Surg Endosc (2007) 21: 275–279
DOI: 10.1007/s00464-006-0019-2

SURGICAL ENDOSCOPY
and Other Interventional Techniques

Problems with technical equipment during laparoscopic surgery

An observational study

E. G. G. Verdaasdonk,[1,2] L. P. S. Stassen,[1,2] M. van der Elst,[1] T. M. Karsten,[1] J. Dankelman[2]

[1] Department of Surgery, Reinier de Graaf Group, Delft, The Netherlands
[2] Man Machine Systems Group, Department of BioMechanical Engineering, Faculty of Mechanical, Maritime and Materials Engineering, Delft University of Technology, Mekelweg 2, 2628 CD Delft, The Netherlands

Received: 10 January 2006/Accepted: 25 May 2006/Online publication: 21 November 2006

Abstract
Background: This study was designed to investigate the incidence of technical equipment problems during laparoscopic procedures.
Methods: A video-capturing system was used, consisting of an analog video recorder with three camera image inputs and a microphone. Problems with all technical equipment used by the surgical team, such as the insufflator, diathermy apparatus, monitors, light source, camera and camera unit, endoscope, suction devices, and instruments, were registered.
Results: In total, 30 procedures were randomly videotaped. In 87% (26/30) of the procedures, one or more incidents with technical equipment (49 incidents) or instruments (9 incidents) occurred. In 22 of those incidents (45%) the technical equipment was not correctly positioned or not present at all; in the other 27 (55%), the equipment malfunctioned as a result of a faulty connection (9), a defect (5), or the wrong setting of the equipment (3). In 10 (20%) cases the exact cause of equipment malfunctioning was unclear.
Conclusions: The incidence of problems with laparoscopic technical equipment is high. To prevent such problems, improvement and standardization of equipment is needed, combined with the incorporation of checklist use before the start of a surgical procedure. Future research should be aimed at development, implementation, and evaluation of these measures into the operating room.

Key words: Surgical — Technical — Cholecystectomy — Laparoscopy — Adverse events — Technical equipment

Correspondence to: E. G. G. Verdaasdonk

The report "To Err is Human, Building a Safer Health System" emphasized the occurrence of errors in medicine [5]. It is estimated that each year at least 44,000 people die as a result of medical errors in the United States, but this number may be as high as 98,000. Thus, even when the lower estimate is used, more people die in one year as a result of a medical error than from motor vehicle accidents,

A common site for adverse events in the hospital is the operating room (OR) [6]. In the study by Leape [6], most of the adverse events were considered preventable. At present, it is unclear what kinds of problems or incidents occur in the OR and what their incidence and impact is. In the literature, several authors plea for a systems approach [1, 7, 13]. In a systems approach it is assumed that adverse effects due to human error will always occur, because to err is human. The causes and solutions should be searched for in the environment—the system. Reason [7] used the systems approach to study major adverse events (AE) and accidents such as the 1979 Three Mile Island nuclear incident. He concluded that seemingly unimportant incidents occur prior to major accidents or adverse events [7]. Prevention of future accidents starts with investigating the occurrence of these minor incidents in order to design adequate defenses. The "cheese model," after the theory postulated by Reason (Fig. 1), clarifies how these defenses in a system can influence the occurrence of adverse events. In complex environments such as the OR several defense mechanisms secure the safety of the patient. Examples include the design of equipment, experience of the personnel, and the use of certain protocols and OR etiquette. Weaknesses in these defenses clear the way for incidents (represented in the model as holes in the defenses). According to the model, because effective defenses exist on different levels, not all incidents in the OR lead to adverse events that endanger the patient's health. For this reason, most incidents seem to have no consequence at all, but if all occur at the

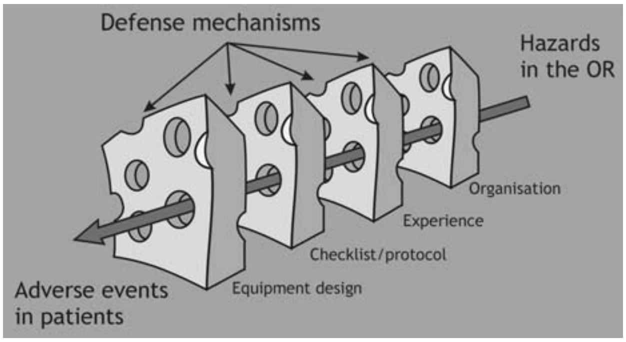

Fig. 1. Cheese slices represent defense mechanisms such as hospital organization, (team) experience, checklists/protocols, and equipment design. Holes represent incidents and are weaknesses in these defenses. In a complex environment (such as the OR) incidents may cause an accident trajectory (large arrow) and lead to adverse events.

same time or in sequence, the result can be an adverse event.

The introduction of sophisticated technical equipment in minimally invasive surgery (MIS) has made the surgical environment even more complex. New problems are created in the domain of man–machine interaction during high-tech procedures, thereby creating opportunities for errors or incidents to occur. The problems related to the skills of the surgeon were studied by Sarker et al. [9], but the problems related to mechanical instrumentation and technical equipment (the laparoscopic tower and the diathermy), have not been assessed before.

The aim of this observational study, therefore, was to investigate the incidence of technical equipment problems during laparoscopic cholecystectomies in order to develop adequate specific defense strategies. An incident was defined as a problem with the mechanical instruments, or with the positioning, presence, or malfunctioning of the technical equipment.

Methods and materials

To identify risks that might lead to breaches in the OR defense, a video-capturing system was used, consisting of an analog video recorder with three camera image inputs and a microphone. The image of the endoscope, an overview of the OR, and an image of the hands of the surgeon were automatically synchronized in one image and recorded. A microphone was placed on the surgeon's head. Between June 2004 and December 2004, laparoscopic cholecystectomies were recorded in the setting of a large non-university training hospital. The standard operating equipment consisted of a laparoscopic tower trolley and two Sony PVM-Trinitron Color Video Monitors. Several instruments are placed on the tower, including an insufflator, a xenon light source, a digital 3-chip camera and camera-unit. Separately, on another trolley, a diathermy apparatus was mounted. Each team consisted of a surgical trainee, a (supervising) surgeon, a scrub nurse, and a circulating nurse.

Videotapes were recorded as part of a larger project that aims at improving training of surgical residents in the performance of minimally invasive procedures.

A researcher was present during the recording of all procedures. Afterwards, the tapes were reviewed and analyzed by the first author (E. G. G.). Procedures converted to open or conventional cholecystectomies were analyzed up to the point of removal of the trocars. Problems with technical equipment, such as the insufflator, diathermy apparatus, monitors, light source, endoscope, or suction device were counted. These problems were divided into two categories: (1) positional (apparatus in the wrong position or not present at all) (2) functional (malfunction resulting from a wrong setting or connection or due to an unclear cause). Problems with instruments were also counted. Time to solve a problem was counted in seconds and calculated to minutes.

Results

A total of 30 laparoscopic cholecystectomies were recorded and analyzed. The participating surgeons included 7 different staff surgeons and 11 surgical trainees. In all 20 procedures (66%), a surgical trainee (resident) started the operation, supervised by one of the staff surgeons. A staff surgeon was present in the operating room during each procedure. In 9 of 20 (45%) procedures, started by a trainee, partial or total take over by the supervising surgeon occurred. In four procedures, the laparoscopic approach was converted to an open procedure. These conversions were not related to technical problems with equipment or instrumentation.

In the course of 26 procedures, one or more incidents with technical equipment or instruments were noted. Figure 2 shows the number of procedures by number of problems. A total of 58 incidents were recorded, ranging from 1 to 6 incidents per procedure. In 84% (49/58) there was a problem with the technical equipment only, and in 16% (9/58) a problem with the mechanical instruments occurred. Table 1 presents all incidents, and Figure 3 displays incident frequencies with the laparoscopic technical equipment only, subdivided by causes. In 45% of the cases (22/49), the laparoscopic equipment either was not present (6/49) or was not optimally positioned (16/49). In 55% (27/49) the laparoscopic equipment was malfunctioning. In 9 cases the malfunctioning was due to a faulty connection (twice the monitor, five times the diathermia apparatus, and twice the insufflator), and in 3 incidents (once the monitor, and twice the insufflator) the malfunction was due to an incorrect setting of the equipment. A defect caused a problem on 5 occasions (3 times of one of the monitors; once, of the diathermy cable; and once, of the endoscope). In all these incidents the technical equipment needed readjustments or direct replacement. In 10 cases (20%) the exact cause of equipment malfunctioning remained unclear. These incidents involved interference of diathermy with the image (four times), suboptimal image quality (five times) and inferior but acceptable light quality (once). In one occasion, the light quality was adjusted by the hospital technical service, after the procedure.

In 16% (9/58) of all incidents, there was a problem with the mechanical instruments. In one case, the laparoscopic retrieval bag for the gallbladder was not present, and 6 times a mechanical instrument was defective and had to be replaced.

With each incident, operation time was lost. Total operation time needed to solve the problems (of all the procedures together) was 110 minutes. The median time needed per incident was 1.5 minutes (range: 0.2–20.3 minutes). Figure 4 shows the total time lost per procedure. Most problems occurred during the initial phases of the procedure.

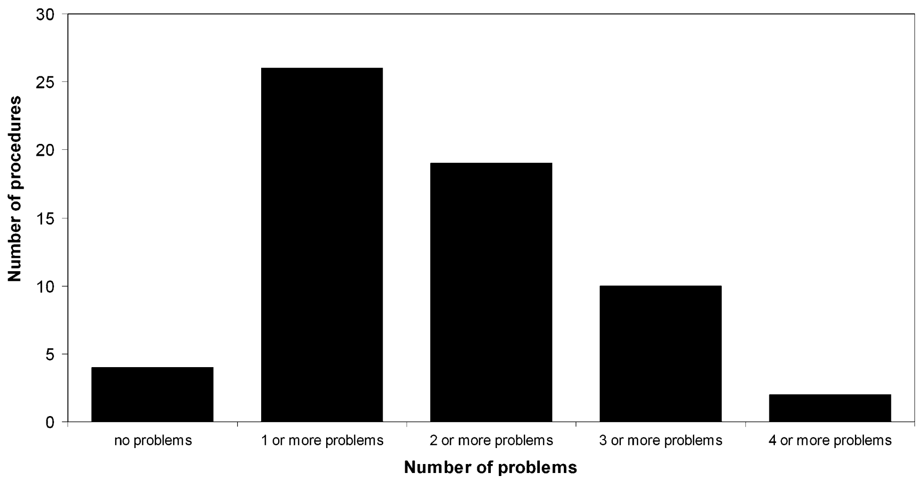

Fig. 2. Number of problems by number of procedures.

Table 1. Frequency of problems with technical equipment and mechanical instruments

	Positional problem		Malfunction and cause				
Type of equipment involved	Not present	Not position	Setting	Connection	Defect	Unclear	Subtotal
Image/monitor	6	7	1	2	3	5	24
Pedals		9					9
Endoscope					1		1
Light source						1	1
Diathermy				5	1	4	10
Insufflator			2	2			4
Instruments	1				6	2	9
Total	7	16	3	9	11	12	58

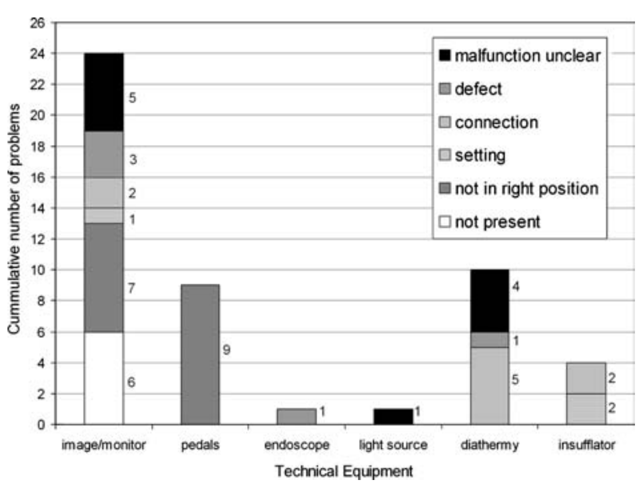

Fig. 3. Frequency of incidents with technical equipment only, subdivided by causes.

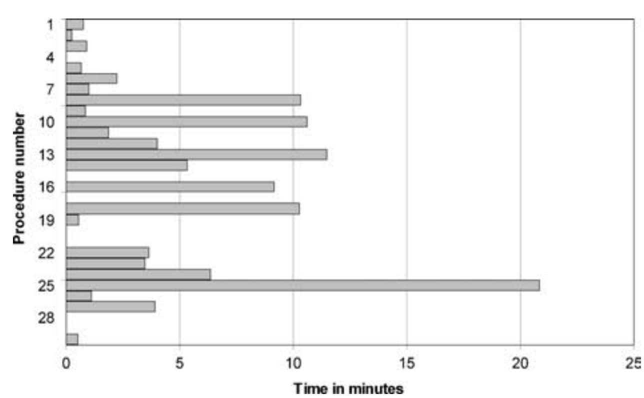

Fig. 4. Total time to solve incidents per procedure.

All of the observed problems caused no direct postoperative complications affecting the patients. All operation reports were reviewed, and none of the above-described incidents were noted in any of the reports.

Discussion

In 26 of 30 laparoscopic cholecystectomies analyzed, one or more incidents with technical equipment or instruments was documented. These incidents concerned mainly (84%) problems with the technical equipment only. In half of these cases the equipment was malfunctioning, and in 20% of those, the cause of the problem was unclear. In our observations the rate of incidents was high, and in some cases it took a lot of valuable operating time to solve the problem.

Surgical outcome is usually evaluated by the extent to which the pathologic condition has been treated and by morbidity and mortality. These outcome parameters can be affected by factors such as the working environment, the design and the use of technical equipment, communication, and team co-ordination [13]. Assessment of all these factors together is complex. Previously, other investigators have looked into surgical skill factors such as instrument and tissues handling. Such assessment proved feasible and showed a high number of errors, as well [4, 9, 11, 12]. The present study focused on another factor: problems with the use of technical equipment.

At present there are no data available in the literature on the exact incidence of problems with technical equipment. Therefore it is unclear if different hospitals share the same experiences, although when comparable instruments and equipment are used, similar problems can be expected. The laparoscopic cholecystectomy is a well-standardized procedure that is usually used as "educational" for trainees. Nevertheless, even in the presence of an experienced laparoscopic surgeon (supervisor), as was the case in our study, problems with equipment occur regularly. In more complex laparoscopic procedures, where more instruments and additional equipment are needed, the incident frequency could even be higher.

Incidents with positioning or just the absence (45%) of necessary equipment in the OR seems to be a problem of a lesser importance than equipment malfunctions. The most common problem relating to missing equipment concerns availability of the second monitor for the surgical assistant. Equipment positioning incidents also often concerned the monitors. In a cramped OR, proper placement of the screens requires thorough planning. In the present study some of the monitors were positioned on trolleys and some on booms. Whatever the mounting system, monitors are generally positioned before the surgeon starts to operate. According to hospital protocol, normally two monitors are used during a laparoscopic cholecystectomy. In our hospital all staff surgeons share the opinion that two monitors are mandatory, both for ergonomic reasons and for provision of the optimal view. Nevertheless, for logistical reasons, a second monitor was not always present, and repositioning of monitors that were present after the surgeon had started the procedure was also recorded as a procedural incident. It can be argued that repositioning a monitor during the procedure is not a problem. However, it takes time and draws attention away from the task at hand—operating on the patient.

Our thorough observations were documented with a specially developed video-capturing system that had been used in earlier studies [2]. Recently, other investigators have begun using video-capturing systems, consisting of multiple camera inputs and audio, mostly digital, to monitor performance during open or laparoscopic surgery. An example is the Clinical Data Recorder of Royal College of Surgeons in London (8 cameras and 4 microphones) [13]. Comparable systems are used in trauma resuscitation settings [3, 14]. Published reports show the potential of these systems to investigate surgical performance beyond the traditional clinical outcome. The results will be used to develop and apply strategies that will enhance efficiency and safety of the surgical procedures. In complex working environments, such as nuclear power plants and aviation, these strategies have been in place for some time, with a tremendous positive influence on safety and efficiency. For example, pilots are explicitly trained in using protocols and checklists in solving common problems encountered as they do their job. It is striking that a surgical procedure can be started without a structured check and clearance of all personnel that are actively part of the procedure.

It is of interest that none of the observed incidents of equipment malfunctioning were described in the operation reports. Therefore, the current reporting system cannot be used to analyze these problems. If an organization wants to learn from previous mistakes, another recording system is needed. Video monitoring is a good option, but there are some difficulties. Use of video monitoring as a "black box" inside the operation room is, unfortunately, limited, both because later analysis of its content is time-consuming and because it reveals weaknesses in the surgical system that may be of legal importance. Such issues will have to be resolved before the use of video recording can become common practice.

The problems with technical equipment analyzed in this article led us to question why such easy-to-prevent incidents happen at all. A possible conclusion might be that handling of complex technical equipment and solving problems associated with its use are not a part of the natural domain of doctors and healthcare workers. Classical education and training is focused on solving medical problems of patients asking for knowledge and strategies unrelated to solving problems with technical equipment that a surgeon might encounter during laparoscopic surgery. Nevertheless the potential risk of these seemingly unimportant incidents is illustrated by the theoretical model of Reason [7, 8], who contends that real adverse events are the end result of a spectrum of coinciding incidents (Fig. 1). According to Reason these incidents can be caused by active failures or latent conditions. Active failures are unsafe acts committed by people who are in direct contact with the patient or system. Latent conditions arise from decisions made by designers, builders, procedure writers, and top-level management.

A number of approaches can be put in place to prevent problems: (1) redesign of the equipment, (2) improvement of training/proficiency checks, (3) use of protocols and checklists.

The redesign of equipment and systems is expensive and a slow process. Nevertheless, there are already systems imbedded in new operating room design that might provide solutions for some of the problems found in this study. Unfortunately, not many hospitals have the financial resources for ORs of the future. Furthermore, increasing high-tech applications often creates new unforeseen problems.

Proper training to prevent incidents has great potential. However, training is difficult if there is no clear and generally accepted protocol of equipment handling. The advantage of implementing a training program is that it provides the opportunity to create a specific and standardized safety culture among OR personnel. Cultural change is important, because medical staff indicate that error reporting is important but that it is difficult to discuss and often not handled well [10]. It should be noted that training can be time consuming, and knowledge and skills fade over time. Recurrence training is therefore continuously needed.

The third approach, the use of checklists or protocols, can provide a quick and inexpensive solution for preventing small incidents. At present a specially developed checklist for OR set-up and equipment handling is being tested and evaluated in our institute. It is expected that the combination of a relatively short training period focussed on the consequent use of the equipment checklist will help to decrease the number of incidents.

Conclusions

The existence of equipment problems in the OR is known, but up to now has not been measured objectively. Observations from the present study revealed that the incidence of problems associated with equipment and instrumentation during laparoscopic cholecystectomy was strikingly high. To prevent these problems, improvement and standardization of equipment is needed, ideally in combination with use of short equipment checklist before the start of each surgical procedure. Future research should aim at development, implementation, and evaluation of these measures into the OR.

Acknowledgments. Financial support for this study was provided by a national healthcare insurance company in the Netherlands (DSW, Schiedam, The Netherlands).

References

1. Calland JF, Guerlain S, Adams RB, Tribble CG, Foley E, Chekan EG (2002) A systems approach to surgical safety. Surg Endosc 16: 1005–1014; discussion 1015
2. den Boer KT, de Wit LT, Davids PH, Dankelman J, Gouma DJ (2001) Analysis of the quality and efficiency in learning laparoscopic skills. Surg Endosc 15: 497–503
3. Guerlain S, Adams RB, Turrentine FB, Shin T, Guo H, Collins SR, Calland JF (2005) Assessing team performance in the operating room: development and use of a "black-box" recorder and other tools for the intraoperative environment. J Am Coll Surg 200: 29–37
4. Joice P, Hanna GB, Cuschieri A (1998) Errors enacted during endoscopic surgery—a human reliability analysis. Appl Ergon 29: 409–414
5. Kohn LT, Corrigan JM, Donaldsen MS (1999) To Err Is Human: Building a Safer Health System. National Academies Press, Washington, DC
6. Leape L (1994) The preventability of medical injury. In: Marilyn Sue Bogner (ed). Human Error in Medicine, Lawrence Erlbaum Associates, Hillsdale, NJ
7. Reason J (1990) Human Error. Cambridge University Press, New York
8. Reason J (2000) Human error: models and management. BMJ 320: 768–770
9. Sarker SK, Chang A, Vincent C, Darzi AW (2005) Technical skills errors in laparoscopic cholecystectomy by expert surgeons. Surg Endosc 19: 832–835
10. Sexton JB, Thomas EJ, Helmreich RL (2000) Error, stress, and teamwork in medicine and aviation: cross sectional surveys. BMJ 320: 745–749
11. Seymour NE, Gallagher AG, Roman SA, O'Brien MK, Andersen DK, Satava RM (2004) Analysis of errors in laparoscopic surgical procedures. Surg Endosc 18: 592–595
12. Tang B (2004) Analysis of technical surgical errors during initial experience of laparoscopic pyloromyoptomy by a group of Dutch pediatric surgeons. Surg Endosc 18: 1716–1720
13. Vincent C, Moorthy K, Sarker SK, Chang A, Darzi AW (2004) Systems approaches to surgical quality and safety: from concept to measurement. Ann Surg 239: 475–482
14. Xiao (2004) Introduction to the special issue on video–based research in high risk settings: methodology and experience. Cognition Technol Work 6: 127–130