Aspects of teamwork and intraoperative factors in the operating room

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Cover illustration: The operating team

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-James Reason

To Margit

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ABSTRACT

The work in high-risk environments like an operating room is complex. The operating team consist of many professions with different tasks cooperating towards a common goal, the performance of safe surgery. The operating teams' technical and non-technical skills may affect the surgical outcome. The aim of this thesis was to explore some of the factors that may influence safe surgery.

Study I evaluated the operating team's perceptions of an implemented intraoperative pause routine. The operating team felt positive about the implementation, many perceived that communication and teamwork was enhanced and some of the surgeons stated that a pause made them feel refreshed and sometimes contributed to changes of surgical strategy.

Study II was an interventional study to evaluate teamwork and safety climate in the operating room after an intervention with education on safety climate and teamwork, and the introduction of a revised WHO Surgical Safety Checklist. We found deficiencies in communication and teamwork in the operating team. The intervention did not change teamwork or safety climate.

Study III evaluated surgeons' self-assessed satisfaction with the performance of prostatectomies in a large clinical trial. There was a strong correlation between surgeons' satisfaction and intraoperative difficulties or complications, which became stronger with every additional difficulty or complication.

Study IV was a randomized controlled trial to assess if surgeons' stress levels were affected by an intraoperative pause during simulated operations. There were no significant differences in stress levels but the surgeons' perception of the intraoperative pause was positive.

In conclusion, to study non-technical skills in the operating team is complex as surgical outcome and patient safety are multi-factorial. Many among the operating team members believed that improved teamwork and communication could benefit patient safety. Thus, one way to enhance patient safety could be to introduce intraoperative pauses as they were perceived to be beneficial for teamwork and communication.

Keywords: operating room, non-technical skills, teamwork, intraoperative stress

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SAMMANFATTNING PÅ SVENSKA

Bakgrund

Arbetet inom högriskorganisationer som operationssalen är komplext. Operationsteamet är ett dynamiskt team där olika professioner, med olika utbildning och olika arbetsuppgifter arbetar tillsammans mot ett gemensamt slutmål, utförandet av säker kirurgi. Då flera olika professioner arbetar tillsammans är det viktigt att teamarbetet har en tydlig struktur och att man inom teamet har respekt för varandras professioner. Operationsteamets såväl tekniska som icke-tekniska färdigheter (kommunikation, teamarbete, ledarskap, situationsmedvetenhet, beslutsfattande, hantering av stress respektive trötthet) kan påverka det kirurgiska resultatet och på så sätt även patientsäkerheten.

Syfte

Ett övergripande syfte med avhandlingen var att studera vissa icke-tekniska färdigheter och andra faktorer i operationssalen som kan påverka patientsäkerhet i samband med kirurgi.

Studie I utfördes med syftet att utvärdera operationsteamets erfarenheter av implementeringen av en pausrutin under långa operationer. Pausrutinen innebar att kirurgen efter två timmars operation skulle bli påmind om att ta en paus, dricka ett glas saft och röra på axlarna. Efter fyra timmars operation skulle kirurgen uppmuntras att ta ett kortare måltidsuppehåll. Därefter ta en saftpaus varannan timme. Utvärderingen skedde med hjälp av frågeformulär till kirurger, operationssjuksköterskor, anestesisjuksköterskor och undersköterskor. Många i operationsteamet upplevde att teamarbetet och patientsäkerheten förbättrades i och med implementering av pausrutinen. Många kirurger angav att de efter paus ibland fått en annan syn på anatomin och det hände att de efter paus ändrat operationsstrategi.

Studie II var en interventionell studie med syftet att på en operationsavdelning utvärdera en intervention som innebar utbildning i säkerhetsklimat och icke-tekniska färdigheter samt en förändring i användandet av WHO checklista för säker kirurgi. Studiepersoner var kirurger, operationssjuksköterskor, anestesisjuksköterskor, anestesiologer och undersköterskor som jobbar i operationsteam. Fokusgrupper utfördes vilka efter analys visade att operationsteamet var positiva till förslaget att lägga till en punkt i checklistan med ”operationsbeskrivning av kirurg”. Observationer under operationer angående utförandet av checklistan visade att det fans brister i följsamheten både före och

efter interventionen. Säkerhetsklimat, teamarbete och kommunikation mättes före och efter interventionen med frågeformuläret ”the Safety Attitude Questionnaire”. Resultatet visade inte på någon förändring från före till efter interventionen. De flesta personalkategorier angav att teamarbete och WHO checklista är viktigt för patientsäkerheten men upplevde samtidigt att kommunikation inom den egna professionen fungerade bäst.

Studie III hade syftet att undersöka om kirurgers nöjdhet med en operation var relaterad till svårigheter och komplikationer som inträffade under operationen. Uppgifter om händelser under operationen bokfördes av kirurgen i anslutning till respektive operation, liksom kirurgens upplevelse av nöjdhet med utförandet av ingreppet. Detta var en del av datainsamlingen i LAPPRO-studien, som jämförde utfall mellan öppen operation för borttagande av prostata med robot-assisterad titthålskirurgi. Studiepersoner var urologer som opererat i LAPPRO-studien. Vi fann ett starkt samband mellan kirurgens nöjdhet med en operation och förekomst av svårigheter och komplikationer under operationen. Sambandet blev starkare för varje ytterligare negativ händelse. Vi fann inget samband mellan operationsmetod och kirurgens nöjdhet.

Studie IV var en randomiserad kontrollerad studie som utfördes med syftet att jämföra kirurgers stressnivåer vid simulerade operationer med titthålskirurgi där man som kirurg antingen blev lottad till att ta en paus med saft under operationen eller att inte ta någon paus. Studiepersoner var ST-läkare inom kirurgi eller kirurger med högst fem års erfarenhet som specialistläkare. Studiepersoner opererade vid två tillfällen och blev vid varje simulering lottad till att ta en paus eller inte. Stress mättes genom kortisol i saliv, hjärtfrekvens och självuppskattad stress. Frågeformulär delades ut innan och efter simuleringarna, där fanns bland annat frågor om kirurgens upplevelse av en paus. Vi fann ingen statistiskt signifikant skillnad i kortisol i saliv mellan simulering med en paus eller utan paus. Vi fann inte heller någon skillnad i hjärtfrekvens eller i självuppskattad stress. Däremot var kirurgernas upplevelse av att ta en paus positiv.

Slutsats

Att studera icke-tekniska färdigheter hos operationsteamet är komplext då utfall efter kirurgi och patientsäkerhet i samband med kirurgi är multifaktoriellt. Operationsteamet angav att teamarbete och kommunikation var viktiga faktorer för ökad patientsäkerhet på operationssalen, samtidigt som de angav att den införda pausrutinen medförde bättre kommunikation, teamarbete och patientsäkerhet. Ett sätt att förbättra teamarbete och kommunikation inom operationsteamet och på så sätt även öka patientsäkerheten kan därför vara att ta regelbundna pauser under operationer.

LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals (I-IV).

I. **The surgical teams' perception of the effects of a routine intraoperative pause.**
Erestam S, Angenete E, Derwinger K.
World J Surg. 2016 Dec;40(12):2875-2880.

II. **Changes in safety climate and teamwork in the operating room after implementation of a revised WHO checklist: a prospective interventional study.**
Erestam S, Haglind E, Bock D, Erichsen Andersson A, Angenete E.
Patient Saf Surg. 2017 Jan 31;11:4.

III. **Associations between intraoperative factors and surgeons' self-assessed operative satisfaction**
Erestam S, Bock D, Erichsen Andersson A, Bjartell A, Carlsson S, Stinesen Kollberg K, Sjoberg D, Steineck G, Stranne J, Thorsteinsdoottir T, Tyritzis S, Wallerstedt Lantz A, Wiklund P, Angenete E, Haglind E.
Surg Endosc. 2019 Mar 18. doi: 10.1007/s00464-019-06731-z.

IV. **Stress assessment among surgeons during simulated operations with or without an intraoperative pause – a randomized controlled trial**
Erestam S, Bock, D, Erichsen Andersson A, Haglind E, Park J, Angenete E.
Submitted manuscript

CONTENTS

ABBREVATIONS

ASA	American Society of Anaesthesiologists
BMI	Body Mass Index
CI	Confidence Interval
LAPPRO	LAParoscopic Prostatectomy Robot Open
nmol	nanomole
ml	millilitre
OR	Odds Ratio
SBAR	Situation Background Assessment Recommendation
WHO	World Health Organization

1 INTRODUCTION

1.1 SURGERY

The number of major surgical procedures performed each year over the world have been estimated to approximately 234 million, which implies that one out of 25 persons each year are going through a major surgical procedure[1]. In Sweden, 410 000 operations are performed on admitted patients and about 1.2 million surgical procedures on outpatients[2].

A patient undergoing surgery is dependent on the operating team's ability to perform safe surgery and maintain high patient safety in the operating room. The responsibility for maintaining safety is shared between different professions, the management and organization[3]. In Sweden, physicians and nurses are legally obliged to strive for high patient safety[3 4]. In addition they have their core competencies as a guidance in providing safe care[5 6]. The 'Safe care' competency defines patient safety as an ongoing process, always changing and needing to be re-assessed over and over again: at the beginning of every new shift or with every decision being made, at every level in the organization[6].

'Safe surgery saves lives', is a declaration by the World Health Organization (WHO) that seems obvious, but in reality, safe surgery is complex as the work inside the operating room is multifaceted. With many different professionals working side by side in a high-tech environment, patient safety becomes complex. This thesis will explore some of the different pieces of the big puzzle that together forms the picture of safe surgery.

1.2 INTRAOPERATIVE FACTORS INFLUENCING SAFE SURGERY

The World Health Organization (WHO) defines patient safety as: 'the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum'[7].

Patient safety in relation to surgery can be defined as the absence of postoperative morbidity and mortality. Morbidity and mortality are two outcome measures sometimes used as surrogates for lack of patient safety[8-11].

In the operating room work is complex and covers more than the surgical procedure alone[12]. The work culture, the organization and the safety climate

among front-line workers are some factors that can influence safe surgery[13-15]. Others are surgical performance, technical and non-technical skills, patient specific factors and comorbidities and intraoperative care[16-24].

In this thesis the following aspects of safe surgery will be considered:

- intraoperative adverse events
- safety culture and climate
- the role of the operating team
- the WHO surgical safety checklist
- intraoperative communication and team work
- management of intraoperative stress and fatigue
- surgeons' perception of their technical performance in relation to intraoperative difficulties and complications

1.2.1 ADVERSE EVENTS

There are several definitions of an adverse event, a summary of them could be the following: an adverse event is a medical injury or complication that occurs during health care and causes prolonged hospital stay, morbidity, or mortality[25-27]. Almost 50% of all adverse events in health care in industrialized countries are related to surgical care, and half of those are considered preventable[28]. With this in mind reduction of adverse events in surgical care is important.

The reporting of adverse events related to surgery in Sweden today is increasing. Some of the reasons may be an ageing population, and more advanced surgical procedures[29]. In a study on patients going through abdominal surgery under general anesthesia, it was reported that the patients undergoing complex surgical procedures are more likely to suffer intraoperative adverse events[19]. Many of the participants in the studies of this thesis work in operating teams performing advanced surgery, such as procedures for advanced colorectal cancer, colorectal disease, and radical prostatectomies due to prostate cancer[30-33].

The root causes of adverse events are often derived from several interacting factors and can be categorized as: human errors, patient-related factors, organizational factors, and technical factors[34]. Many adverse events can be avoided with the right prerequisites present[25 35]. Adverse events from surgical care often stem from deficiencies in communication, teamwork and the organization[35]. Strategies recommended to prevent adverse events are evaluation of safety behavior, using safety checklists, team training, and quality assurance by incident reporting[8 34 36-38].

1.2.2 SAFETY CULTURE & SAFETY CLIMATE

Within high-risk environments, there are different views on how to define the two concepts safety culture and safety climate. Occasionally both are described as the same, and are then usually named safety culture[39]. In this thesis, the two concepts are defined and described separately.

Safety culture within an organization is here described as a broad term that is complex and mirrors the organizations fundamental values and beliefs, expressed as basic assumptions. It reflects the way an organization works towards high patient safety standards. Positive safety culture within an organization depends on the degree to which the organization prioritizes and supports safety improvements[39 40].

Safety climate describes the individual employee's perceptions and attitudes towards risks and safety, and can be measured by questionnaires that gives us an estimation of the current state of safety climate[39 40]. It can be beneficial to use questionnaires measuring safety climate to assess the function of various implemented safety strategies[40-44].

The topic safety within high-risk organizations has its root in the airline industry[45] although the first high-risk organization that was described to have 'poor safety culture' was the Chernobyl nuclear plant, after the tragedy in 1986[39].

Safety management in the health care sector is a more recent discussion, which has been inspired by work done in other sectors. The airline industry Crew Resource Management tool is a good example of a tool that is often used to educate teams in communication and teamwork[38 46 47]. Another concept transferred from the airline industry are human factors engineering[48].

The study of human factors (i.e. ergonomics) is a scientific discipline that are defined as; 'the understanding of the interactions among humans and other elements of a system, and the profession that applies theoretical principles, data and methods to design in order to optimize human well-being and overall system performance'[48]. The adoption of the human factors approach recognizes the complexity of safety within health care.

Through the years, there has been different views on how to handle safety issues within high-risk organizations; a shift has been made from the person approach focusing on the errors of frontline personnel associated with naming, blaming, and shaming[49] to a system approach focusing on pre-existing organizational factors that contribute to accidents[50]. From the system perspective the term patient safety concerns conditions within the system that arises through

interactions inside the system[51]. Patient safety becomes the result of interactions between materials, components and processes that take place within the system. Therefore, patient safety is complex, with many barriers[51]. In Sweden, the introduction of the patient safety law implied a transition from the person approach to an approach with a system-oriented perspective[52]. In the system approach people are expected to make errors, and those errors are seen as consequences of the system[49]. When things go wrong the important issue is to understand how and why it happened, not because of whom[49]. As stated by James Reason "We cannot change the human condition, but we can change the conditions under which humans work"[49].

Safety within an organization has also been described with the expression 'resilience', where safety within organizations is dependent of the flexibility and capacity to transform together with changes within the dynamic system and the world[53]. Safety is the ability to adjust to the current conditions, both within the organization and among individuals within the organization. To be able to do so the organization has to be one-step ahead with continuous risk-analysis[53].

Many have used the illustration of the Swiss cheese model of accident causation where every layer has its own role in preventing accidents[49]. Some of the holes in the cheese are caused by the actions of front-line personnel and others by conditions within the system[51]. The different layers within surgical care could also represent political decisions, hospital management, department management, and front-line personal at the operating ward, who are the last layer of protection from failure or error (Figure 1).

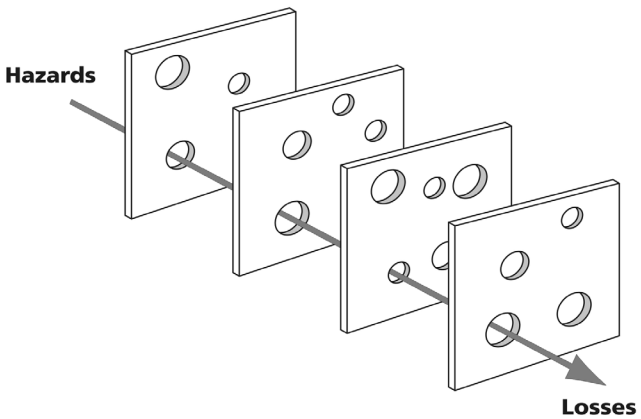

Figure 1. The Swiss cheese model of accident causation. By James T. Reason(1997).With license from: https://creativecommons.org/licenses/by-sa/3.0/legalcode

In this thesis, the different layers of the Swiss cheese will also demonstrate different aspects of safety where each study included in the thesis adds different layers to enhance patient safety, such as managing intraoperative stress, enhancing teamwork, and use of the World Health Organization (WHO) Surgical Safety Checklist.

1.2.3 THE OPERATING TEAM

The operating team is a multi-professional team consisting of many different professions[54]. The professions included in the team may vary depending on country, operating ward and surgical specialty. The operating team included in the studies in this thesis consisted of the following professions: anesthesiologist, nurse anesthetist, nurse assistant, scrub nurse, and surgeon.

Awareness of team dynamics inside the operating room requires a knowledge and recognition of the different roles of the team members. The roles will be described from a Swedish context where the anesthesiologist is the physician who is responsible for providing anesthesia care. Anesthesiology is characterized by an intra-professional approach[54] where the anesthesiologist work closely together with the nurse anesthetist. Often the anesthesiologist is responsible for several patients at the same time and he/she is therefore not present in the operating room during the entire operation. The nurse anesthetist induces, maintains and terminates the general anesthesia with some support of the anesthesiologist, works with the patient throughout the procedure and monitor the patient closely[55].

As physicians the anesthesiologist and the surgeon are required to possess leadership skills, characterized by collaboration, openness and dialogue with the other team members[56]. The surgeon is the physician responsible for the performance of the surgical procedure[54] and has to be able to work in a multi-professional team as well as knowing surgical pathophysiology, surgical technique, and have some knowledge about effects of anesthesia[56].

The role of the scrub nurse has changed over time and differs between countries and operating wards[57]. In a Swedish setting, the scrub nurse should aim for high patient safety by preventing adverse events, ensure asepsis, control and manage of biological specimens, and ensure that surgical instruments and towels are not left in the body[58]. In addition, the scrub nurse is responsible for instrumentation and also, together with the nurse anesthetist, of the nursing care during surgery[55 58 59]. The nurse assistant is an unregistered nurse who assists both the scrubbed team and the anesthetic team in the operating room.

Although the surgeon is medically responsible for the patient during surgery the leadership within the operating room has been described to be distributed over the different professions[60 61], where in a Swedish context it has been reported that the surgeon conducted most of the leadership followed by the scrub nurse and nurse anesthetist[61]. Common for all participants of the operating team is the core competencies for health care professions, which include; patient-centered care, teamwork and collaboration, evidence-based practice, quality improvement, safety, and informatics[59 62]. Although the core competencies are the same, the specific content in each of them differs between the professions.

Sub-teams within the operating team

Even if everyone in the operating team has the same main goal, the team consists of various sub-teams[63] with their own specific sub-culture, tasks and goals during an operation.

- The nurse-team involves the nurse anesthetist, the scrub nurse, and the nurse assistant. In a Swedish setting, the nurses work together in the operating room with surgical preparations, like the positioning of the patient. Inside this team another sub-team, the specialist nurse-team consisting of the anesthetic nurse and the scrub nurse. These two professions are responsible for the intraoperative care of the patient[55 58].

- The physician-team consists of the surgeon and the anesthesiologist. Both professions have a medical education with an MD degree, but the training leading to specialist degrees differs[56].

- The anesthetic team is made up of the anesthesiologist and the anesthetic nurse. They cooperate regarding the anesthesia, intravenous fluid therapy, and pain treatment of the patient undergoing surgery.

- The scrubbed team includes the surgeons and the scrub nurse. They are scrubbed in and work in the sterile field. They are operating, assisting and instrumenting. The surgeon is responsible for the surgical operation and performs the surgery and assists. The scrub nurse is in charge of the perioperative care, including infection prevention, instrumentation and assisting the surgeon.

1.2.4 NON-TECHICHAL SKILLS

In the 1970s the aspects of human factors on accidents in the aircraft industry were discussed. These accidents were what generated the interest in the non-technical skills that have been defined as 'the cognitive, social and personal resource skills that complement technical skills, and contribute to safe and efficient task performance'[64]. These skills are important in high-risk organizations, and are often divided into the following seven skills: communication, teamwork, leadership, situation awareness, decision-making, managing stress, and coping with fatigue[64].

Associations between surgical team behavior and surgical outcome has been found where high-quality non-technical skills improves the outcome for the patient[16] [17] [65]. There are also correlations between non-technical skills and technical skills among teams and individuals in the operating team[66].

Non-technical skills further discussed in this thesis are communication, teamwork, and managing stress and fatigue.

Communication & Teamwork

To communicate means to share[67] and can be divided into 'what information', 'how, the means to communicate', 'why, the reason', and 'to whom' [64]. One-way communication entails a sender of information and a receiver of information. This is an easy and rapid way of communicating but lacks the feedback from the receiver. Two-way communication has the advantages of confirmation through receiver response where the opportunity to form a closed loop exists. In closed loop communication, the receiver has the role of confirming that the information sent by the sender is understood[64] (Figure 2).

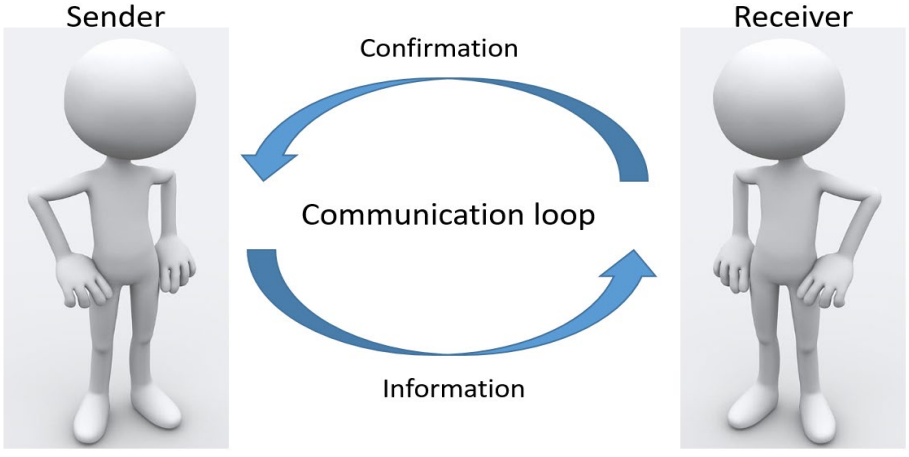

Figure 2. Communication loop

Inside the operating room, communication has been shown to be essential for teamwork and patient safety[8 38 66 68 69]. Of all communication during surgery, one-third has been described as communication failures, which could be categorized into 'occasion' with poor timing, 'content' with incorrect information, 'purpose' without a solution, and 'audience' where key persons were excluded[70]. Many of these communication failures led to visible effects like inefficiency, team tension, resource waste, workaround, delay, patient inconvenience, and procedural error.

Since communication is an essential part of teamwork, the two are often discussed together. To enable high quality teamwork and good communication different tools have been constructed. The already mentioned Crew Resource Management tool is one good example that has been reported to increase the quality of teamwork and communication within the operating room[38]. Another is the WHO surgical safety checklist and the communication tool Situation, Background, Assessment, Recommendation (SBAR)[8 71] all frequently used within surgical care.

Teamwork has been described as 'social entities composed of members with high task interdependency and shared and valued common goals', who need to integrate, share information, coordinate and cooperate to accomplish their work[72]. Teamwork is one of the core competencies for health care professionals[5]. Teams exists in many contexts and have different prerequisites for performing high quality teamwork (Figure 3). The complexity of the multi-professional operating team and its many sub-teams has already been mentioned. One aspect of the complexity that has been reported is that there seems to be diverse perceptions of teamwork and communication between the different professions in the operating team[63 73-75].

Figure 3. Teams in different contexts

Deficiencies in non-technical skills such as teamwork and communication can lead to increased morbidity and mortality for the patient[8 41].

Although there are many sub-teams within the surgical team, it is important that everyone has a shared mental model, without which teamwork may be threatened[54]. Shared mental models has been described as 'socially constructed

cognitive structures that represent shared knowledge or beliefs about an environment and its expected behavior'[76]. In the operating room where the team members may shift from day to day, it can be challenging to create a high functioning team with a shared mental model[54].

Managing Stress & Fatigue

Stress can be both acute and chronic, and part of this thesis will focus on the effects of acute stress and possible ways of preventing it. Stress has been defined as 'a particular relationship between the person and the environment that is appraised by the persons taxing or exceeding his or her resources and endangering his or her well-being'[77].

Stress can have both positive and negative effects on performance[78]. The positive aspects, alertness and enhanced focus, are related to the fight-or-flight response[79 80]. Stress in this context can be defined as 'a constellation of events, consisting of a stimulus (stressor), that leads to a reaction in the brain (stress perception), that activates physiological fight or flight systems in the body (stress response)'[81]. Stressors, personal resources and mediating factors (personality, fitness, coping strategies and social support) have been described to affect how an individual responds to stress[64 82].

As mentioned earlier the health care sector has many times been influenced by the military and airline industry when it comes to safety issues. The prerequisites for the military, pilots, and the operating team varies where the military and pilot are risking their own lives while the operating team's safety concerns the patient. But even so there are lessons that can be learned from work cultures with a longer tradition of managing stress and safety issues in a structured way. In the military training, management of stress is an essential part, where training under stress is an important component in developing behavioral and cognitive skills to facilitate performance under stress[83]. This is somewhat different from the surgical scene although it has been implied that acute stress may affect the intraoperative teamwork, surgical performance, and patient safety negatively, as team members under acute stress are more prone to focus on their own tasks instead of working effectively as a team[84-88].

Stress can also contribute to increased fatigue, which in turn can have negative consequences on cognitive performance, motor skills, communication and social skills, all of which may be important for the operating surgeon[78 89-92].

Stress among the professions of the operating team is experienced in different ways, where some events are reported to be more stressful than others. Circulating nurses (nurse assistants in the studies included in this thesis) have described

teamwork performance as particularly stressful, while scrub nurses perceived that certain surgical specialties, patient Body Mass Index (BMI), blood loss and American Society of Anaesthesiologists (ASA) physical status class related to intraoperative stress[93]. Anaesthesiologists reported that friction in the operating teamwork contributed strongly to stress[94], while surgeons described surgical complications, complex procedures, team factors, time and management, distractions, lack of experience, equipment problems and personal problems to be stressful in the operating room[84 95]. Surgeons have also reported that stress sometimes affects other surgeons but seldom themselves[45 84]. An operating team where team members support and understand each other are positive for stress handling. It has been reported that individuals, who feel the support from other team members, and who have a shared mental model, and who have handled stressful events together in the past, are better equipped to cope with stress in the future[64 96].

It is important to avoid fatigue and reduce negative intraoperative stress among the operating team members. Mental practice before performing simulated operations have been reported to be one way of reducing stress among novice surgeons[97]. Another way of reducing stress may be by regular work breaks for everyone in the team. Structured work breaks among the professionals in the operating team may vary dependent on country, hospital, operating ward, and type of operations performed. In some settings, surgeons are performing long surgical procedures without pauses. It has been suggested that regular intraoperative pauses may be beneficial for the surgeon and the patient, and some studies support this[98 99]. Since intake of sugar has been reported to increase performance, reduce cortisol, and enhance self-reported energy during physical activity[100-102], a beneficial addition to intraoperative pauses may be sugar intake for the surgeon and the operating team.

1.2.5 WHO SURGICAL SAFETY CHECKLIST

One initiative taken to make surgery safer around the world was the construction of the WHO Surgical Safety Checklist. At the time of the development of the checklist, there were few medical checklists to be inspired by, hence the model was taken from the aviation industry[103]. The checklist was constructed to be used in most surgical settings around the world and is intended to reduce unnecessary surgical morbidity and mortality[8 103 104] by focusing on the improvement of three common and preventable safety issues during surgery: inadequate anesthesia, poor communication within the team, and surgical infection[8 104].

The checklist is divided into three phases that follow the normal flow of an operation; 'Sign in', before induction of anesthesia, 'Time out' before incision, and 'Sign out' before the patient leaves the operating room (Figure 4)[8 104].

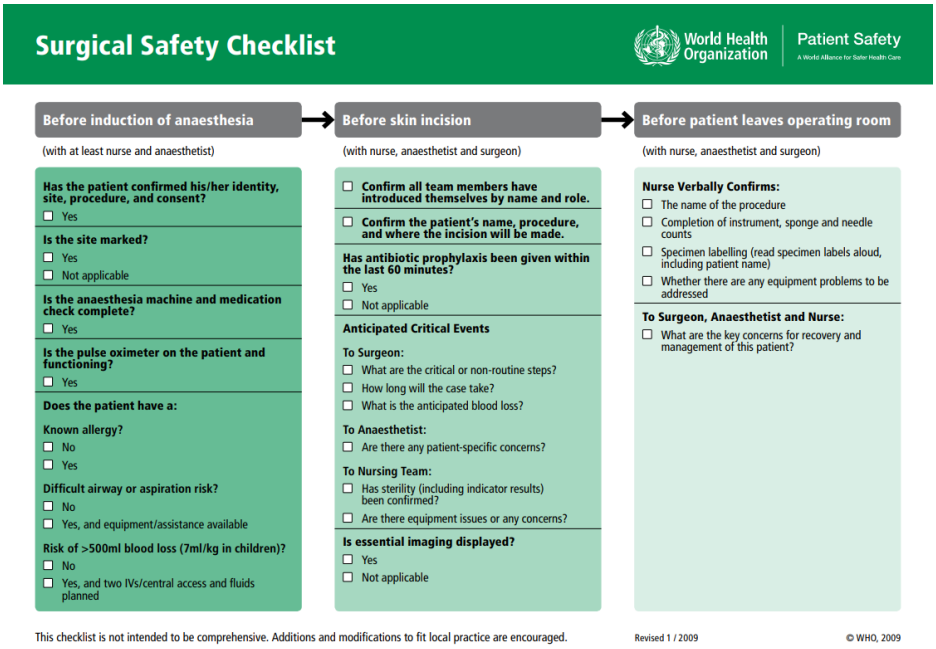

Figure 4. The WHO Surgical Safety Checklist

In 2009 the results after the implementation of the Surgical Safety Checklist at eight different hospitals and countries was published[8]. The results were impressive and showed a significant decrease in both morbidity and mortality. The rate for surgical site infections and reoperations also decreased[8]. An evaluation of the safety climate reported that there was a significant increase in participants' safety attitudes post implementation, and 93.4% stated that they would want the checklist to be used, if they were having surgery themselves[41]. A conclusion was that the changes seen in the safety climate could be a part of the effect the checklist.

The WHO states that the implementation of the checklist is very important for the outcome[105] and has encouraged local modifications of the checklist to fit different settings. When changing the checklist, essential safety items should not be removed, but new items considered important for patient safety can be added[103]. Since the first implementation, the checklist has been implemented in many countries and hospitals. The effect of the implementation has varied, and there seems to be great variation in how the checklist is performed[106]. Some of the outcomes reported by the use of the checklist are: decreased mortality rate[8-10 107], and decreased postoperative complication rate[8 9 108], among those a decreased rate of postoperative infections[8 108] and re-operations[8 109], and shorter length of

hospital stay[110]. A meta-analysis of seven studies using the Surgical Safety Checklist (one study used a modified version of the checklist) indicated that the implementation of the checklist had led to a reduction in complications, wound infections and blood loss, although they did not find a significant reduction in mortality or re-operations[111]. Another meta-analysis showed reductions in both morbidity and mortality[11], and other studies have not been able to demonstrate a reduction in morbidity[112] or mortality[113].

Since there seems to be a variation of the effects of the use of the checklist, compliance to the checklist have been studied, which have indicated that there is often a lack in the adherence to the checklist where most times the checklist is initiated but not completed[114-116]. The lack of compliance to the checklist has been described as leading to a false sense of security[114 115], and one study demonstrated a correlation between checklist compliance and postoperative mortality rate, where mortality rate was significantly decreased when the compliance was high[117].

Barriers to effective use of the Surgical Safety Checklist seems to be multifactorial[116 118 119]. One could reason that it has roots in both organizational, cultural and climate dimensions. Some barriers that have been found in studies are: duplication of items within the checklist, poor communication, time for completion of the checklist, and lack of understanding of the benefit of the items[116]. Other identified barriers to a successful implementation of checklists include discipline-specific factors, where physicians are more likely to succeed with an implementation than nurses are, and the involvement of frontline personnel in the design and implementation process of the checklist[120 121]. A review of the barriers and facilitators suggested that a successful implementation requires more than the elimination of barriers and suggests that implementation leaders must foster a mutual understanding of the importance of the checklist by rearranging routines and facilitate team learning[122]. This is in line with the recommendation to implement the checklist as an integrated part of risk-management including education to enhance the understanding of safety[123].

In a recent qualitative study on perceived risk factors during surgery, both patients and health care workers specified a need of a surgical safety checklist[124].

2 AIMS OF THE THESIS

The overall aim of the thesis was to study some intraoperative factors that may be related to patient safety in the operating room.

The specific aims of the four studies were:

I. To explore how the operating team members perceived a pause routine and its' implementation.

II. To evaluate the teamwork and the safety climate in a Swedish operating room setting before and after an intervention including education, focus groups and implementation of a revised version of the WHO checklist.

III. To evaluate if intraoperative difficulties or complications during a radical prostatectomy (open retropubic and robot assisted laparoscopic) was associated with surgeons' self-assessed satisfaction with the performance.

IV. To study whether the surgeons' stress levels were affected by an intraoperative pause during simulated operations.

3 METHODS & METHODOLOGICAL CONSIDERATIONS

Research questions regarding non-technical skills and intraoperative factors in the operating room are to some extent interdisciplinary and can be explored with different methods. To answer the four different research questions in this thesis the studies used different study designs, data collections, and data analysis. As the overall aim of the thesis was to study some intraoperative factors that may be related to patient safety in the operating room, the study participants consisted of different professions in the operating team: anesthesiologists, nurse anesthetists, nurse assistants, scrub nurses and surgeons. Both qualitative and quantitative methods were used in the attempt to answer our research questions (Table 1).

3.1 CAUSAL RESEARCH QUESTIONS AND STUDY DESIGN

The choice of scientific method is dependent on the type of research aim we seek to address. One important distinction is whether the aim is to address a causal relationship. A causal research question is about whether the outcome will change or not depending on an intervention. For example, will teamwork in the operating room be enhanced by the implementation of the WHO surgical safety checklist? An example of a non-causal research question could be the prediction of an outcome: Can we predict the level of teamwork in the operating room dependent on the compliance of the WHO surgical safety checklist?

To answer a question on causality there is a need to control for factors that may influence the outcome, in other words there is a need for separation of the causal effect from confounding factors. The randomized controlled trial is an appropriate method used to answer causal research questions, since it determines causal inference without presence of systematic errors, i.e. bias.

Even though the research question is causal, it may not be possible to construct a randomized controlled trial, hence the study design will have to control for confounding factors present due to the lack of randomization. In observational studies, the influence of confounding factors is always present; hence, there is a risk of the presence of bias.

Table 1. Overview of the studies included in the thesis

Study	Objectives	Participants	Design	Data collection	Primary outcome
I	To explore how the operating team members perceived a pause routine and its implementation	Nurse anesthetists, Nurse assistants, Scrub nurses, Surgeons	Retrospective evaluation	Questionnaires	The operating teams' professions perspectives on an intraoperative pause routine
II	To evaluate teamwork and safety climate before and after an intervention including education, focus groups and implementation of a revised version of the WHO checklist	Anesthesiologists, Nurse anesthetists, Nurse assistants, Scrub nurses, Surgeons	Prospective interventional study	Questionnaires Focus groups Observations	Changes in SAQ** from baseline to post-intervention
III	To evaluate if intraoperative difficulties or complications during a prostatectomy was associated with surgeons' self-assessed satisfaction with the performance	Surgeons	Prospective controlled Trial - LAPPRO	Questionnaires CRF*	Surgeon's perceived satisfaction with the surgical procedure
IV	To study whether the surgeons' stress levels were affected by an intraoperative pause during simulated operations	Surgical residents, Surgeons	Randomized controlled cross-over study	Salivary cortisol Heart rate Questionnaires CRF*	Changes in salivary cortisol between pre-intervention and post-intervention

*CRF Clinical Record Form
**SAQ Safety Attitude Questionnaire

3.2 PERCEPTIONS OF A PAUSE ROUTINE - STUDY I

3.2.1 CONTEXT

This study was a retrospective evaluation of the implementation of an intraoperative pause routine at our operating ward, which was introduced in 2013.

The background of this study was that the unit for Colorectal surgery had implemented an intraoperative pause routine. The Colorectal unit was a referral center for both inflammatory bowel disease and advanced colorectal cancer, therefore the operating procedures were many times complex and operating times often long.

At the time for the introduction of the pause routine the nurses and anesthesiologists of the operating team already had scheduled breaks, hence the pause routine was introduced specifically with regard to the surgeons. Apart from the surgeons employed at the Colorectal unit, the pause routine indirectly affected the nurse anesthetists, the nurse assistants, and the scrub nurses.

By conducting this study, we would receive knowledge on how the different professions of the operating team perceived the pause routine, and if they expected the intraoperative pauses to affect the operation, the surgeon and the teamwork.

3.2.2 DESIGN AND OUTCOME MEASUREMENTS

The pause routine consisted of a short break of one to two minutes including a glass of liquid refreshment. The pauses took place every other hour, and after about four hours of surgery, a longer pause with a snack or quick lunch was taken. In case of a longer pause, the patient had to be stable and everyone in the team apart from the surgeons remained in the operating room. A pause was also encouraged after an adverse event or when having trouble with the surgical strategy.

To explore the operating teams' experiences, we estimated that a questionnaire would be useful for the data collection. Since it was the experiences of the study participants that were of interest, we could also have chosen a qualitative approach with questionnaires with more open-ended questions, focus groups or interviews. The evaluation of the operating teams' perception of the pause routine was made by four different questionnaires, one for each participating profession:

nurse anesthetists, nurse assistants, scrub nurses, and surgeons (Appendix 1), in 2015.

To compare operating times before and after the implementation of the pause routine operating times for all rectal cancer procedures from 2011 and 2014 were obtained from data registries. Rectal cancer procedures were chosen since they often have an operating time over four hours, and therefore are influenced by the pause routine.

3.2.3 QUESTIONNAIRE DEVELOPMENT

The questionnaires constructed contained items relating to different aspects of the surgical teams' perception of the pause (Supplement 1). The questionnaires were face validated on members of operating teams at an operating ward not included in the study, as it would seem important to validate the questionnaire on persons as similar as possible to the study participants. When face validating a questionnaire, the researcher observes a person filling out the questionnaire, hesitations or questions are noted, and the questionnaire is revised until there are no remaining question marks. This process ensures that items are understood by the target group[125].

3.2.4 ANALYSIS AND STATISTICAL CONSIDERATIONS

Descriptive statistics were used to analyze the operating teams' perception of the implementation of the pause routine, which were described in percentage and proportion. No comparisons between the different professions were performed as we aimed to describe the study participants' perceptions.

Differences in operating time from 2011 and 2014 were analyzed with a two-sample t-test, since the two groups analyzed were independent of each other and operation time was assumed to be normally distributed.

3.2.5 GENERAL CONSIDERATIONS

Selection bias refers to potential differences between groups that may exist and influence the result. When including study participants there is always a possibility of selection bias. In this study the amount of missing data was substantial as only 64% answered the questionnaires. For the data to be valid in addressing our research question, it is important to assess whether the missing data was random. We concluded that there is a possibility that the participants who choose to answer were more interested in the research question. If this was the case, the pattern of missing data is not at random and thus the study participants were not a representative sample of the target population. The consequence of this was that the study results will be biased, i.e. the results will give rise to systematic

errors. This is further implied by the response rate of the surgeons (94%) and scrub nurses (74 %), as a pause routine affects the scrubbed sub-team in a more distinct way; during surgery they are normally not able to take short pauses or a sugar-containing drink.

When questionnaires are being used, one should always be aware of the possibility of recall-bias. The possibility of recall-bias is a potential concern in retrospective studies. The questionnaires asked the participants whether the intraoperative pause routine made things better, for example if the teamwork was better. To be able to answer this type of questions, the study-participants had to rely on their memories of how it was before the introduction of the pause routine, hence the possibility of recall-bias. One way to avoid recall-bias could have been to construct a prospective interventional study, where the same questions were asked before and after implementation of the pause routine.

A limitation in this study is that one profession among the operating team, the anesthesiologists were not included. There were two reasons for not including them. They were rarely present during the pauses since they often were responsible for multiple operations at the same time but the nurse anesthetist was attendant during the surgical procedure. In addition, the anesthesiologist were reluctant to participate in study II and were therefore not asked to participate in this study. By not including the anesthesiologists, we cannot describe all members of the operating team's perception of the pause routine.

3.3 SAFETY ATTITUDES & TEAMWORK – STUDY II

3.3.1 CONTEXT

This study was a prospective single center interventional study, where both qualitative and quantitative methods were used. The study was conducted from November 2014 to June 2015 with the aim to evaluate the teamwork and the safety climate in a Swedish operating room setting before and after the intervention consisting of education, focus groups and the implementation of a revised version of the WHO Surgical Safety Checklist.

Previous research had indicated that the use of the WHO Surgical Safety Checklist in combination with compliance to the checklist could contribute to safer surgery[8] [117]. Among members of the operating team in our research group a lack of focus during the performance of the checklist was experienced. We wanted to study the different professions' attitudes to the Surgical Safety Checklist, and to understand why the presentation of the checklist often failed. At the same time, we wanted

to re-educate the operating team about the importance of using the checklist as it was intended, and to get the entire operating team committed to the performance of the checklist.

We hypothesized that by using the Surgical Safety Checklist in a structured fashion and by adding the item, 'description of the surgical procedure' commitment to the checklist and intraoperative teamwork would be improved. Our intention with this item was to increase the team's shared mental model, teamwork and clinical assessment by getting a more in-depth explanation of the patient, the underlying indication for surgery, and the surgical procedure.

3.3.2 DESIGN

All members of the operating team participated in the study. Since the implementation of the checklist in 2009, there had been no further education on the importance of using the checklist. The study started with an information meeting where the study participants received information that a study regarding the work inside the operating room would be conducted, and that we wanted to measure the safety climate at baseline before the start of the study. Then, the Safety Attitude Questionnaire was distributed followed by baseline observations and focus groups. The intervention started with educational meetings with information on safety culture, safety climate, the importance of the WHO Surgical Safety Checklist, and non-technical skills in the operating room, followed by focus groups and lastly by a re-implementation (January 2015) of the revised Surgical Safety Checklist. The post-intervention period occurred during 4 months (January - May 2015), the post-intervention questionnaire Safety Attitude Questionnaire was distributed in June 2015 (Figure 5).

*Figure 5. Timeline for Study II. *Safety Attitude Questionnaire, ** Surgical Safety Checklist*

3.3.3 OUTCOME MEASUREMENTS

The Safety Attitude Questionnaire

The Safety Attitude Questionnaire Operating Room version was used[126] which assessed the operating teams perception of safety climate, teamwork, and communication. The questionnaire consists of six domains; Teamwork Climate, Job Satisfaction, Perception of Management, Safety Climate, Stress Recognition, and Working conditions[126]. In addition to the items in the six domains the Safety Attitude Questionnaire includes questions regarding the quality of communication and collaboration within and between professions; a number of independent questions not included in the domains and therefore not analyzed in this study, and one open ended question.

The Safety Attitude Questionnaire Operating Room version had been translated to Swedish[127]. The original Safety Attitude Questionnaire Operating Room version and the Swedish version were validated and reported to have both adequate reliability and validity[126-128].

Two parts of the questionnaire had not been previously translated to Swedish. We performed a back-and-forward translation[129] and face validation of the sections 'Use the scale to describe the quality of communication and collaboration you have experienced with: surgeons, anesthesiologists, scrub nurses, nurse anesthetists and nurse assistants' and the open ended question 'What are your top three recommendations for improving patient safety in the operating room?' (Appendix 2).

The Safety Attitude Questionnaire was used at baseline (November 2014) and post-intervention (June 2015) to assess changes is domain scores and the section regarding collaboration and communication and the open-ended question (Figure 5). Some of the reasons for choosing the Safety Attitude Questionnaire Operating Room version to evaluate the intervention was that the questionnaire had been translated to Swedish and validated in a Swedish operating room context. Since it has been used in earlier studies, there was an opportunity to compare our results with those of others.

Structured Observations

Structured observations with a pre-defined clinical record form was made at baseline and post-intervention (Figure 5). The clinical record form was tested in a clinical setting and thereafter revised before being used. The observations were conducted in operating rooms, during surgery with the aim to gather information about the performance of the surgical safety checklist. When performing

observations there is always the risk of influencing the study participants being observed, this is called the Hawthorne effect[130]. In this study the observer was one of the operating nurses working at the operating ward, which might have reduced the Hawthorne effect as she was dressed like the operating team, and was a part of the operating team and not a stranger.

To reach saturation the observations were performed until there was no additional information gained through further observations. Saturation during data collection is always an important factor using qualitative methods and refers to when no new information is gathered through more data collection[131].

3.3.4 FOCUS GROUPS & THE REVISED WHO SURGICAL SAFETY CHECKLIST

Six focus groups sessions, separated by profession, with the aim to discuss the checklist were performed (Figure 5). During the focus groups participants were informed about the suggestion of adding the item 'Description of the surgical procedure'. To ensure that each focus group had the same prerequisites to discuss the checklist the same questions were asked to all focus groups. Analysis resulted in two categories: 'Inadequate structure concerning the WHO Surgical Safety Checklist' and 'Benefits of improved description of the surgical procedure' that were used in the revision of the Surgical Safety Checklist used as part of the intervention, the changes in the checklist were (Figure 6):

1. The checklist coordinator filled out the Surgical Safety Checklist on paper at every operation.
2. At Sign in, the item 'presence of metal implant' was added.
3. At Time out, 'description of the surgical procedure' was added. This item was presented to the study participants during the focus groups. All focus groups were positive to the change.
4. At Time out, 'How to manage incoming telephone calls' was added.

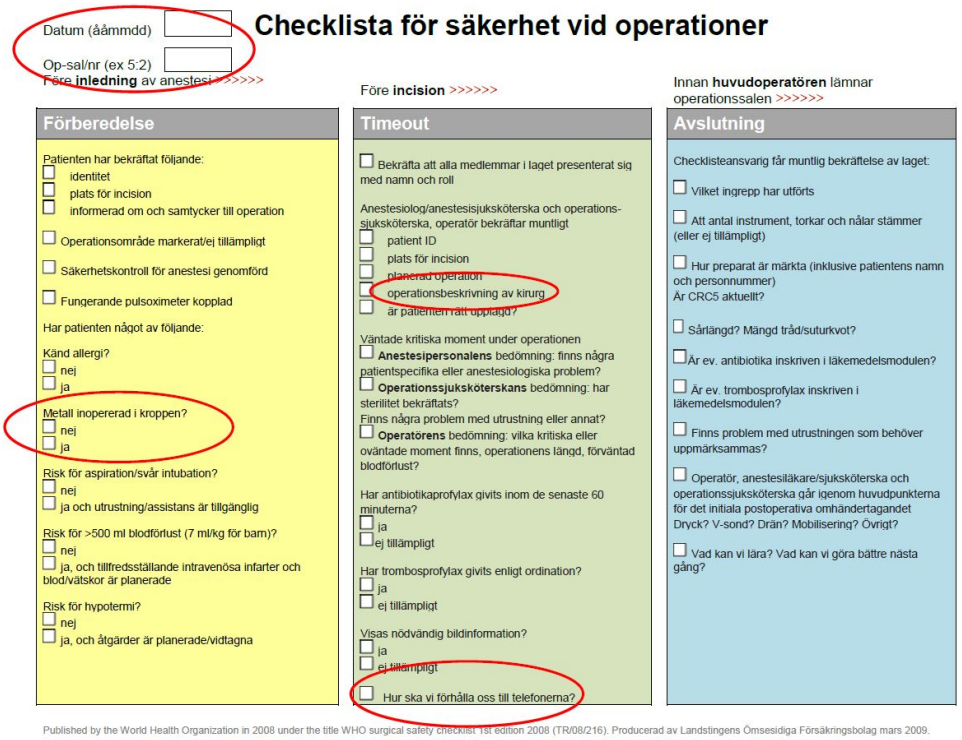

Figure 6. The revised Surgical Safety Checklist. The red markings show the changes made to the checklist.

3.3.5 ANALYSIS AND STATISTICAL CONSIDERATIONS

Both qualitative and quantitative methods were used in the attempt to answer the research question 'is there any change in teamwork climate, communication and collaboration by the intervention and the revised WHO Surgical Safety Checklist?' Often qualitative and quantitative research complement each other by tackling different kinds of research questions, or by addressing the same issue from different aspects[132]. The qualitative features of this thesis entails a more thorough understanding of different aspects of teamwork, and experiences of using the WHO Surgical Safety Checklist, here it complements the questionnaires analyzed with quantitative methods, that evaluate the safety climate and teamwork within the operating team before and after the intervention.

Qualitative content analysis[133] was used to analyze information gathered at the focus groups, from the observations, and from the open-ended question in the Safety Attitude Questionnaire 'What are your top three recommendations for improving patient safety in the operating room?'. The qualitative content analysis

was chosen since we wanted to stay close to the text and categorize and describe what the study participants said or wrote. The manifest content analysis helped us to analyze the text in a structured way, sorted by categories. With the content analysis, we focused on what was read and obvious in the text, we did not try to interpret the text or seek a deeper understanding[133].

We were interested in studying intra-individual changes, and the groups analyzed compared at baseline and post-intervention were dependent on each other. Therefore, we used a Paired *t*-test and a linear model adjusting for the baseline value (ANCOVA) to analyze the intra-individual and intra-professional changes for the Safety Attitude Questionnaire domain scores. The dependency between the groups consists of the same study participants answering the Safety Attitude Questionnaire at both times.

The results from the 'collaboration and communication' part of the study was demonstrated with a cross-table, where the study participants evaluated the communication and collaboration within their own profession and with the other professionals included in the study.

3.3.6 GENERAL CONSIDERATIONS

The research question whether the intervention changed safety climate and teamwork in the operating room was causal, but even so the study was designed as an interventional non-randomized study. We discussed the possibility to design a randomized trial, but due to practical reasons, it was not considered possible since the operating teams included in the study were flexible, with a change of team members from day to day. Instead of having a control group the study was designed to be able to assess intra-individual comparisons where every study participant became their own control.

3.4 SURGEON SATISFACTION - STUDY III

3.4.1 CONTEXT

The third study was conducted with data collected within the prospective, non-randomized, multicenter, controlled Laparoscopic Prostatectomy Robot Open (LAPPRO) trial[125] that compared open radical prostatectomy, with robot-assisted laparoscopic prostatectomy, with the primary outcome urinary incontinence one year after surgery[30].

This study has its origin in a discussion in our research group whether the surgeons' satisfaction with an operation was of importance for the outcome, and difficulties and technical problems.

Surgeons operating in the LAPPRO-trial filled out a clinical record form after each operation without knowing how each item would be used. The clinical record form included questions on various parts of the surgical technique (for example degree of nerve sparing), about difficulties and complications, and also on the surgeon's experienced degree of satisfaction with the operation performed. This data were used to answer the research question for the current study that was conducted with the hypothesis that surgeons' self-perceived satisfaction with a surgical procedure was associated with intraoperative difficulties and complications.

3.4.2 DESIGN & OUTCOME MEASUREMENTS

The study participants were all surgeons, operating patients included in the LAPPRO-trial. They performed the operations at 14 different medical centers in Sweden. To be included in this study they had to have reported their own identifiable study-id in the intraoperative clinical record form.

The outcome variable 'surgeon satisfaction' was collected from the surgical clinical record form and the question 'How satisfied are you with the performed surgical procedure technically?' (Appendix 3).

The clinical record form used was based on quality control forms used at two of the departments participating in the trial. A group of experts revised the clinical record form to function in daily practice, which was then validated in a clinical setting by face validation, and revised until there were no more hesitations or questions[125].

3.4.3 ANALYSIS AND STATISTICAL CONSIDERATIONS

To answer the research question, whether there was an association between intraoperative difficulties, complications and surgeon satisfaction, a hierarchical i.e. multi-level (mixed effect) logistic regression with an intra-surgeon dependency by a random intercept and with a variance component covariance structure was used.

The hierarchical aspect in the model implies that we have taken into account that most surgeons have operated many patients included in the study. Surgeons tend to respond quite similarly and therefore, there is a dependency between patients operated on by the same surgeon (intra-surgeon dependency). The random

intercept implies that the surgeons were allowed to start wherever they wanted on the 'scale of surgeon satisfaction'.

Our primary outcome 'surgeon satisfaction' was dichotomized to be binary, 'yes' or 'no'. When summarizing binary data they are often presented in odds and odds ratios. The odds ratios can be described as 'the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure'[134]. We choose to present our data with odds ratios (OR) and confidence intervals (CI).

Adjustments for the two different surgical procedures open radical prostatectomy and robot assisted laparoscopic prostatectomy, tumor stage, and prostate weight were performed. The two surgical procedures were analyzed separately regarding the variables operating time and blood loss since there are a known difference regarding those factors between the two procedures.

3.4.4 GENERAL CONSIDERATIONS

The present research question was whether the satisfaction of the surgeons was influenced by intraoperative difficulties or complications. To use data from a national large study with data already collected was regarded as an effective way to answer our research question.

3.5 INTRAOPERATIVE STRESS - STUDY IV

3.5.1 CONTEXT

This study was a randomized controlled trial performed in the laparoscopic simulator LapSim® with the additional software TeamSim®, and was conducted with a two-period crossover design at a room at a University Hospital designed for laparoscopic simulations and to mirror an operating room.

The aim was to evaluate if the pause routine previously studied (study I) affected intraoperative stress levels. The hypothesis was that an intraoperative pause with a sugar-containing drink would decrease surgeon's intraoperative stress levels.

3.5.2 DESIGN

All residents in training to become surgeons and surgeons with a maximum of five years' experience in the profession, who were employed at three hospitals within the Region Västra Götaland were asked to participate in the study. To be included in the study they had to be able to perform a standard laparoscopic appendectomy without help from a senior college. Exclusion criteria were:

smokers, Addison's disease, medication with steroids or medication affecting heart rate. The reason for choosing residents and surgeons with maximum five years of experience was to find participants who were similar in regard to laparoscopic experience. Including more experienced surgeons would have increased the number of possible participants but it is possible that more experienced surgeons may not have perceived the simulations as stressful enough, as the LapSim® is constructed as a teaching tool to shorten the laparoscopic learning curve. The exclusion criteria for study participants were decided from some of the known confounding factors of salivary cortisol and heart rate.

Sample size was calculated for the primary endpoint change in salivary cortisol[98 135 136]. A 35% reduction in salivary cortisol between stressful operations and not stressful operations had previously been reported[135]. With 80 % power and a two sided test at a 5% significance level, we included 17 participants to be able to detect a 35% reduction in mean salivary cortisol. Study participants operated in the simulator at two different occasions, so called periods, in total each period took about 2 h to 2.45 h. During each period four simulated operations were performed; appendectomy, cholecystectomy, retrocekal appendectomy, and cholecystectomy. Each period consisted of a pre-intervention phase and a post-intervention phase with the intervention, if any in between (Figure 7).

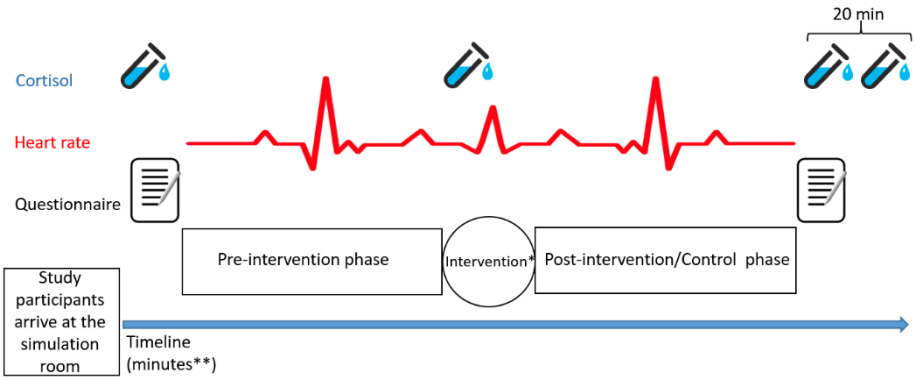

*Figure 7. Timeline simulations. *Pause = 3 min, **Simulation time varied between 0:40 hours to 2:02 hours.*

The intervention consisted of a three-minute long pause including a sugar-containing drink. The study participants were randomized to 'pause' or to 'no pause' (Figure 7).

By randomizing the study participants to the four different sequences: 'pause – no pause', 'no pause –pause', 'pause –pause', 'no pause – no pause' (Figure 8), and not to the two sequences: 'pause – no pause' and 'no pause –pause', we

ascertained blinding. A negative aspect of the four sequences was that we lost the possibility to study the difference between 'pause' and 'no pause' for four of the 17 participants.

Both study participants and researchers were blinded to conceal the group allocation until time for the intervention. Blinding was done to prevent both surgeons and researcher from behaving in a different way, depending on if they were going to have an intraoperative pause or not.

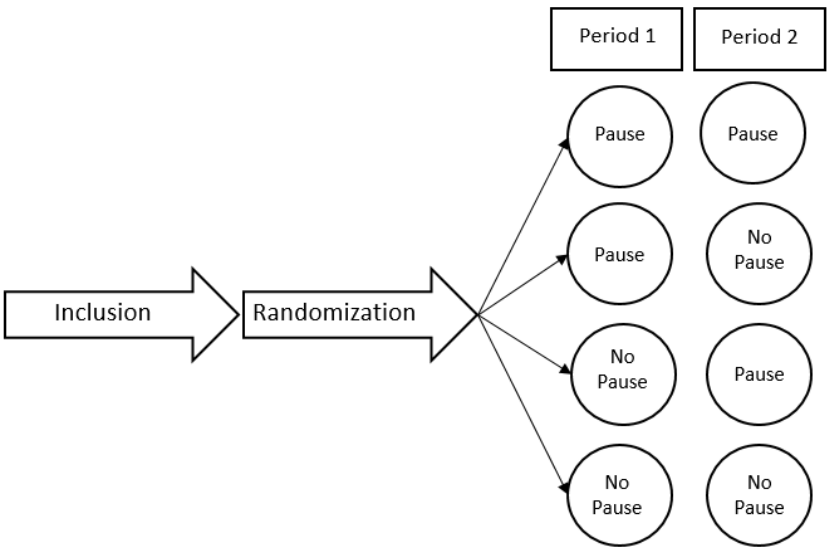

Figure 8. Randomization to one of the four sequences.

3.5.3 OUTCOME MEASURMENTS

The outcome measures were chosen to display both objective and subjective aspects on stress therefore we chose salivary cortisol, heart rate and the Stait-Trait Anxiety Inventory and surgeons self-perceived assessment of the pause.

The Imperial Stress Assessment Tool is a validated tool to capture both subjective (self-report State-Trait Anxiety Inventory) and objective (heart rate, cortisol) responses to stress during surgery[135 137].

Since the Imperial Stress Assessment Tool has reported a correlation between the three methods to measure stress it was evaluated to be a good way to measure stress in this study. Except from the adjustments made in the analysis of salivary cortisol other actions were taken in the design of the study to decrease confounding factors affecting the salivary cortisol. Study participants were

instructed to not eat, drink (other than water), use "snus" (tobacco/ dry snuff) or brush their teeth for one hour before each simulation. When arriving to the simulations the study participants noted time for last drink and food in a questionnaire and the time for the first salivary cortisol was at sometimes adjusted after this. The diurnal variation in cortisol levels was taken into account by starting each simulation at approximately the same time either at 9 am or at 1 pm.

Change in heart rate was measured with the Polar H10 pulse-band (https://www.polar.com) that the study participants applied at the arrival at the simulation room. As we wanted to synchronize the heart rate measurements with the simulation time, we started to monitor the heart rate at the same time as the simulation started. It could have been better to start the monitoring of the heart rate when the study participants arrived to get a correct baseline measurement.

Four different questionnaires were used before and after the simulations. Surgeons' perception of the intraoperative pause was made by using two questions from Study I, 'Has the pause made you handle problems in a better way?', and 'Do you feel more alert after a pause?'[138]. The reason for choosing these items was that they did not treat the teamwork or communication aspect and were assessed to suit the design of the present study.

The questionnaires included the short version of the Stait-Trait Anxiety Inventory questionnaire[139 140] that was used to assess change from pre- to post-intervention in self-perceived stress. Except from being a part of the Imperial Stress Assessment Tool[135] the Stait-Trait Anxiety Inventory[139] was chosen as it measures stress and is responsive to changes in stress[141] and we wanted to be able to detect a change in stress between a simulation with and without pause. It has also been used in the surgical environment before[97 135 142].

The Safety Attitude Questionnaire 'stress recognition' domain was included to evaluate the surgeons' awareness of how their surgical performance are normally influenced by stress[126] (Appendix 4), as it seemed important to get an understanding of the study participants preunderstanding of intraoperative stress.

During each simulation there were two researchers present. One of the researchers is a scrub nurse and tried to have the same influence on each simulation. The study participants were instructed to talk to the researcher as if she was their scrub nurse. The researcher changed laparoscopic instruments when requested by the study participant. During the simulations, the researchers collected data on time for each period, time for salivary cortisol sampling, and time and type of each stressor added with the TeamSim® software.

3.5.4 ANALYSIS AND STATISTICAL CONSIDERATIONS

The calculation of change from pre-intervention to post-intervention was performed on the log-scale, since salivary cortisol was presumed to be non-normally distributed. The following statistical model was used, a mixed effect analysis of covariance (ANCOVA) with intervention/no intervention, period and sequence as fixed effects, and subject nested within sequence as random effect. The covariate included in the model was mean log cortisol at baseline.

There are many confounding factors that potentially could influence salivary cortisol, to account for some of them adjustments were made regarding treatment (intervention or control), period, sequence, subject nested within sequence, and time for simulation (9am or 1pm).

3.5.5 GENERAL CONSIDERATIONS

This was an experimental study performed in a laparoscopic simulator. In the design phase we discussed designing the study as a clinical trial in an operating room, but since the clinical setting would have meant multiple confounding factors regarding surgeons' stress levels we preferred a more controlled environment. The confounding factors in the operating room during surgical procedures with the entire operating team present would have made it more difficult to quantify causal relationships. The standardized simulator environment with pre-specified operations and stressors implies a model where each study participant are exposed to the same amount of stress during each simulation, making it easier to control for confounding factors and assess causality.

In cross-over studies one should always be aware of the possibility of a carry-over effect between the two periods, however we did not assess that there was a risk in this study. Since the study participants' experiences from the first period exist during the second period, it is likely that a period effect is present. We did note a possible period effect since the participants performed the same simulation at two different occasions, where they performed the second simulation faster, but seemed to be more stressed before the second simulation, reflected in the outcome measurements.

3.6 ETHICAL APPROVAL

For study I, an ethical approval was not considered as needed, since the study was a retrospective evaluation of an already implemented routine. Before the distribution of the questionnaires the professionals of the operating team were informed that participation in the study was voluntary.

Ethical approval was obtained for study II by the Regional Ethical Board in Göteborg, EPN dnr 958-14, for study III the Regional Ethical Review Board in Sweden (EPN Dnr. 277-07) approved the LAPPRO trial, and study IV obtained the ethical approval from the Swedish Ethical Committee (Dnr: 2019-02316).

In the second study the management approved of the changes in routine (information/education, focus groups, observations and introduction of a revised checklist), and the participants consented to participate by answering one or both questionnaires, in accordance with the ethical permission.

4 RESULTS

The results from the four studies will be presented separately.

Table 2. Overview of primary and secondary outcomes for the four studies included in the thesis

	Results	
Study	Primary outcomes	Secondary outcomes
I	The operating teams' different professions perspectives on the intraoperative pause routine was positive	Operating times from before to after implementation of the pause routine did not change
II	There were no significant changes in the SAQ* 'Safety Climate', 'Teamwork Climate' or 'Communication and Collaboration' from baseline to post-intervention	Observations showed a lack of structure and low compliance regarding the use of the Surgical Safety Checklist
III	The odds of surgeon satisfaction decreased for each intraoperative difficulty and complication (0.60, 0.56; 0.63)	There was no difference in surgeon satisfaction between the two procedures ORP**, RALP*** Operative time and blood loss decreased when surgeons were satisfied
IV	There was no statistically significant change in salivary cortisol between pre-intervention and post-intervention phase, mean ratio 0.92(95%CI0:75;1.18)	Surgeons' perception of taking a pause was positive There were no changes in heart rate or self-perceived stress from before to after the intervention

*Safety Attitude Questionnaire, **Open radical prostatectomy, ***Robot assisted laparoscopic prostatectomy

4.1 PERCEPTIONS OF A PAUSE ROUTINE - STUDY I

Teamwork and communication were perceived as better after a pause; many of the scrub nurses stated that it was easier to communicate with the surgeons after a pause (Figure 9). There were also comments on more alert and less irritable surgeons after a pause. There was no significant change in operation time from before the implementation of the pause routine to after.

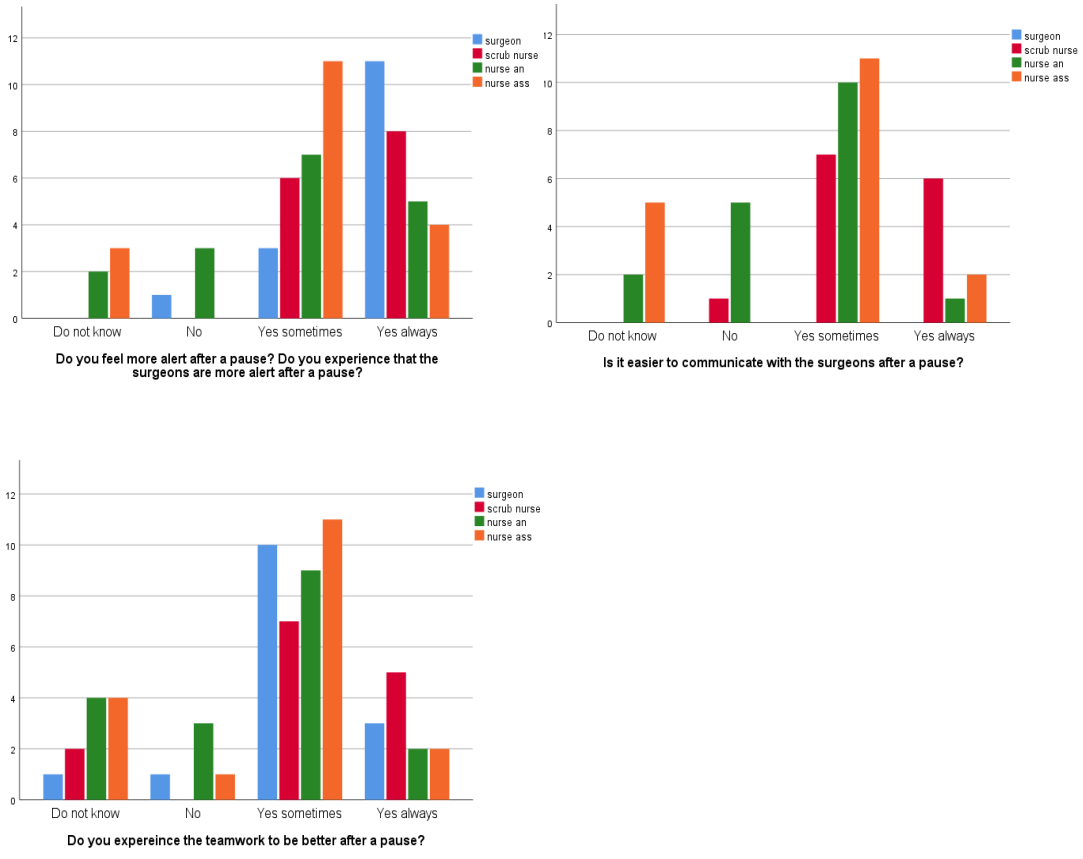

Figure 9. Results from Study I. The operating team's perception of the intraoperative pause routine, shown as number of participants from each profession answering the question.

4.2 SAFETY ATTITUDES & TEAMWORK – STUDY II

Baseline observations of the performance of the WHO Surgical Safety Checklist showed that many of the items in the checklist were often omitted.

When study participants suggested important factors for increased patient safety, many mentioned the use of the Surgical Safety Checklist and specified that the focus during the performance was important. Interestingly there were at baseline comments regarding extended information about the surgical procedure during 'Time out'. Preoperative planning, an open climate, respect for each other, and improved communication and teamwork were also stated as important. Focus by all professions on the operation were specified as important by the scrubbed sub-team, surgeons and scrub nurses. To reduce stress and to follow clinical guidelines and routines were stated as important.

There was no change from baseline to post-intervention in the quality of communication and collaboration between operating team members, but the different professions had diverse experiences of communication and collaboration amongst the operating team, where most professions stated that communication and collaboration functioned best within their own profession.

The intervention with the education, focus groups and the revised Surgical Safety Checklist did not result in a change in the Safety Attitude Questionnaire domain scores for either 'Safety Climate' or 'Teamwork Climate'. Doctors scored significantly higher than nurses did in the domain "Teamwork Climate", both at baseline and post-intervention. The nurse assistants scored significantly higher in the domain 'Safety Climate' post-intervention.

Observations post-intervention showed at 'Sign in' a lack of coordination and structure, where the nurse anesthetist and nurse assistant alone often performed 'Sign in' after 'Time out'. At 'Time out' the quality depended on the individuals performing the checklist and was often performed with a lack of focus, where team members did not listen to each other. The added item 'Description of the surgical procedure' was many times imperfect, which made the nurses frustrated. 'Sign out' was affected by a lack of structure and with an unfocused team.

4.3 SURGEON SATISFACTION - STUDY III

The surgeons were satisfied respectively dissatisfied in 2905 (81%) and 702 (19%) of the surgical procedures included in the study. Surgeon satisfaction did not differ regarding surgical technique, open radical prostatectomy vs. robot-assisted laparoscopic OR 1.36 (95%CI:0.76;2.43). There were strong associations between intraoperative difficulties and complications and the surgeons' satisfaction; the odds of surgeon satisfaction decreased for each intraoperative difficulty and complication OR 0.60(95%CI:0.56;0.63) (Figure 10).

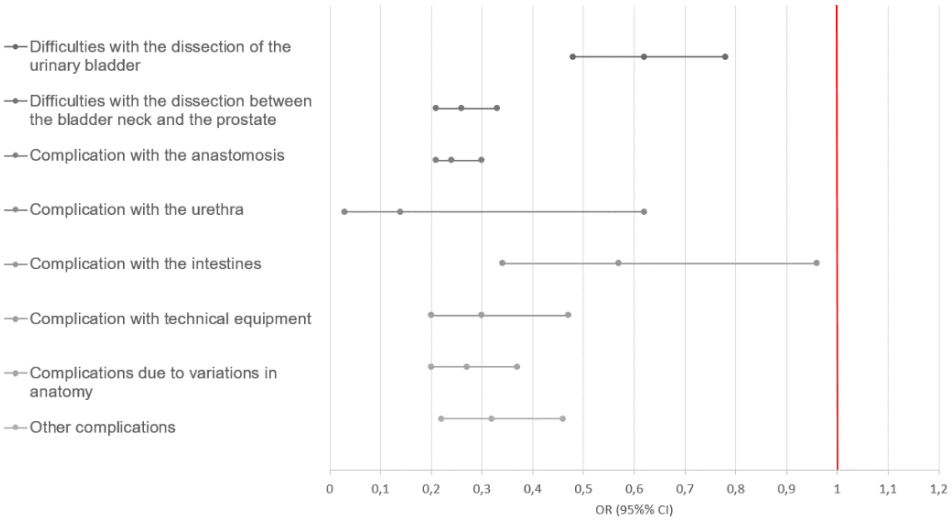

Figure 10. Results Study III, Odds ratios and 95% CI for associations between the surgeons' satisfaction and intraoperative difficulties and complications

4.4 INTRAOPERATIVE STRESS - STUDY IV

Simulation time differed between 0.40h and 2:02h and the median (interquartile range) time for the first period was longer than the second one 1:39h (0.33) vs. 1:06h (0.10).

Salivary cortisol during the pre-intervention phase was higher than median (IQR) 4.9(3.5) nmol/l it was during the post-intervention phase independent on control 4.3(2.39) nmol/l or intervention 4.6(2.10) nmol/l. There was no statistically significant difference between the intervention and the control group, mean ratio 0.92(95%CI:0.72;1.18).

Most surgeons had positive experiences of taking a pause, 9/16 surgeons stated that they handled problems in a better way, and 14/16 surgeons felt more alert after an intraoperative pause.

Heart rate from 31 simulations were analyzed (1 missing), without a statistically significant result between simulations with or without a pause 0.97(95%CI;0.94;1.00). Stait-Trait Anxiety Inventory score was calculated for 30 simulations (2 missing), with no statistically significant change in self-assessed stress between simulations with or without pause 0.99(95%CI:0.89;1.09).

5 DISCUSSION

The findings of the four studies included in this thesis implied that it can be complex to study intraoperative factors and non-technical skills in the operating room. But as intraoperative factors and non-technical skills are linked to outcome measures such as adverse events and thereby patient safety, it is important to continue studying them[8 41 66 143].

We found that the compliance to the WHO Surgical Safety Checklist was incomplete, both before and after the intervention. Only in 21% of the 1267 checklists collected during the intervention-period all items were filled out. Although there was a high compliance to initiate the checklist, most times it was not performed the way it is intended, and often without checking all items. Other studies have also found a lack in the compliance to the Surgical Safety Checklist, where the checklist most times was initiated but not completed, described as contributing to a false sense of security[114-116]. Barriers to effective use of the checklist seems to be complex and multifactorial[116]. Involving the operating team, engaging senior personnel who show their support, and continuous education with reminders of barriers to the correct use of the checklist before, during and after the implementation seems to be important[120 144]. Additionally, the compliance to the checklist has been reported to be better when surgeons led them[106 120]. Although efforts were made to involve the operating team in the intervention of the revised Surgical Safety Checklist, it was not enough; it is possible that more time, more education, the involvement of senior key-persons, and the implementation led by a surgeon would have changed the results, since the study participants' perception of the revised checklist was positive.

Previous research has reported that high compliance to the Surgical Safety Checklist increased patient safety. In addition, a more thorough information about the surgical procedure and patient should be beneficial, which we could not demonstrate in our study. Presumably, the intervention dose was too small, but even so, how do we know that we measured what we intended to measure? Did the responses in the SAQ post-intervention reflect the domain perception of management, which significantly decreased between the two measurements? We did also note a decrease in the scores for the domains 'Job satisfaction' and 'Working conditions', although not significant, which might imply that study participants were more dissatisfied with their job situation at the time for post-intervention measurements. This also demonstrated the complexity of measuring interventions in the complex surgical environment.

As part of the intervention, the added item 'description of the surgical procedure' to the WHO Surgical Safety Checklist had many aspects and possible benefits. One aspect was that it would provide a better basis for both an individual's situational awareness and the team's shared mental model, as all professions of the operating team had the same information regarding the patient and the surgical procedure. Situation awareness and the shared mental model is about the ability for the operating team or a professional of the team, to be one step ahead, to anticipate events and their consequences and create alternative solutions to avoid adverse events and increase patient safety.

One of the reasons that the Surgical Safety Checklist is important for team communication, is the fact that team members need to respond to the different items, and thereby communicate with closed-loops[8 64]. The shared mental model within the team has been reported to be improved through team planning[145] and situational awareness has been identified as important for a surgeons technical skills[146]. The 'description of the surgical procedure' could also be of importance for the scrub nurse who constantly has to know what is going on in the operating room and assess the progress of the surgical procedure to be able to 'think ahead of the surgeon'[57].

We found that the team members had different perception of communication and collaboration within the operating team, and physicians scored higher regarding teamwork climate than did nurses, both before and after the intervention. This is in line with results from earlier studies[147 148]. This result might be important as it implies that the safety climate among different members of the operating team may vary. In the introduction the importance of recognition of other team members roles were described, the professions among the operating team have different sub-goals, the same thing applies to the sub-teams. It is somewhat worrisome that the two professions included in the scrubbed sub team have different views of communication and teamwork. Not get understanding for one's own sub-goals or understand others may lead to a feeling of being misunderstood and undervalued, which might result in impaired teamwork and negative stress.

In two studies we saw basically the same result, where the study participants' perception of intraoperative pauses was positive. The intraoperative pause routine was introduced at our operating ward in 2013, today (seven years later) the routine is still frequently practiced, which could mean that the pause routine is here to stay.

Apart from the possible benefit of preventing fatigue before it is evident, the intraoperative pause routine could have other benefits. During complex surgery

or in combination with intraoperative difficulties or complications a pause routine could also give the surgeon a minute to regain cognitive self-control and re-assess the situation before leading others through a stressful situation, which have been earlier described[84 149]. During introduction of the intraoperative pause routine, the surgeons were encouraged to take a break after a major adverse event or when hesitating regarding the surgical strategy, and some of the surgeons stated that they sometimes had changed surgical strategy after a pause.

Among the open-ended questions there were comments that the surgeon during the longer pause had worked out a new surgical strategy, which is positive. Therefore, another positive addition to the longer paus could have been to add a 'Time out' before starting to operate again, where all members of the operating team get the possibility to understand the surgical plan, and for the team to have a shared mental model. The idea of making the pause routine mandatory and even more structured, where the surgeons before entering the operating room for a long surgical procedure had a plan for when taking a longer break could be beneficial.

Even though one could argue that the surgeons' experiences of the pause routine should be sufficient to promote the routine, we suspected that it would be easier to implement the pause routine if we could demonstrate that the surgeons' perceptions was positive together with objective measurements on stress reduction. But we could not demonstrate a significant reduction in either of the parameters salivary cortisol, heart rate, or the Stait-Trait Anxiety Inventory to assess surgeons stress levels in the experimental study. It is possible that the simulations performed were not stressful enough for the surgeons included in the study, or that the intervention with a three minute long intraoperative pause including a sugar containing drink was not sufficient to show a significant difference between pause vs. no pause. It is also possible that our sample size calculation was inaccurate. When calculating the sample size, we used results from a study with comparisons between non-stressful and stressful operations (reduction in salivary cortisol from 3.60 – 2.95 (35%))[137], our results showed 8% reductions in cortisol. Since the Imperial Stress Assessment Tool[135] previously has shown correlations between salivary cortisol, heart rate and the Stait-Trait Anxiety Inventory when measuring stress in a surgical environment, one could assume that one of the alternatives mentioned above or a combination of them explains our result.

The results from the domain stress recognition in the Safety Attitude Questionnaire implies that the residents and surgeons included in study IV were more aware of the influence stress can have on their performance median (IQR) 62.5 (23.44), than the doctors participating in study II were, mean (SD) 76-74

(16.8-14). This implies that the participants in study IV were interested in the research question and in preventing intraoperative stress and fatigue.

Except from trying to objectively measure reduction in intraoperative stress, study IV is important as it raises the awareness of intraoperative stress as an issue. To study stress among surgeons, who sometimes have reported that stress affects others more than themselves[45 85] is one way to raise awareness of that stress is a factor that may affect their performance and subsequently the outcome of an operation.

When operating team members are influenced by negative stress or working in a non-functioning team, it would be easier to make mistakes that could lead to adverse events and thereby decreased patient safety. Individuals who feel the support from other team members, and who have a shared mental model, and have handled stressful events together in the past, are better equipped to cope with stress in the future[64 96]. This is one reason to work with the compliance to the WHO Surgical Safety Checklist and why it is important to find ways to reduce stress among members of the operating team.

Preoperative planning, an open climate, respect for each other, and improved communication and teamwork were mentioned as important for high patient safety, and the intra-operative pause routine was perceived to lead to better communication and teamwork, therefore it is reasonable to deduct that a pause routine may be of importance for patient safety.

The pause routine could also lead to better focus on the operations by all professions, which was stated as an important aspect of patient safety. In study II many surgeons identified coffee breaks during surgery as unnecessary disruptions, suggestions were made to arrange a more flexible system for intra-operative pauses and lunchbreaks, including all professions in the operating team. In the operating rooms that we studied in study I, all members of the operating team except from the surgeons had scheduled coffee- and lunch breaks. By expanding the pause routine to include the entire operating team surgeons might experience fewer intraoperative disruptions which could also be beneficial for patient safety[150-153]. This would also enable continuity among the operating team during the entire surgical procedure.

We established correlations between intraoperative difficulties and complications and surgeons' technical satisfaction with a surgical procedure. Earlier surgeons have reported that technical difficulties were a stressor in the operating room[85 95]. Problems within the operating team were also perceived as very stressful[95 154]. Another association between surgeon satisfaction and intraoperative teamwork is

that effective teams have been reported to have fewer miner problems, better intraoperative performance and shorter operating times[155]. Associations between major problems and intraoperative performance, teamwork and number of minor problems were also reported[155]. This may be related to disruptive behavior in the operating room, as one could suspect that a dissatisfied surgeon would be more prone to show disruptive behavior than a satisfied surgeon would. Disruptive behavior has been reported to increase stress and frustration within the operating team, which can influence communication and collaboration among team members[156]. Some of the nurses in study I wrote in the open-ended question that an intraoperative pause reduced disruptive behavior.

It would be of interest to explore possible relationships between technical difficulties, surgeons' satisfaction, intraoperative teamwork and stress reduction through intraoperative pauses. It may be that many of the factors and non-technical skills studied in this thesis are bound to each other in a circle; for example, fewer surgical complications and difficulties leads to a more satisfied surgeon that could lead to better teamwork, which might lead to a beneficial work environment, with less stress and fatigue. But could it begin in the other end of the circle by reducing stressors in the operating room or by learning to manage stress and fatigue, which might lead to a better work environment, which could promote teamwork with high quality, a satisfied surgeon and fewer intraoperative complications and difficulties.

6 CONCLUSION

An intraoperative pause routine was perceived as positive by both the operating surgeon and from the operating team. The positive experience was present during surgical procedures and simulated operations. The implemented pause routine did not lengthen the operating time and was perceived to increase teamwork, communication and patient safety. Intraoperative teamwork and communication among operating team members were estimated as important for patient safety. The impact on patient safety, for example, as effect on adverse events or complications remains to be studied. With this in mind, a mandatory pause routine during long surgical procedures with short pauses including a sugar-containing drink every other hour or after adverse events or complications, and shorter lunch breaks after four hours of surgery could be introduced.

Surgeons were more satisfied with a surgical procedure when the number of intraoperative difficulties and complications were low. This is interesting, as satisfaction appears to reflect problems in the operating room. Perhaps the association between a satisfied surgeon, surgical performance and teamwork could benefit from further exploration of an association between a satisfied surgeon and his/her ability to cope with stress.

Introducing new routines are difficult and the compliance to the WHO Surgical Safety Checklist was unsatisfactory. Education of the operating team together with a revised checklist did not change teamwork climate. This may be due to an insufficient intervention dose. To reach high compliance to the Surgical Safety Checklist, ongoing education and further education of the operating team is important. Perhaps more focus on the effects that the WHO Surgical Safety Checklist has on outcomes could be one way of addressing an increased use? As the operating team had different perceptions of teamwork and communication, it would be interesting to study differences in teamwork and communication between operating teams who shift from day to day with more coherent operating teams.

As well as enhancing team communication, the use of the WHO Surgical Safety Checklist could contribute to a possibly raised awareness of the importance of safety issues among front-line personnel in the operating room. Therefor one could assume that by studying the operating teams' non-technical skills their attitudes to safety concerns might be more prominent, hence rendering a safer surgical environment. The same thing could be applied when studying intraoperative stress; it makes the study participants more aware of the effects stress may have on the intraoperative performance.

7 FUTURE PERSPECTIVES

The findings of these studies imply that it is complex to study intraoperative factors and non-technical skills in the operating room, and even more complex to assess their outcomes. But since adverse events from surgical care may be severe and can lead to additional interventions or treatments, disability, prolonged hospital stay, and more outpatient visit it would seem important to try avoid adverse events as far as possible. One way of doing that is by continuing to study intraoperative factors and non-technical skills that affect surgical outcome and patient safety.

My aspiration is that the results of this thesis might inspire some management, operating teams and personnel working in operating teams to learn more about the importance of non-technical skills. This may take the form of teambuilding in the workplace, by discussing non-technical skills among the operating team, by listening to the front-line workers' experiences regarding non-technical skills, by having journal clubs on the subjects, or even at informal coffee breaks.

In some high-risk organizations, non-technical skills is a natural part of the education. Health care has traditionally been late with the acknowledgement of the importance of good non-technical skills for safe care. One goal with this thesis was to illustrate the subject of non-technical skills in surgical care. A vision for the future is to continue exploring the different aspects of non-technical skills among the operating team. Interesting questions to study could be: What non-technical skills are important for the different professions in the operating team? What non-technical skills are a shared common ground for the entire operating team? What non-technical skills are of most importance to avoid adverse events and increase patient safety? Which stressors are more difficult to coop with? How do we prevent negative stress in the operating room?

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APPENDIX

1. Questionnaires regarding the intraoperative pause routine (used in study I)

2. The Safety Attitude Questionnaire (used in study II)

3. Items from the LAPPRO trial (used in study III)

4. Items regarding intraoperative stress (used in study IV)