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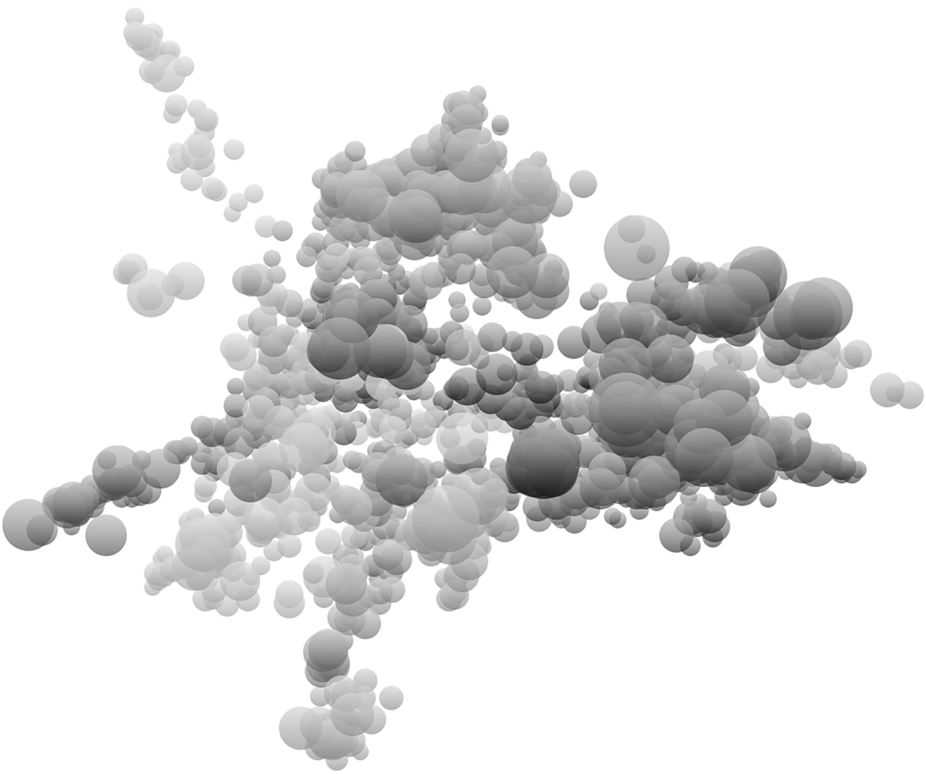
Title: Towards safety in minimally invasive surgery : patient safety, tissue handling and training aspects
Issue Date: 2014-12-17

CHAPTER 1

GENERAL INTRODUCTION



TO ERR IS HUMAN

Ever since the infamous 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 has become the focus of improvement in healthcare. The IOM report stated that an estimated 44000 to 98000 patients in the US die every year due to medical errors.[1] In April 2007 the results of a Dutch national study assessing the number of hospital adverse events in the Netherlands were presented. 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.[2] Subsequently in February 2009 the same research group published a study in the Dutch medical journal (NTvG), which showed that in the Netherlands 64% of all hospital related adverse events occur under the responsibility of the surgical specialisms. More than 40% of these adverse events could probably be prevented.[3] Furthermore, a systematic review[4] of eight studies including a total of 74,485 patients 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 related to surgery.

Following the before mentioned Dutch reports, a national safety program has started in the Netherlands in the beginning of 2008: *Voorkom schade, werk veilig*. This program's objective was to reduce the amount of potentially preventable damage due to healthcare by 50% in five years. The report that followed in the end of 2013: *Monitor Zorggerelateerde Schade 2011/2012, Dossieronderzoek in Nederlandse ziekenhuizen*[5] showed a reduction of potentially preventable damage of 30% and a reduction of potentially preventable death of 37% compared to 2004. Not only newly implemented safety programs but also the extensive (media) attention for the issue, lay at the base of this improvement. However, the amount of potentially preventable damage due to medical technology (0.7%) had not reduced compared to previous reports. Minimally invasive surgery, mainly laparoscopy, was still named as one of the most common causes of potentially preventable damage due to medical technology. In general when it comes to damage due to medical technology human factors played a main role.

Patient safety in minimally invasive surgery

The report by the Dutch inspectorate of health care *Risico's minimaal invasieve chirurgie onderschat*[6], published in 2007, directed attention in the Netherlands towards minimally invasive surgery (MIS), especially in advanced procedures. The report emphasized that in addition to the known patient safety risks in the operating room, the technological complexity of MIS increases risks in patient safety. It stated that specific measures are needed on hospital and national level in order to develop a formal quality system for laparoscopic procedures and thus enhance patient safety.

However, it is not clear what the requirements for such a formal quality system should be. A formal quality system should be verifiable in order to provide an objective form of quality control for hospital staff and government agencies. Therefore patient safety should be objectified. However *patient safety* is a complex, multidimensional concept and cannot be merged together in one measurable parameter. The WHO has long recognized the complexity of the concept patient safety. Since 2005 the WHO assigned a drafting group to develop an International Classification for Patient Safety (ICPS) to facilitate research and communication concerning patient safety. ICPS comprises ten high level classes which include around 600 concepts.[7] The WHO has also developed a patient safety research cycle to structure the research done on this topic. This research cycle describes five areas of patient safety research: (1) measuring harm, (2) understanding causes, (3) identifying solutions, (4) evaluating impact, and (5) translating evidence into safer care. This research cycle makes it possible to classify research. However, so far there is no large scale overview of available literature or different on going developments in patient safety literature available.

Current assessment of patient safety

Currently a comparison between hospitals is often made based on complication and mortality rates, usually normalized for the amount of performed procedures. This indicator can be used to set up a ranking, at which the lowest normalized complication rate represents the best patient safety. Based on these figures a department can benchmark their performance. However, these figures do not indicate which aspects of patient safety should be focused on for improvement. Furthermore, these figures are normalized for the number of performed procedures, but they do not take in account the severity of the procedure and patient characteristics that increase the complexity. Nor do they take in account the experience and skills of the surgical team.

Current patient safety research in surgery

In the operating theatre an area of patient safety research has been focusing on quantifying intra-operative interferences, i.e. surgical flow disruptions. Surgical flow disruptions have been defined as deviations from the natural progressions of an operation.[8] They have the potential to compromise patient safety during the surgery and could potentially lead to near misses.

For instance, Lynch et al[9], conducted an observational study of foot traffic in the OR, they recorded the nature of door movements by subspecialty, time of incision, reason and by personnel type. It was concluded that the rate of OR door movements was remarkably high regardless the surgical specialty. A total of 3071 door movements were recorded during 28 observed surgeries. The total number of door movements ranged from 13 to 316 per surgery (5 to 87 per recorded hour). Perioperative, surgical site infections (SSI) represent a major cause of morbidity and mortality. Frequent opening of the OR door is known to disrupt the airflow system and may compromise the sterile environment of the operating room. Lynch et al. showed that the number of door openings increased in direct proportion to the length of surgery, and that they have an exponential relationship to the number of persons in the OR. Besides their potential to compromise sterility in the OR, door openings and many persons in the OR can be distracting. Therefore, reducing door openings and the number of persons in the OR to an absolute minimum is a potential improvement in patient safety.

Wiegmann et al[8], studied surgical errors and their relationship to several surgical flow disruptions. They observed that disruptions in surgical flow due to problems in teamwork and communication accounted for the greatest percentage of these events (52%). Furthermore those problems are the only surgical flow disruptions with a significant relation to surgical errors. Other surgical flow disruptions they observed were external interruptions (17%), supervisory and training-related distractions (12%), equipment and technological problems (11%) and issues concerning resource access (8%).

Other research groups have also reported communication failures to be an important surgical flow disruptions related to surgical errors and adverse events.[8;10] In fact, communication failures have been reported to occur in approximately 30% of team exchanges. About a third of these communication failures resulted in visible effects that can influence patient safety. [11]

Verdaasdonk et al have studied technical problems, which are especially important in laparoscopy. They investigated the incidence of technical problems during laparoscopic procedures with a video-capturing system. In 87% (N = 26 out of 30) of the procedures, one or more incidents with technical equipment (N = 46) or instruments (N = 9) occurred.[12]

In summary, it appears that patient safety risk domains in the operating room (OR) can be divided into 5 main categories:

1. Social aspects (e.g. teamwork, communication) [13 14]
2. Technological aspects (e.g. instruments, equipment) [12]
3. External aspects (e.g. door movements, irrelevant conversations etc.) [9;15]
4. Functioning (e.g. skills, experience, knowledge) of the OR team members (e.g. surgeon, OR assistant, anaesthesiologist) [8]
5. Organizational aspects (schedules, workload, staffing etc.).

In an attempt to express patient safety in a single number the concept of the *APGAR score* has been used. The APGAR score is a technique to assess the condition of a newborn by the appraisal of five characteristics: respiration, muscle tonus, skin colour, hart rate and irritability. This simple technique was introduced to the world in the fifties by Virginia Apgar and is used at one and five minutes after birth to ensure consistent and systematic assessment of the newborn's condition. With this score a standardized cut off point for the initiation of resuscitation is provided. With the APGAR score Virginia Apgar captured a complex and elusive concept, e.g. the newborn's condition, and expressed it in a number, which could be evaluated and compared. Since the introduction of the APGAR score the quality of obstetrics all over the world changed and maternal and perinatal mortality drastically declined[16]. Atul Gawande and his research group have developed a Surgical Apgar Score (SAS) in which they try to capture the relationship between intraoperative care and surgical outcome[17-19]. SAS is also a ten point score in which a few patient characteristics are appraised. They conclude that the score can be effective in identifying patients at higher- and lower-than average likelihood of major complications. However, with this score they appraise intraoperative patient characteristics, which cannot be influenced or improved. Furthermore, this score focuses on only one patient safety risk domain, e.g. identifying high complication risk.

In the Netherlands research initiatives focusing on patient safety in surgery are rising. For instance a multidisciplinary checklist (SURPASS) is currently being implemented in several clinics in the Netherlands.[20;21] This checklist covers the entire surgical patient pathway of the general surgical patient. Other general checklists, used during a briefing procedure, have already shown to reduce adverse events and communication failures in the OR.[13;22] Technical checklists have shown to reduce the number of technical problems.[23] In literature debriefing has also been mentioned as a potential way to improve patient safety.

The aforementioned report by the Dutch inspectorate of health care *Risico's minimaal invasieve chirurgie onderschat*[6] emphasised that patient safety, especially in laparoscopic surgery, must be improved. Improvements should preferably be based on a systems approach rather than a person approach. However, evidence based research supporting requirements for patient safety improvement methods, is lacking and highly necessary. The current thesis explores aspects of patient safety in laparoscopic surgery based on the aforementioned main categories of risk domains. Since patient safety is such a comprehensive topic, this thesis shall focus on the basics of the main risk domains from a clinical point of view. The risk domains shall be examined in the operating room and an understanding of the impact of MIS on patient safety shall be obtained by comparing the different surgical techniques. However, the fourth risk domain (functioning of the OR team members, e.g. technical skills surgeon) is difficult to objectively assess in a clinical context. It has been shown that surgical skills in part can be objectively assessed in a non-clinical setting such as a skills laboratory. For example objective assessment of time to complete a task[24] and economy of movements[25] are have been shown to be valuable assets. These parameters however do not give sufficient insight one of the most important surgical skills when it comes to patient safety, namely tissue handling. Tissue handling is directly related to patient outcome measurements (e.g. blood loss, adverse events etc.). Therefore to examine the fourth risk domain the focus shall be on tissue handling in a non-clinical setting. Combining these patient safety aspects and risk domains, the main objectives of this thesis are:

- To analyse patient safety risk factors in minimally invasive surgery
- To determine differences in patient safety between minimally invasive surgery and conventional surgery.
- To find ways to train tissue handling skills in a non-clinical setting and thereby improve patient safety in minimally invasive surgery.

OUTLINE OF THE THESIS

The thesis is divided in two parts: part 1 explores patient safety in laparoscopic surgery and part 2 is devoted to the improvement of patient safety in laparoscopic surgery by examining training of tissue handling skills.

Part I Exploring Patient Safety

Patient safety is such a complex multifactorial concept about which has been widely published in recent years, that the amount of scientific literature available on this topic is overwhelming. This makes it difficult to have a good overview of the literature and to see the relations between the different developments that are going on. Therefore **chapter 2** focuses on obtaining a large scale overview of patient safety literature and developments in this topic by using a visualisation technique based on bibliometric data.

In recent years major changes occurred in the perception of patient safety. From a blame culture (the persons-approach) a switch has been made towards a systems-approach.[26] A number of important studies have suggested frameworks of factors that influence patient safety based on the systems-approach to quality and safety in surgery.[27-29] These frameworks were adapted for minimally invasive surgery (Figure 1). In **chapter 3** this framework is validated and the clinical relevance of different patient safety risk factors is examined. **Chapter 4** describes an observational study that measures what goes wrong in laparoscopic surgery based on the above-mentioned framework. The number of events in different risk domains were identified during laparoscopic surgery and compared to the number of events during general surgery.

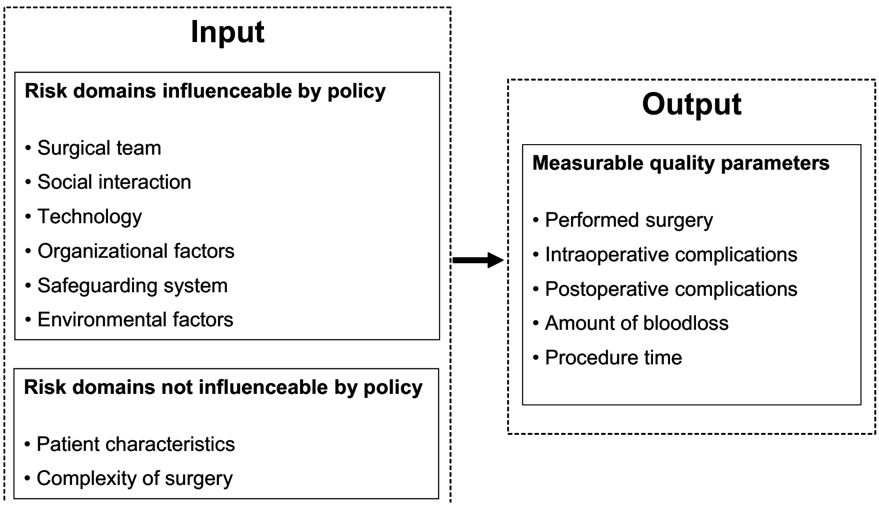


Figure 1. Framework of risk domains explaining patient safety in surgery according to a systems approach.

Part II Training tissue handling skills

The surgical skills of the surgeon, in particular tissue handling skills, are generally assessed as one of the most important and clinically relevant risk factors in surgery. In minimally invasive surgery additional obstacles have to be overcome compared to conventional surgery. Such as loss of depth perception and special orientation due to two dimensional (2-D) vision[30-32], perceived inversion of movement from the handle to the working end of the instrument "the fulcrum effect"[33-35], limited motion freedom and degrees of freedom (DOF's) due to the use of long rigid instruments[32;35] and loss of haptic feedback due to due to resistance inside the trocars[36] and the use of long laparoscopic instruments[37]. All these factors alter the laparoscopic surgeons' tissue handling abilities.

It has been well established that training of basic minimally invasive surgical skills should preferably be done in a non-clinical setting without exposing patients to risks.[38-40] Therefore part two of this thesis focuses on improving the surgeons' tissue handling skills in a laboratory setting.

To objectively assess tissue handling, interaction forces with tissue should be measured. Until now no objective measurement tools are (commercially) available. **Chapter 5** describes the development of a force measurement platform (Delft university of technology, Tim Horeman) that is able to measure these interaction forces and accompanying force parameters for the assessment of tissue handling skills. To assess the clinical impact of this newly developed force measurement platform, several studies were conducted in close collaboration with the Delft University of Technology. To get insight in the clinical relevance of the measured interaction forces an understanding of the amount of force needed to cause tissue damage is necessary. In **chapter 6** the force ranges causing tissue damage are determined in different tissue types. The clinical relevance of tissue handling in laparoscopic surgery is stressed in **chapter 7**, which describes the difference in applied forces during suturing in an open setting versus laparoscopic setting. This chapter examines intra-corporeal as well as extra-corporeal knot tying.

Using feedback on the used interaction forces during a training and the understanding of force limits that cause damage, a trainee can train him or herself on controlling the applied forces and thus tissue handling. In previous studies objective feedback on minimally invasive surgical skills (e.g. economy of movements) has successfully been used for assessment. This feedback is provided after completing a task, i.e. post processing. Providing feedback during the training of a task, i.e. real time feedback can provide the trainee the possibility to adjust their strategy immediately during the training, therefore making the training more efficient. **Chapter 8** describes the development and validation of an application that provides real time feedback on the applied forces during training. The most efficient training method, i.e. post processing versus real time feedback, is examined in **chapter 9**.

In addition to dealing with diminished haptic feedback laparoscopic surgeons have to interpret a 2D image and translate it into a 3D operating field. Dividing the obstacles that a starting trainee has to overcome in several stages might benefit the trainees' proficiency gain curve. **Chapter 10** explores the effect of training a task in two stages first in an open box trainer without camera, followed by a classical closed box trainer with camera. The proficiency gain curves of this experimental training are compared to the standard training method.

Chapter 11 provides the general discussion of the findings and future perspectives for research. Finally a summary of this thesis is given.

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