by distraction, as shown in a previous study\textsuperscript{18}.

Social factors such as communication and teamwork have been shown to be important risk factors in PS. In fact, optimizing teamwork in order to reduce error stands at the basis of a whole new era of research: Crew Resource Management. Communicational difficulties have previously been reported to occur in approximately 30\% of team exchanges.\textsuperscript{19} About a third of the communicational failures resulted in visible effects that can influence PS.\textsuperscript{20} In the current study however, the frequency of the observed social events is very low compared to those previous reports. The most obvious reason could be an underestimation of the true quantity of these events. The previously published studies only focused on communicational (or teamwork) events, reporting also small social mishaps, whereas this study also focused on technical, organizational and environmental events. The social events reported in this study must have been prominently present and therefore more prone to influence safety than small social mishaps, which might not have any influence at all. Furthermore, since observations of both MIS and CS were done by the same observer, a comparable (under)estimation is expected for both types of surgery and a relative comparison remains possible. Hence it can be stated that there is no difference in the amount of observed events of social nature between MIS and CS.

Another observational study investigated different types of surgical flow disruptions during cardiac surgery, showing that the greatest amount observed surgical flow disruptions were of social nature (52\%).\textsuperscript{21} This is in contrast to our observations in MIS, in which the highest percentage of events are disturbing environment events (44.7\%), followed by events of technical nature (30.5\%). Events of social nature accounted for only 19\% of the observed events. In CS the highest percentage of observed events were disturbing environment events (86.2\%) followed by events of social nature (8.3\%). Technical events during cardiac surgery accounted for 5.5\% of the events. Hence, the outcome is highly procedure dependent.

A pitfall of all observational studies is observational bias. It was attempted to reduce observational bias by selecting an independent researcher to perform the observations. Ideally more than one observer should have observed all procedures to test for inter rater agreement. However, this would crowd the operating room, as observations were done in academic hospital where also professionals in training (students, nurses, interns and
residents) attend surgical procedures, and that is not in the interest of PS. Furthermore, it is well recognized that the Hawthorne effect (the awareness of being observed alters the way a person behaves)\textsuperscript{22} takes place. Taking this in consideration, the most accurate method to perform observations of surgical procedures is probably with some sort of black box in which video and audio recordings are made. Than less influence of the Hawthorne effect and multiple independent observations would be possible.

**CONCLUSION**

A large number of events have been observed during both MIS and CS. The technological complexity inherent in MIS makes this type of surgery more prone to technology related events than CS, even in a specially designed minimally invasive surgical suite. A regular time out procedure as used for CS lacks the necessary attention for the complex technology which is used in MIS and is therefore insufficient for briefing MIS procedures. Incorporating a specially designed technology checklist in a regular briefing protocol could be a solution to decrease the number of events in MIS.

**ACKNOWLEDGMENTS**

The authors would like to thank D.D. Rodrigues for the technical support. They thank all gynaecologists, anaesthesia personnel and OR nurses who assisted during the observed procedures at the Leiden University Medical Center, for their input, cooperation and support during the observational period.
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