

University of Dundee

DOCTOR OF MEDICINE

The effect of surgical checklists on the laparoscopic task performance

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The effect of surgical checklists on the laparoscopic task performance

By

Michael El Boghdady

A thesis for the Degree of

Doctor of Medicine at the

University of Dundee

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LIST OF ABBREVIATIONS

WHO: World Health Organization

ATLS: Advanced Trauma Life Support

ISC: Intraoperative Surgical Checklist

GMC: General Medical Council

RCSEd: Royal College of Surgeons of Edinburgh

WPBA: Workplace-based Assessment

GRS: Global Rating Scale

HRA: Human Reliability Assessment

OCHRA: Observational Clinical Human Reliability Assessment

DEDICATIONS

Thanks to God who gave me strength and knowledge to continue this research. I dedicate this thesis to my constant motivator, my mother, for her love and support. I would like to thank her for being the main source of encouragement to me throughout my life. I would also like to dedicate this thesis to my father for his support.

Another special dedication goes to my fiancée and my parents in law for their love and patience.

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DECLARATION

I declare that the studies described in this thesis were completed by me at the Cuschieri Skills Centre, Ninewells Hospital and Medical School, University of Dundee under the supervision of Mr Afshin Alijani. This thesis is composed by myself and has not been submitted previously for any higher degree.

Ethical approval for both, the lab-based and clinical-based trials were granted by the University of Dundee Research Ethics Committee; in addition to a registration of the clinical trial at the Clinical Governance and Risk Management, NHS Tayside.

Michael El Boghdady

October 2016

STATEMENT FROM SUPERVISOR

This is to certify that Michael El Boghdady has fulfilled the relevant conditions of ordinances of the University of Dundee and he is qualified to submit the following thesis for the degree of Doctor of Medicine (MD).

Mr Afshin Alijani

(Research Supervisor)

PUBLICATIONS ORIGINATED FROM THE THESIS

- **El Boghdady M.**, Alijani A. (2016) Feedback in Surgical Education. ***The Surgeon***. 10.1016/j.surge.2016.06.006.
- **El Boghdady M.**, Tang B., Tait IS., Alijani A. (2016). The effect of a simple intra-procedural checklist on the task performance of laparoscopic novices. ***The American Journal of Surgery***.10.1016/j.amjsurg.2016.07.019.
- **El Boghdady M.**, Tang B., Alijani A. (2016). The effect of a performance based intra-procedural checklist on a simulated emergency laparoscopic task in novice surgeons. ***Surgical Endoscopy***. DOI: 10.1007/s00464-016-5223-0

PRESENTATIONS TO LEARNED SOCIETIES

- **M El Boghdady**, B Tang, IS Tait, A Alijani. The effect of a self-administered performance based intra-procedural checklist on the laparoscopic learning curve of novice surgeons. ***The Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI)***, Southport, 26th and 27th November 2015.
- **M El Boghdady**, B Tang, PT Donnan, IS Tait, A Alijani. The effect of a self-administered performance based intra-procedural checklist on an emergency simulated laparoscopic task performance. ***The Society of Academic and Research Surgery (SARS)***, Royal College of Surgeons of London, 6th and 7th January 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. The formulation of a simple error reduction checklist to be applied by junior trainees during laparoscopic tasks. ***Barts & The London National Surgical Conference***, London, 13th February 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. The study of a simple intra-procedural checklist on the laparoscopic task performance of novices. ***Barts & The London National Surgical Conference***, London, 13th February 2016.
- **M El Boghdady**, B Tang, PT Donnan, IS Tait, A Alijani. The study of a performance based intra-procedural checklist on an emergency simulated laparoscopic task. ***Barts & The London National Surgical Conference***, London, 13th February 2016 (Prize: best oral presentation).

- **M El Boghdady**, B Tang, IS Tait, A Alijani. The effect of a self-administered intra-procedural checklist on the laparoscopic task performance of novice surgeons. ***University of Dundee School of Medicine, School of Dentistry and School of Nursing & Health Sciences Annual Research Symposium***, Crieff, 25th and 26th February 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. Comparison between the effect of a self-administered and a trainer-administered surgical checklist on the laparoscopic task performance. ***The Association of Surgeons in Training (ASiT) International Surgical Conference***, Liverpool, 18th to 20th March 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. The study of a performance based intra-procedural checklist on the laparoscopic task performance of novices. ***The Royal College of Surgeons of Edinburgh Annual Audit Symposium***, 15th April 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. Comparison between the effect of a self-administered and a trainer-administered surgical checklist on the laparoscopic task performance. ***The Royal College of Surgeons of Edinburgh Annual Audit Symposium***, 15th April 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. The effect of trainee-administered versus trainer-administered methods in applying a surgical checklist during a laparoscopic task. ***International Surgical Congress of The Association of Surgeons of Great Britain and Ireland (ASGBI)***, Belfast, 11th to 13th May 2016.

- **M El Boghdady**, B Tang, IS Tait, A Alijani. The study of a simple error reduction checklist on the laparoscopic task performance of higher surgical trainees. ***International Surgical Congress of The Association of Surgeons of Great Britain and Ireland (ASGBI)***, Belfast, 11th to 13th May 2016.
- **M El Boghdady**, A Alijani. Can we improve the performance of surgical trainees during laparoscopic cholecystectomy? ***26th Annual Postgraduate Research Student Symposium, School of Medicine, University of Dundee***, 15th June 2016.
- **M El Boghdady**, B tang, A Alijani. The effect of a self-administered performance based intra-procedural checklist on the laparoscopic learning curve of novice surgeons. ***26th Annual Postgraduate Research Student Symposium, School of Medicine, University of Dundee***, 15th June 2016.
- **M El Boghdady**, B Tang, IS Tait, A Alijani. The formulation of a simple error reduction checklist to be applied by junior trainees during laparoscopic tasks. ***International congress of the European Association for Endoscopic Surgery (E.A.E.S.)***, Amsterdam, 15th to 18th June 2016.
- **M El Boghdady**, W Wang, A Alijani. Can a simple performance based intra-procedural checklist decrease the errors of surgical trainees during laparoscopic cholecystectomy? ***The Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI)***, London, 10th and 11th November 2016.
- **M El Boghdady**, A Alijani. The formulation of a training checklist for emergency situations to be applied by trainees during simulated laparoscopic tasks. ***The Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI)***, London, 10th and 11th November 2016.

- **M El Boghdady**, A Alijani. A review of feedback in surgical education. ***The Society of Academic and Research Surgery (SARS)***, Royal College of Surgeons of Ireland, 18th and 19th January 2017.
- **M El Boghdady**, A Alijani. The comparison between the effects of a performance based intra-procedural checklist on a virtual reality emergency simulated laparoscopic task in novice surgeons and senior trainees. ***The Society of Academic and Research Surgery (SARS)***, Royal College of Surgeons of Ireland, 18th and 19th January 2017 (Training and Education Prize Session).
- **M El Boghdady**, W Wang, A Alijani. The study of a self-administered intra-procedural checklist on the performance of surgical trainees during laparoscopic cholecystectomy. ***The Society of Academic and Research Surgery (SARS)***, Royal College of Surgeons of Ireland, 18th and 19th January 2017 (Patey Prize Session).

PRIZES AND GRANTS:

- Travel grant to present at the Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI) conference, University of Dundee, £ 378.
- Best oral presentation at Barts & the London National Surgical Conference, London, 13th February 2016. (The study of a performance based intra-procedural checklist on an emergency simulated laparoscopic task).
- Training and Education Prize session at The Society of Academic and Research Surgery (SARS), Royal College of Surgeons of Ireland, Dublin, 18th and 19th January 2017. (The comparison between the effects of a performance based intra-procedural checklist on a virtual reality emergency simulated laparoscopic task in novice surgeons and senior trainees).
- Patey Prize Session at The Society of Academic and Research Surgery (SARS), Royal College of Surgeons of Ireland, Dublin, 18th and 19th January 2017. (The study of a self-administered intra-procedural checklist on the performance of surgical trainees during laparoscopic cholecystectomy).

SUMMARY OF THE THESIS

Background:

Surgical checklists are in use as means to reduce errors for safer surgery. Checklists are infrequently applied during procedures and have been limited to lists of procedural steps as aid memoires.

Aims:

We aimed to formulate a performance based checklist and to study its effect on the surgical task performance of novice surgeons when applied during both, routine knot tying and simulated emergency laparoscopic tasks.

We also aimed to study the effect of the performance based intra-procedural checklist in clinical environments during elective laparoscopic procedures as a way of error reduction mechanism and improvement of patient safety.

Methods:

The study was conducted in two settings, lab-based and clinical-based environments. The lab-based study was conducted during both routine and emergency tasks.

Lab-based study- routine task:

Twenty novices were randomised into two equal groups, those receiving paper feedback (control group), and those receiving paper feedback and the checklist that was applied at 20 seconds intervals (checklist group). The task involved performing laparoscopic double knots which were repeated over 5 separate stages. Human reliability assessment technique was used for error analysis on unedited video

recordings of the tasks. Endpoints included number of errors, error probability (number of errors/number of knots), error types and number of completed knots.

Non-parametric statistics were used for data analysis.

Lab-based- emergency task:

Thirty consented laparoscopic novices were exposed unexpectedly to a bleeding vessel in a laparoscopic virtual reality simulator as an emergency surgical scenario.

The task consisted of using laparoscopic clips to achieve haemostasis.

Subjects were randomly allocated into 2 equal groups; those using the checklist (checklist group) and those without (control group). The checklist was applied by the trainees in the checklist group at 20 seconds intervals. The surgical performance was computed on eight predetermined technical factors.

Clinical-based study:

Surgical trainees in the general surgery at Tayside NHS were included in this study and required the attendance of a trainer during the procedure as per routine practice. Record year of trainees and previous experience on laparoscopic cholecystectomy were noted. Two elective laparoscopic cholecystectomies for each trainee were video-recorded without the use of the checklist, directly followed by 2 further operations after the introduction of the checklist. The unedited videos were analysed for error detection using human reliability analysis technique. Total number of errors per time during each procedure, total number of errors per number of instrument movements, total number of instrument movements per time and number of trainer intervention while per time were noted as assessment points.

Results:

Lab-based- routine task:

2341 errors were detected in 141 tasks, 408 subtasks and 2249 steps during the 5 stages. During the first stage, the errors were not significantly different between groups. The checklist group committed significantly fewer errors as compared to the control group during all the later 4 stages ($p < 0.01$).

The checklist group had an enhanced learning curve as the last 4 stages showed significant fewer errors compared to the first stage ($p < 0.05$), while the control group showed no improvement. Error probability was significantly higher in the control group compared to the checklist group: median [IQR] 32.6 [25.89] vs 11.7 [10.72] ($p < 0.01$).

Individual error types during each step of the laparoscopic task were identified. The checklist group performed better with fewer errors for all the error types. While, there was no significant difference in each of 'the lack of supination', 'tissue bite' and 'out of vision'; the differences in all the rest of error types were highly statistically significant ($p < 0.01$). Number of completed knots was not statistically different between the 2 groups.

Lab-based- emergency task:

The checklist group performed significantly better in 6 out of 8 technical factors when compared to the control group median [IQR]: Right instrument path length (m) 1.44 [1.22] vs 2.06 [1.70] ($p = 0.029$), and right instrument angular path (degree) 312.10 [269.44] vs 541.80 [455.16] ($p = 0.014$), left instrument path length (m) 1.20 [0.60] vs 2.08 [2.02] ($p = 0.004$), left instrument angular path (degree) 277.62 [132.11] vs 385.88 [428.42] ($p = 0.017$). The checklist group committed significantly fewer

number of errors in the number of badly placed clips ($p= 0.035$) and number of dropped clips ($p= 0.012$).

Although statistically not significant, total blood loss (lit) decreased in the checklist group from 0.83 [1.23] to 0.78 [0.28] ($p= 0.724$), and total time (sec) from 186.51 [145.69] to 125.14 [101.46] ($p=0.165$).

Clinical-based study:

Participants performed statistically better with fewer number of errors per time with the application of the checklist compared to when no checklist was used respectively: Median [IQR] total number of errors 1.51 [0.80] vs 3.84 [1.42] ($p=0.002$), consequential errors 0.20 [0.12] vs 0.45 [0.42] ($P=0.005$), inconsequential errors 1.32 [0.75] vs 3.27 [1.48] ($p=0.006$) and total number of errors per number of instrument movements 0.16 [0.04] vs 0.29 [0.16] ($p= 0.003$). With the introduction of the checklist, the number of interventions by the trainer per time decreased from 2.79 [1.85] to 0.43 [1.208] ($p=0.003$) and the number of instrument movements per time decreased from 11.90 [5.34] to 10.38 [5.16] ($p=0.04$).

Conclusions:

We have developed standardised checklists to be applied during elective and emergency laparoscopic tasks. The performance based self-administered intra-procedural checklist had a significant accelerating effect on the acquisition of technical skills when applied by novices during a standardised laparoscopic lab-based routine task and improved the task performance during a simulated laparoscopic emergency scenario.

The checklist enhanced the performance of surgical trainees and decreased the number of interventions of the trainer during laparoscopic cholecystectomy.

Chapter 1

1 Introduction and literature review

Chapter 1

1.1 Checklist

1.1.1 Background

A checklist has been defined as a comprehensive list of important actions or steps to be taken in a specific order. It is used to reduce failure by compensating for potential limits of human memory and attention and helps to ensure consistency and completeness in carrying out a task.

Checklists are often presented as lists with small checkboxes. A small tick or checkmark is drawn in the box after the item has been completed. Other formats are also used as aviation checklists generally consist of a system and an action divided by a dashed line, and lack a checkbox as they are often read aloud and are usually intended to be reused.

Excessive dependence of checklists may make it more difficult, especially when dealing with a time-critical situation, for example a medical emergency or an in-flight emergency. Rote-learning of checklists can be useful in the training and help integrate use of checklists with flexible problem solving techniques.

Stig Muller and R.H. Patel (2013) issued guidelines on the design of an ideal checklist (Table 1). In general, checklists should be regarded as a dynamic tool of quality control. The form and content should be audited regularly and amended based on the findings.

- **Chunking:** Group items that share a common factor
 Each chunked section should not contain more than nine items
- **Flow:** Items should be listed with a logical progression
- **Completion call:** each section of the checklist should be completed by a call/answer
- **Recency:** Place the most critical item at the beginning of the list
 (e.g. patient identity in the WHO checklist)
- **Redundancy:** Repeat critical items to ensure completion
 (e.g. patient identity in the WHO checklist)
- **Size:** Make the checklist as short as possible but as long as needed

Table 1 How to structure the content of a checklist

1.1.2 Applications of checklists

1.1.2.1 Non-medical applications of checklists

An example for checklist applications in non-medical fields is the use in quality assurance of software engineering to check process compliance, code standardization and error prevention. Another important example is the aviation checklist.

1.1.2.1.1 Use of checklists in aviation

1.1.2.1.1.1 Routine use

In aviation, the application of checklists has expanded to a tool for quality control from the original purpose of making sure that nothing is overlooked. Checklists are applied in flight operations, technical maintenance and repair, training for pilots, as well as for technical and aircraft personnel. Traditionally, checklists are designed to be carried out from the beginning to the end all at once. Segmented checklists, however, are constructed so that specific segments are completed at appropriate times which makes it more convenient to use. Turner and Huntley (1991) described the use and design of the before-takeoff and before-landing checklists.

Each checklist is divided into two sections:

- 1) The before-takeoff checklist is meant to be completed down to "final items" after the engine is being conducted, run-up and systems checks. This stopping point is convenient when there are takeoff delays or when the run-up area is not located at the end of the active runway. The final items has to be completed when it is number one for takeoff, with the exception of lights, camera, and action. These items are executed when the pilot is cleared onto the runway for takeoff.

To help make sure that the pilot has followed each step and he does not forget where he left off, a few announcements can be made out loud, even if he is alone in the airplane. After the run-up, he announces, "Before-takeoff checklist complete down to final items." When he is number one for takeoff, announce, "Before-takeoff checklist complete — lights, camera, action to go."

- 2) The before-landing checklist works much the same way. It should be completed to "final items" just before leaving cruise altitude, because these items are a distraction if the pilot attempts to execute them and reads the checklist while descending or entering the traffic pattern. The final items has to be completed after the landing gear, propellers, and flaps are positioned for landing.

The verbal responses are as follows: When the airplane is prepared for arrival, announcing "Before-landing checklist complete down to final items — gear, props, and flaps to go." When these remaining items have been accomplished, announcing, "Before-landing checklist complete."

The segmented checklist enhances the ability to manage the cockpit and comply with standard operating procedures.

Before-Takeoff Checklist:

- Auxiliary fuel pump — Off
- Flight controls — Free and correct
- Instruments and radios — Checked and set
- Landing gear position lights — Checked
- Altimeter — Set
- Directional gyro — Set
- Fuel gauges — Checkedtr
- Trim — Set
- Propeller — Exercise
- Magnetos — Checked
- Engine idle — checked

- Flaps — As required
- Seat belts/shoulder harnesses — Fastened
- Parking brake — Off

Final items:

- Doors and windows — Locked
- Mixture — Full rich unless above 3,000 feet msl
- Lights — Landing, taxi, strobes on
- Camera — Transponder on
- Action — Engine instruments checked

Before-Landing checklist:

- Fuel selector — Fullest tank
- Directional gyro — Aligned with magnetic compass
- Seat belts/shoulder harnesses — secure
- Mixture — Full rich unless airport above 3,000 feet msl (mean sea level)
- Cowl flaps — As required

Final items:

- Landing gear — Down
- Propeller — High rpm
- Flaps — As required

1.1.2.1.1.2Emergency use

In Pilot's Handbook of Aeronautical Knowledge (2009), checklists are used in pilot training for standardization of operating procedures and for training for reaction patterns to unexpected events. A training checklist for unexpected events (Table 2) develops a safe reaction pattern to those events in the cockpit. Training with this checklist in a simulated environment, prepares the trainee to handle emergencies in real flight.

Adapted from Operations Guide to Human Factors in Aviation issued by the Flight Safety Foundation European Advisory Committee.

Remain calm, do not rush.

Fly the aircraft, maintain controlled flight: altitude, speed, height.

Navigate, avoid terrain, leave bad weather, and check fuel.

Communicate with your crew and air traffic control; they may be able to help.

Review actions already taken.

Manage the immediate threat.

DECIDE

D – Detect Gather all the facts and information about the event. What still works, what does not?

E – Estimate Assess and form an understanding of the situation. Have you seen something similar? Consider possible solutions

C – Choose the safest practical solution

I – Identify the actions necessary to carry out the safest option.

Have you done this before? What are the expected outcomes?

D – Do Act, carry out the safest option

E – Evaluate the changes due to the action; reassess the situation, revise the plan if necessary.

Review the situation. If it has changed sufficiently, return to the aircraft emergency checklist.

Table 2 Training checklist for unexpected events in aviation

1.1.2.2 Medical application of checklist

1.1.2.2.1 WHO surgical checklist

The surgical checklist has been introduced in the WHO guidelines for safer surgery. Haynes et al (2009) in a global multicentre study proved that the implementation of the checklist reduced mortality and complications in surgical patients. The 19 items surgical checklist ensure that essential information such as patient identity, the type of procedure and its risks (e.g. estimated blood loss) and other patient factors (e.g. allergies) are brought to the team's attention. In addition, equipment issues and anaesthetic concerns are checked. This essential information is accompanied by an introduction of all team members by name and role in the operating theatre. Weiser et al (2010) proved that the implementation of the checklist was associated with a greater than one-third reduction in complications among patients undergoing urgent non-cardiac surgery in a diverse group of hospitals. They suggested the use of the WHO Surgical Safety Checklist in urgent operations as it is feasible and should be considered.


 World Health Organization			SURGICAL SAFETY CHECKLIST (FIRST EDITION)		
Before induction of anaesthesia		Before skin incision		Before patient leaves operating room	
SIGN IN		TIME OUT		SIGN OUT	
<input type="checkbox"/> PATIENT HAS CONFIRMED • IDENTITY • SITE • PROCEDURE • CONSENT		<input type="checkbox"/> CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE		NURSE VERBALLY CONFIRMS WITH THE TEAM:	
<input type="checkbox"/> SITE MARKED/NOT APPLICABLE		<input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM • PATIENT • SITE • PROCEDURE		<input type="checkbox"/> THE NAME OF THE PROCEDURE RECORDED	
<input type="checkbox"/> ANAESTHESIA SAFETY CHECK COMPLETED		ANTICIPATED CRITICAL EVENTS		<input type="checkbox"/> THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)	
<input type="checkbox"/> PULSE OXIMETER ON PATIENT AND FUNCTIONING		<input type="checkbox"/> SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?		<input type="checkbox"/> HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)	
DOES PATIENT HAVE A: KNOWN ALLERGY?		<input type="checkbox"/> ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?		<input type="checkbox"/> WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED	
<input type="checkbox"/> NO <input type="checkbox"/> YES		<input type="checkbox"/> NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?		<input type="checkbox"/> SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT	
DIFFICULT AIRWAY/ASPIRATION RISK?		HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?			
<input type="checkbox"/> NO <input type="checkbox"/> YES, AND EQUIPMENT/ASSISTANCE AVAILABLE		<input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE			
RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?		IS ESSENTIAL IMAGING DISPLAYED?			
<input type="checkbox"/> NO <input type="checkbox"/> YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED		<input type="checkbox"/> YES <input type="checkbox"/> NOT APPLICABLE			

Figure 1 WHO checklist 1st edition

1.1.2.2.2 Advanced Trauma Life Support

This is a training program in the management of acute trauma cases. It is commonly abbreviated as ATLS. The program has been adopted worldwide in more than 60 countries and its goal is to teach a simplified and standardized approach to manage trauma patients. It was originally designed for emergency situations where only one doctor and one nurse are present, ATLS is now widely accepted as the standard of care for initial assessment and treatment in trauma centers. The premise of the ATLS program is to treat the greatest threat to life first, but also the lack of a

definitive diagnosis should not slow the application of treatment for life-threatening injury, with the most time-critical interventions performed early.

The primary survey is the first and key part of the assessment of patients presenting with trauma. During this time, life-threatening injuries are identified and simultaneously resuscitation begins. ABCDE checklist is used as a memory aid for the order in which problems should be addressed. The 5-checklist components of this schema are 1) Airway maintenance with cervical spine protection, 2) Breathing and ventilation, 3) Circulation with hemorrhage control, 4) Disability/Neurologic assessment and 5) Exposure and environmental control. It is known that ATLS teaches a standardized and established approach to the trauma patient in the emergency room in form of a simple algorithm that can be lifesaving.

1.1.2.2.3 Intra-procedural checklist

There are only few previous studies that have looked at the effect of checklists during routine surgical procedures. Intra-procedural checklist has been loosely defined by different authors. Robb WB et al (2012) studied the effect of an intraoperative surgical checklist (ISC) on decreasing the rates of conversion from laparoscopic to open cholecystectomy. This study documented the introduction of a 10-step intraoperative surgical checklist (ISC) in form of aid memoires dividing the procedure into steps in order to standardize performance, decision-making, and training during laparoscopic cholecystectomy. In 2004, a standardized intraoperative surgical checklist (ISC) was introduced by a single consultant surgeon for the performance of laparoscopic cholecystectomies. The introduction of the ISC was motivated by a desire to standardize the operative technique used in every

operation, ensure consistency and reproducibility in operative decision-making, and to minimize the risk of operative complications.

Five years after the introduction of the ISC, data were collected from the records and operative notes of all patients who underwent a laparoscopic cholecystectomy over the 10-year period from 1999 to 2008. Data on gender, age, American Society of Anaesthesiology grade, biliary complications, conversion to open cholecystectomy, and severity of gallbladder pathology found at operation were all recorded. Data were then compared between the two periods: 1999–2003 (period 1) prior to the introduction and use of the ISC and 2004–2008 (period 2) during which the ISC was utilized for all laparoscopic cholecystectomies. Data on protocol compliance were not systematically recorded; however, all cases were overseen by the senior author who designed and introduced the ISC and therefore assumed to be near 100 %. The grade of severity of each procedure was noted.

As results in total, 637 laparoscopic cholecystectomies were performed, 277 during period 1 and 360 during period 2. Risk factors for conversion (gender, age, previous abdominal surgery, and severity of gallbladder pathology) were not significantly different in the two periods studied. The overall conversion rate to open cholecystectomy fell significantly in period 2 ($p=0.001$). Subgroup analysis also showed a significant reduction in conversion rates in female patients ($p=0.002$) and patients with grades III and IV gallbladder disease ($p=0.001$). In brief, the introduction of the 10-step surgical checklist (Table 3) as aid memoire was temporally related to the reduced conversion rates to open cholecystectomy in this study.

<p>Step1 “Patient position and port site placement”</p> <p>Optical port subumbilical–open Hasson technique</p> <p>Supraumbilical camera port in obesity with pendulous abdomen</p> <p>Establishment of pneumoperitoneum</p> <p>Patient is then positioned in reverse Trendelenburg and with the right side raised</p> <p>Placement of further trocars is under direct vision. The abdominal wall is transilluminated to avoid injury to the abdominal wall vasculature</p> <p>Ten millimetre epigastric trocar, 2 finger breadths inferior to the xiphisternum , placed under direct vision, entering the abdomen to the right of the falciform ligament</p> <p>Two 5-mm trocars placed under direct vision. Lateral trocar placed above the level of the umbilicus anterior to the anterior axillary line, “middle” 5-mm trocar placed 2–3 finger breadths below the costal margin in the midclavicular line</p> <p>Lateral trocar used to grasp and retract the gall bladder cranially and the other two trocars used as working trocars</p>
<p>Step2 “Inspection, retraction, and adhesiolysis”</p> <p>Inspection of the RUQ Gall bladder fundus identified, grasped, and gently retracted cranially via the lateral port site</p> <p>Omental and other adhesions lysed</p>
<p>Step3 “First verbal agreement of anatomy”</p> <p>Visualization and verbal agreement of anatomy including identification of Rouviere’s sulcus, the apparent position of common bile duct (CBD), and the retraction of Hartmann’s pouch</p> <p>Application of lateral and caudal traction on Hartmann’s pouch</p>
<p>Step4 “Opening of the peritoneal envelope”</p> <p>The peritoneal envelope is opened medially and laterally</p> <p>Particular attention being paid to the lateral peritoneal envelope which is opened first to release Hartmann’s pouch</p>
<p>Step5 “Critical view of safety” 23, 24 and second verbal confirmation</p> <p>The critical view of safety is developed by mobilizing the gallbladder neck from the gallbladder bed of the liver allowing the complete unfolding of Calot’s triangle</p> <p>Second verbal confirmation of anatomy is then performed</p> <p>The operating surgeon asks for verbal agreement from first assistant as to the identification of Hartmann’s pouch, the cystic duct and artery, and the position of the CBD</p>
<p>Step6 “Calot’s triangle completion”</p> <p>Dissection of Calot’s triangle is completed both laterally and medially with clear identification of the cystic duct and the cystic artery</p>
<p>Step7 “Final verbal confirmation”</p> <p>A final formal verbal confirmation of agreed anatomy is performed prior to sequential division of cystic duct and artery</p>
<p>Step8 “Dissection of gallbladder”</p> <p>Hook diathermy is used for dissection of the gallbladder from the liver bed</p> <p>Hemostasis of the liver bed is checked, and both irrigation and drainage are considered prior to detachment of the gallbladder</p> <p>Again, verbal agreement and confirmation are made by the operating surgeon and first assistant regarding the adequacy of hemostasis and the need for drainage</p>
<p>Step9 “Removal of gallbladder”</p> <p>The gallbladder is routinely removed using an endobag through the epigastric 10-mm port site</p>
<p>Step 10 “Lastlook”</p> <p>A final lastlook is performed prior to removal of the ports under direct vision</p> <p>The abdomen is completely deflated</p> <p>Ten-millimeter port sites are all routinely closed with a 0 Maxon fascial stitch</p>

Table 3 Ten-step protocol for laparoscopic cholecystectomy

Ziewacz JE et al (2012) studied the design, development, and implementation of a checklist for intraoperative neuro-monitoring changes. The purpose of this study was to provide an evidence-based algorithm (Figure 2) for the design, development, and implementation of a new checklist for the response to an intraoperative neuro-monitoring alert during spine surgery.

An algorithm for neurosurgical checklist creation and implementation was developed. A multidisciplinary team surveyed the literature for the best practices for how to respond to an intraoperative neuro-monitoring alert. All stakeholders then reviewed the evidence and came to consensus regarding items for inclusion in the checklist.

A checklist for responding to an intraoperative neuro-monitoring alert was devised (Figure 3). It highlighted the specific roles of the anaesthetist, surgeon, and neuro-monitoring personnel and encouraged communication between teams. It focuses on the items critical for identifying and correcting reversible causes of neuro-monitoring alerts. As a conclusion to this study, authors developed an evidence-based algorithm for the design, development, and implementation of checklists in neurosurgery and have used this algorithm to devise a checklist for responding to intraoperative neuro-monitoring alerts in spinal surgery.

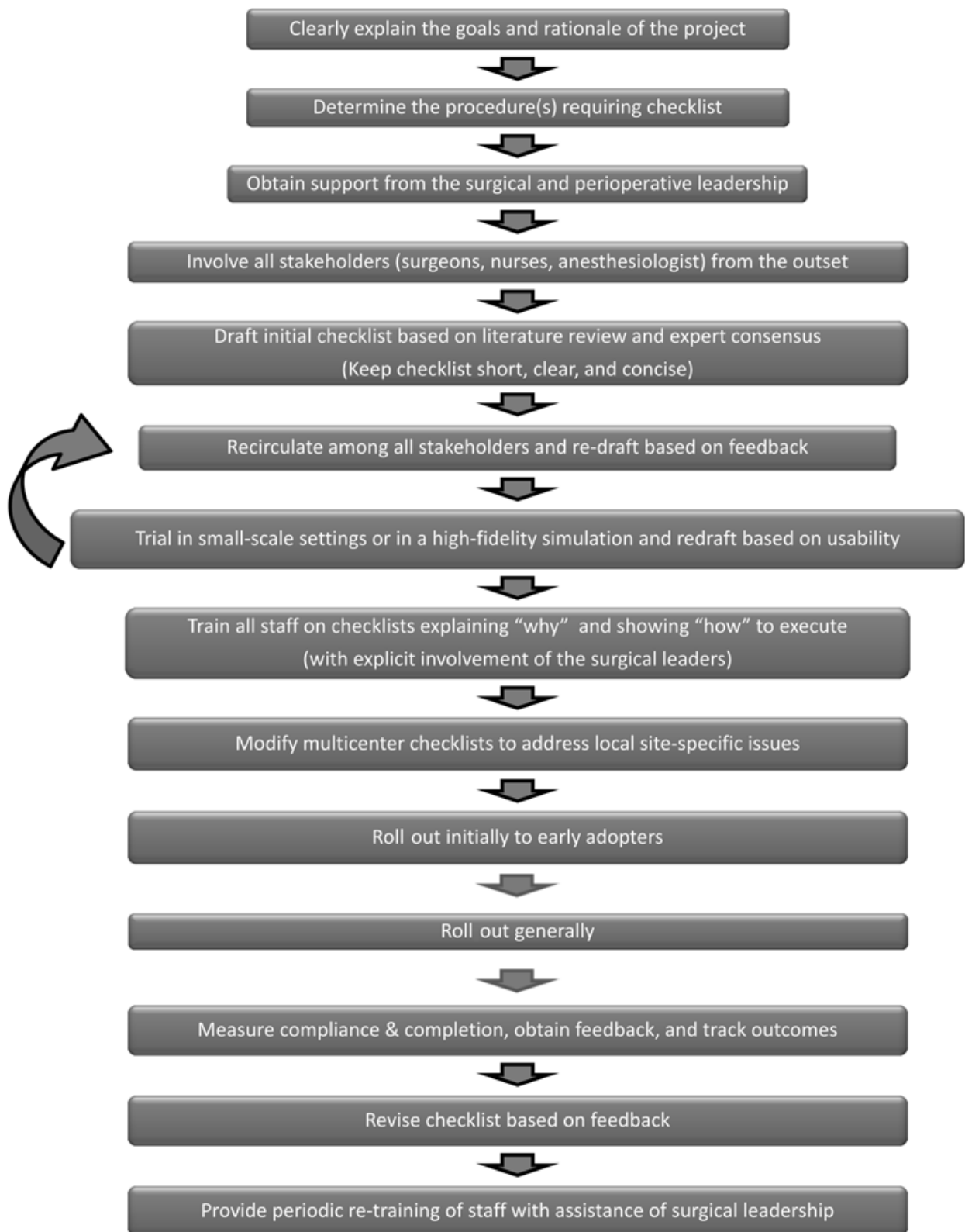


Figure 2 Algorithm highlighting key steps for creation of a neurosurgical checklist

Checklist for Neuromonitoring (MEP) Alert in Patients with Myelopathy or Deformity

Spine Surgeon:

- ☐ Stop current manipulation
- ☐ Assess field for structural cord compression (misplaced hardware or bone graft, osteophytes, or hematoma)
 - ☐ Perform further decompression if stenosis is present
- ☐ Consider reversing correction of a spinal deformity

Neurophysiologist:

- ☐ Repeat trials of MEPs and SSEPs to rule out potential false positive
- ☐ Check all leads to make sure no pull-out, may add leads in proximal muscle groups if possible
- ☐ Assess the pattern of changes
 - ☐ Asymmetric changes (associated with cord or nerve root injury)
 - ☐ Symmetric changes (associated with anesthetic or hypotension issues)
- ☐ Quantify improvement and communicate to the surgical team

Anesthesiologist:

- ☐ Check if neuromuscular blockade (muscle relaxant) given
 - If yes, ☐ Check train of four (TOF)
- ☐ Verify that no change in anesthetic administration occurred
- ☐ Assess anesthetic depth
 - ☐ BP ☐ RR ☐ HR ☐ BIS monitor (if available)
- ☐ Restore or maintain blood pressure (goal mean arterial pressure of 90-100)
- ☐ Check Hemoglobin/Hematocrit (goal hemoglobin >9-10)
- ☐ Check temperature and I/O's for adequate resuscitation
- ☐ Check extremity position in case of plexus palsy
- ☐ Lighten depth of anesthesia
 - ☐ Reduce to 1/3 MAC or temporarily eliminate inhaled agents (i.e. desflurane)
 - ☐ Reduce intravenous anesthetics such as propofol (which may accumulate systemically during the case and blunt MEPs)
 - ☐ Add adjuvant agents such as Ketamine to permit reduction of MEP suppressive agents (i.e. propofol and inhalational anesthetics)

IF No Change:

- ☐ Increase MAP >100
- ☐ Consider Steroid Administration
- ☐ Consider Wake-up test
- ☐ Consider Aborting surgery
- ☐ Consider Calcium Channel Blocker (topical to cord or iv)

*The checklist assumes baseline anesthetic regimen is 1/3-1/2 MAC of halogenated anesthetic (desflurane) and TIVA (total intravenous anesthesia) with propofol +/- ketamine.

Figure 3 Checklist for the response to an intraoperative neuromonitoring alert

BIS = bispectral index; BP = blood pressure; HR = heart rate; I/O = input/output; MAC = minimum alveolar concentration; MAP = mean arterial pressure; MEP = motor evoked potential; RR = respiration rate; SSEP = somatosensory evoked potential.

1.1.2.2.4 Crisis checklists

Operating-room crises (e.g., cardiac arrest, hyperthermia and massive haemorrhage) are common events but their successful management can be difficult. Only few studies have tried to develop checklists that can be used during crisis in the operating rooms in order to decrease errors and improve patient safety.

A research study was done by John E Ziewacz et al (2011) to develop and pilot a tool to improve adherence to lifesaving measures during operating room crises. They identified 12 of the most frequently occurring operating room crises and corresponding evidence-based metrics of essential care for each (46 total process measures). They developed checklists for each crisis based on a previously defined method, which included literature review, multidisciplinary expert consultation, and simulation. After development, 2 operating room teams (11 participants) were each exposed to 8 simulations with random assignment to checklist use or working from memory alone. Each team managed 4 simulations with a checklist available and 4 without. One of the primary outcomes measured through video review was failure to adhere to essential processes of care. Participants were surveyed for perceptions of checklist use and realism of the scenarios. The study of crisis checklists for operating room has proved that checklist use can significantly improve safety and crisis management.

Alexander F. Arriaga et al (2013) worked on developing a tool to improve adherence to evidence-based best practices during emergency events. In this study, operating-room teams from three institutions (one academic medical centre and two community hospitals) participated in a series of surgical-crisis scenarios in a simulated operating room. Each team was randomly assigned to manage half the

scenarios with a set of crisis checklists and the remaining scenarios from memory alone. The primary outcome measure was failure to adhere to critical processes of care. Participants were also surveyed regarding their perceptions of the usefulness and clinical relevance of the checklists. The scenarios were grouped into three categories to provide samples large enough for analysis: scenarios that were directly related to algorithms for advanced cardiac life support (asystolic cardiac arrest, ventricular fibrillation, and unstable tachycardia), scenarios related to algorithms for advanced cardiac life support and preceded by a precode condition (haemorrhage followed by ventricular fibrillation or clinically significant hypoxemia and hypotension followed by unstable bradycardia), and other crisis scenarios (malignant hyperthermia, anaphylaxis, haemorrhage, and air embolism). Overall, every team had a lower failure rate for adherence to key processes when the crisis checklists were available. In this simulated study, checklist use was associated with significant improvement in the management of operating-room crises which have the potential to improve surgical care.

1.1.2.2.5 Other examples of medical checklists

Checklists can also be applicable in daily medical practice apart from operating theatres. Dubose et al (2010) used a quality rounds checklist (QRC) on a busy trauma intensive care unit. It contained 16 items focussing on prophylaxis of ICU complications such as ventilator associated pneumonia (VAP), deep vein thrombosis and venous catheter infections. After 1 year, the rate of VAPs was reduced by 24% and the daily use of the quality rounds checklist had led to a sustained and cost-effective improvement in the complication rate.

1.1.2.3 Comparing aviation checklist to surgical checklist

Stig Muller and R.H. Patel (2013) wrote on the safe surgery checklists through lessons learned from aviation. They argued that the training for implementation of the surgical checklist is preferably done in a simulated environment. An actual team should train in a simulated environment comparable with the everyday environment. After a theory briefing, the team observe examples with the option of film clips of “How to . . .” and “How not to do a surgical checklist”. The team then perform a series of checklists interrupted by debriefings. Ideally, two teams train in parallel and observe each other’s checklist exercises and participate in the debriefings. This training model is widely used as the surgical checklist is currently implemented worldwide. Simulation training is an effective model for training of the surgical checklist because it allows repetitive exercise with interruptive debriefings and the focussed attention of the team.

The reaction pattern is a sequence of actions and/or items to check predefined by their importance in order to resolve the situation. Once a technical problem is identified, a specific checklist for the particular system can be gone through. In principle, a problem or event triggers a response or action algorithm that includes all factors that might be overlooked in a stressful situation. The WHO checklist is one of the tools available for improving patient safety. However, the checklist principle is derived from the aviation industry, it is applicable to new areas in patient care and training of surgeons.

The Advanced Trauma Life Support (ATLS) concept resembles an emergency checklist, whereby the mode of action is predefined by the factors determining outcome. In addition, abbreviations are used in ATLS (ABCDE) as in the unexpected

events checklist in aviation (DECIDE, Table 2) to help with memorizing the algorithm. The capacity of the human mind is limited in stressful situations as experience in the aviation industry shows. This task saturation has been causal to accidents, for example, when unexpected events or distractions disturb the routine so that some tasks are overlooked, leading to disaster. Surgeons can also suffer from task saturation in a routine operation when unexpected events and distractions occur.

In brief, checklists have been adapted and utilized in medical practice. The WHO checklist for safer surgery and sporadically in other areas. The concept of checklists is a familiar concept in medicine as in the ATLS system. However, the aviation industry has implemented checklists in almost every process from flight operations, maintenance and human factors training to flight training. It is not believed that checklists prevent all human errors and accidents but it can decrease errors if it is followed systematically. If the checklist appeared to be too long, it can be subsequently divided into several parts in order to facilitate resumption of the checklist in case of interruption or emergency.

1.2 Feedback

1.2.1 Definition

Kluger and DeNisi (1996) defined feedback as “actions taken by an external agent to provide information regarding some aspect(s) of one’s task performance”. Feedback can also be defined as the process in which the effect or output of an action is 'returned' (fed-back) to modify the next action.

1.2.2 History

Feedback is essential to the working and survival of all regulatory mechanisms found throughout living and non-living nature, and in man-made systems such as education system and economy. The term 'feedback' is taken from cybernetics with self-regulating systems. In its simplest form, feedback is a self-stabilising control system.

Self-regulating mechanisms have existed since antiquity, and the idea of feedback had started to enter economic theory in Britain by the eighteenth century, but it wasn't at that time recognized as a universal abstraction and so didn't have a name. Rocket engineers developed the concept of feedback in the 1940s when the system used information to reach its goal.

1.2.3 Importance of feedback

In a review of 196 studies of feedback in the classroom, Hattie (1999) described feedback as one of the most influential factors in learning, as powerful as the quality and quantity of instruction. Jill Gordon (2003) noted that feedback is vital and that the most effective and helpful feedback is based on observable behaviours.

Moreno (2004) regarded feedback as crucial to improving knowledge and skill acquisition. Jack Ende (1983) mentioned that the importance of feedback in clinical medical education extends beyond pedagogy, and without feedback good performance is not reinforced and mistakes are uncorrected. Feedback is an essential part of education and training programmes.

Hesketh and Laidlaw (2003) suggested that learners should be encouraged to 'seek feedback themselves from others... feedback actually works best when it is sought'. It is also important for the development of learners in healthcare, and helps them to maximise their potential at different stages of training, raise their awareness of strengths, and identify actions to be taken to evaluate and improve their own and the performance of others.

Parsloe also suggested the importance of feedback, as part of effective communication, without which the learner may repeat activities without any improvement in performance:

"Communication is a two-way process that leads to appropriate action...in the context of developing competence, it is not an exaggeration to describe feedback as 'the fuel that drives improved performance.'" (Parsloe 1995)

1.2.4 Classifications of feedback

1.2.4.1 Negative/positive classification

Feedback can be divided into negative and positive. Each type can be subdivided into past and future.

Negative feedback

- Negative past feedback is the corrective comments and assessments about past behaviour. These are things that are not rightly done.
- Negative future feedback or feed-forward is corrective comments about future behaviour or things that do not need to be repeated again.

Positive feedback

- Positive past feedback is affirming comments about past behaviour. These are things that were rightly done and have to be repeated.
- Positive future feedback or feed-forward is affirming comments about future behaviour. These are things that would improve performance in the future.

1.2.4.2 Carl Rogers classification

Humanist Carl Rogers who was an influential American psychologist listed five types of feedback:

- Evaluative:

Evaluation can be personal or behavioural.

In the personal evaluation, the observer is judging the whole person and not only his action. A positive personal evaluation can be very flattering, although the negative personal evaluation can sometimes be very uncomfortable.

In the behavioural evaluation, the actions are being judged and not the whole person. This makes it much easy to accept in case of a negative behavioural evaluation.

- Interpretive:

By interpreting the other person, the understanding of what has been said or done is tested. A discussion on the ideas for correction and questions on the other person's behaviour allow him/her to agree with the interpretation of the person giving feedback for future improvement. Interpretation can also be very flattering as it shows the other person an active interest in his behaviour.

- Supportive:

In supportive evaluation, someone seeks feedback to support the other person in some which is generally a flattering idea. Telling him that he/she is good even if this is not totally true to help supporting his/her ego. Although some criticism may be involved, but the idea is to help the other person change in a positive way.

- Probing:

Asking more specific and deep questions to find more information.

- Understanding:

At this level of evaluation, it is important to understand the person with a closer way and not only his performance.

1.2.4.3 Intrinsic/extrinsic classification

The feedback can also be classified into intrinsic and extrinsic:

- Intrinsic feedback:

It may consist of a self-generated feedback, or in the form of self-assessment in order to improve own performance. The role of self-administered feedback has been well recognised, and different authors studied its effect and application in surgical training.

- Extrinsic feedback:

This type comes from an external source as when provided from a teacher or supervisor. Most feedback in use are of this type.

1.2.5 Models of giving feedback

Pendleton (1984) who was a social psychologist, developed a common model for giving feedback in clinical education and called it "Pendleton's rules". There are five components to this rule:

1. Beginning the feedback process by asking the learner what went well, in the form of a self-assessment.
2. Than providing further discussion of what went well led by the person giving feedback.
3. The learner states what could be improved and how it can be improved again as self-assessment.
4. The observer states how it can be improved.

5. Discussing with the learner what should be developed and an action plan for improvement is made.

These rules are highlighting the positive points at first in order to create a safe environment. At the beginning, the learner identifies his positives. Then followed by the facilitator reinforcing these positives and discussing skills to achieve them. The next step is to ask: "How can it be improved? First by the learner and then by the person giving feedback. The advantage of this method is that the learner's strengths are discussed first. Avoiding a discussion of weaknesses right at the beginning prevents defensiveness and allows reflective behaviour in the learner.

Pendleton's rules are not a method for analysing consultations. The rules may be applied to any of the skills or tasks being analysed, so that each interaction is seen to be fair, and so the learner can express his own thoughts and feelings. As with any skill, practising the components enhances development and increases confidence. Although this model provides a useful framework, there have been some criticisms of its rigid and formulaic nature.

Strengths of Pendleton's Rules:

- Through self-assessment, it offers the learner the opportunity to evaluate his own practice and behaviour.
- Allows positive observations by the learner to be built upon by the observer.
- Ensures strengths are given parity with weaknesses.
- Mentions specifics and target future improvements.

Difficulties with Pendleton's Rules:

- The loss of some important points while separating the positive and weakness points.
- Feedback on the points that had to be improved is held back until part way through the session. The learner may be anxious to explore these as priority which may reduce the effectiveness of feedback on strengths.
- Holding many separate conversations covering the same performance can be time consuming and inefficient.

Interacting while giving a feedback helps to develop a dialogue between the learner and the trainer as well as helping the learner take responsibility for his/her own learning through self-assessment. A structured approach ensures that both the trainer and the trainee know what is expected from them. Typically, the trainer starts with the trainee's agenda and asks what help is needed to achieve a specific goal. Next step, is to encourage the trainee to problem solve. In this way, feedback is kept descriptive, balanced and objective.

1.2.6 Modes of application of feedback

1.2.6.1 Verbal feedback

The most common medium for giving feedback is the verbal feedback given during the task performed by the trainee. Both positive and negative verbal feedback could be potent stimulants for improved performance and motivation. Studies proved that verbal feedback from an expert instructor led to lasting improvements in technical skills performance.

1.2.6.2 Paper feedback

Post-procedural formative assessment in the form of paper feedback is the current gold standard in providing feedback to surgical trainees for the reasons of being cheap, fast, and easily reproducible. The main limitation of paper feedback is its retrospective post-procedural nature requiring the information being retrieved from memory, often resulting in the loss of finer aspects to feedback.

1.2.6.3 Audio feedback

The development of MP3 players is in recent years widely used to provide a new method of giving feedback- the podcast. Students appear to find it a positive experience, giving them quick and detailed feedback they can listen to more than once in their own time, which seems more personal than written comments.

Researches proved that students appreciate audio feedback because it is perceived as being of good quality; easier to understand; has more depth; and is more personal than written feedback. However, audio feedback requires a large file size, slow to be distributed, requires digital access to listen to feedback, and has no visual element.

1.2.6.4 Video feedback

The effect of video feedback has been well recognized. A study indicated that self-observation of performance promotes acquisition and transfer of motor skill knowledge. Video feedback can be used as a tool for assessment and it can improve the surgical task performance.

Henderson and Phillips (2015) mentioned that students found video-based feedback more individualised and personalised than paper feedback. The limitation of video feedback is that it requires a large file size and greater staff workload to produce the feedback.

1.2.6.5 Screencasts

It is particularly useful for demonstrating; as multiple students can access screencasts at the same time. Screencasting allows instructors to provide students with in-depth feedback and/or evaluation. Darrell J.R. Evans (2011) mentioned that the development screencasts to accompany lecture sessions were useful addition to learning for most students and not simply an innovation for technology.

1.2.6.6 Online feedback

One of the advantages of this type of feedback is that it is immediate, and can be accessed by students at a time of their choosing. The feedback can be more or less sophisticated, with software able to go beyond yes-and-no answers to feedback which provides constructive suggestions for improvement. Online feedback has the advantage of flexibility, and the possibility of links to other online resources.

1.2.7 Linking feedback to the learning process

It is very important to ensure that the feedback given to the learner is aligned with the overall learning outcomes of the programme, teaching session or clinical activity in which the learner is engaged. Giving feedback can be seen as part of experiential learning. Kolb (1984) proposed that the learning process begins as experiential or

the practical activities that the learner does himself, then the ideas can be modified later on through his experiences.

As a part of professional development, there is usually a shift from novice to expert regarding the experiences. This can also demonstrate Kolb's cycle (Figure 4). The learning cycle requires four kinds of abilities or learning contexts:

- Concrete experience – learners are enabled and encouraged to become involved in new experiences.
- Reflective observation – gives learners time to reflect on their learning.
- Abstract conceptualisation – learners must be able to form and process ideas and integrate them into logical theories.
- Active experimentation – learners need to be able to use theories to solve problems and test theories in new situations.

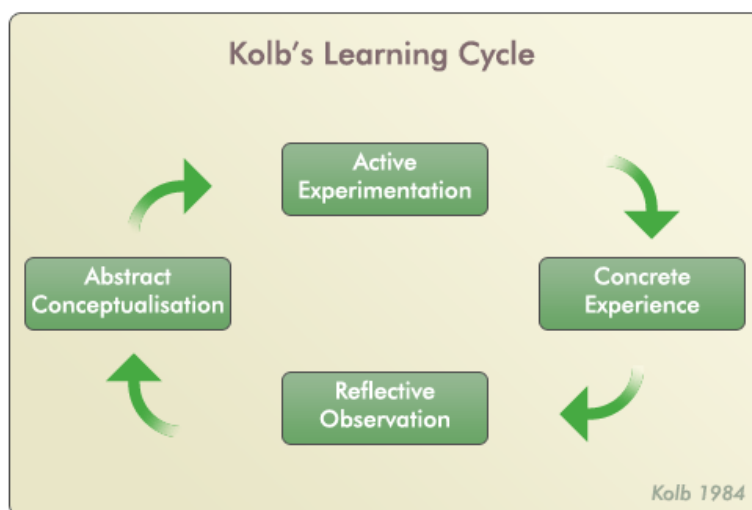


Figure 4 Kolb's learning cycle

1.2.8 Barriers to give effective feedback

Hesketh and Laidlaw (2002) identify a number of barriers to giving effective feedback in the context of medical education:

- Damaging the trainee–trainer relationship by upsetting the trainee.
- A fear of giving more negative feedback than a positive one,
- The trainee being defensive when receiving criticism resulting in disregarding the negative feedback in the future.
- A generalised and non-specific feedback.
- Feedback without a specific guidance on how to improve performance.
- Inconsistent feedback from multiple sources.
- A lack of respect for the person giving the feedback.

Parsloe (1995) who is the author of several coaching books and the director of the Oxford school of coaching and mentoring, has also identified that feedback must be given sensitively and appropriately. He mentioned that giving feedback is easy when the teachers are taking the relationship aspect of their roles and have been working for some time with their learners.

Learners are often dependent on trainers and it is easy to dismiss issues of organisational power and authority that underpin work relationship. When it is aiming to develop a supportive, relaxed, informal environment with a respect to the person giving feedback, it will definitely influence feedback by a positive way.

There are also some aspects between the person giving feedback and the recipient as differences in sex, age or educational and cultural background. These are not necessarily obstacles, but they may make feedback strained and demotivating.

1.2.9 Feedback in medicine

1.2.9.1 Feedback in medical education

Feedback is central to medical education in promoting learning and ensuring that standards are met. It provides students or trainees with an accurate perception of their own performance as well as enhancing their self-awareness.

Mariana G Hewson and Margaret L Little (1998) focused on clinician-teachers, a population that is in need of being studied, particularly because they are the people who give much of the feedback in medical training. Giving feedback, whether reinforcing or corrective, is an essential component of clinical education. When done well, even corrective feedback is seen as helpful and highly appreciated.

Delva D et al (2013) wrote on encouraging trainees to seek feedback. They conducted focus groups of faculty and trainees exploring experiences in giving and receiving feedback, feedback-seeking, and suggestions to support feedback-seeking. It has been proven that trainee feedback-seeking is influenced by multiple factors requiring attention to both faculty and learner roles: the learning climate/culture, relationships with supervisors, quality of feedback and emotional response to feedback. These four influences appeared to interact to support or discourage feedback-seeking.

1.2.9.2 Patient feedback

It is used by many healthcare organisations to bring improvements. Patient feedback consists of views and opinions of patients and service users on the care they have experienced. The first step is to find out what patients and service users think by asking about their experiences. The second step, is to have a guide which is written

for healthcare staff who care about patient experience and engagement and want to improve care for patients and in order to bring improvements to healthcare services.

1.2.9.3 Feedback in surgery

As a part of revalidation (the process by which all doctors practising in the UK can demonstrate to the General Medical Council (GMC) that they are up to date and fit to practise medicine), the Royal College of Surgeons of Edinburgh (RCSEd) made the collection of colleagues and patients feedback as one of the pieces of supporting information needed for revalidation. It is not a stand-alone tool to assess performance and any conclusions about a surgeon's practice should be based on all supporting information. Key points for surgeons:

- Feedback from patients (Figure 5) and colleagues (Figure 6) should be collected and included in the appraisal discussion at least once per revalidation cycle, normally every five years
- Feedback will normally be collected through standard questionnaires that comply with GMC guidance.
- The patients and colleagues chosen to provide feedback should be representative of the whole scope of the surgeon's practice.
- The surgeon should reflect on the feedback provided to him and act as appropriate. All actions should be recorded in his personal development plan.
- An important aspect of the feedback exercise is self-assessment. A self-assessment questionnaire of his own performance should be completed and used as a supplement to the information provided through the patient and colleague feedback.

- The results of the feedback exercise should be given to him, ideally before his appraisal, by someone who has been trained in interpreting and providing feedback.

Patient questionnaire
for Dr _____
**Regulating doctors
Ensuring good medical practice**

Licensed doctors are expected to seek feedback from colleagues and patients and review and act upon that feedback where appropriate.

The purpose of this exercise is to provide doctors with information about their work through the eyes of those they work with and treat, and is intended to help inform their further development.

Please do not write your name on this questionnaire.

Please base your answers only on the consultation you have had today.

Please mark the box like this ☒ with a ball point pen. If you change your mind just cross out your old response and make your new choice.

Please write today's date here: / /

1 Are you filling in this questionnaire for:

☐ Yourself

☐ Your child

☐ Your spouse or partner

☐ Another relative or friend

If you are filling this in for someone else, please answer the following questions from the patient's point of view.

2 Which of the following best describes the reason you saw the doctor today? (Please tick all the boxes that apply)

☐ To ask for advice

☐ Because of an ongoing problem

☐ For treatment (including prescriptions)

☐ Because of a one-off problem

☐ For a routine check

☐ Other (please give details)

3 On a scale of 1 to 5, how important to your health and wellbeing was your reason for visiting the doctor today?

Not very important

☐ 1

☐ 2

☐ 3

☐ 4

Very important

☐ 5

4 How good was your doctor today at each of the following? (Please tick one box in each line)

	Poor	Less than satisfactory	Satisfactory	Good	Very good	Does not apply
a Being polite	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b Making you feel at ease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c Listening to you	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d Assessing your medical condition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e Explaining your condition and treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f Involving you in decisions about your treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g Providing or arranging treatment for you	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Figure 5 RCSEd patient questionnaire

Colleague questionnaire
for Dr _____
**Regulating doctors
Ensuring good medical practice**

Licensed doctors are expected to seek feedback from colleagues and patients and review and act upon that feedback where appropriate.

The purpose of this exercise is to provide doctors with information about their work through the eyes of those they work with and treat, and is intended to help inform their further development.

Please do not write your name on this questionnaire.

Please answer all the questions. If you feel you cannot answer any question, please tick 'Don't know'.

Please mark the box like this ☒ with a ball point pen. If you change your mind just cross out your old response and make your new choice.

Please write today's date here: / /

Please rate your colleague in each of the following areas by ticking one box in each line.

		Poor	Less than satisfactory	Satisfactory	Good	Very good	Don't know
1	Clinical knowledge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Diagnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Clinical decision making	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Treatment (including practical procedures)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Prescribing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Medical record keeping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Recognising and working within limitations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Keeping knowledge and skills up to date	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Reviewing and reflecting on own performance	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Teaching (students, trainees, others)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Supervising colleagues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12	Commitment to care and wellbeing of patients	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13	Communication with patients and relatives	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14	Working effectively with colleagues	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15	Effective time management	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Figure 6 RCSEd colleague questionnaire

In order to compare the effect of a verbal feedback from an expert to a self-accessed one about motion efficiency in surgical task performance, Porte Mc et al (2007) examined the effectiveness of computer-based video training, different types of computer-based motion efficiency feedback, and expert feedback on learning of a basic technical skill (suturing and knot-tying skills) in medical students. The first group received computer-generated feedback about the economy of their movements. The second group received the same motion economy feedback, as well as expert reference values, and the third group received verbal feedback from an expert. Only the third group showed retention of skill on delayed performance testing. The results proved that verbal feedback from an expert instructor led to lasting improvements in technical skills performance. Providing information about motion efficiency did not lead to similar improvements.

1.2.9.3.1 Feedback in laparoscopic surgery

During open procedures, surgeons can directly feel tissue characteristics. However, in laparoscopic surgery, tactile feedback during grip is attenuated and limited to the resistance felt in the tool handle. Excessive grip force during laparoscopic surgery can lead to tissue damage. Providing additional supplementary tactile feedback may allow subjects to have better control of grip force and identification of tissue characteristics, potentially decreasing the learning curve associated with complex minimally invasive techniques.

Wottawa et al (2013) studied the role of tactile feedback in grip force during laparoscopic training tasks. A tactile feedback system has been developed and integrated into a modified laparoscopic grasper that allows forces applied at the grasper tips to be felt by the surgeon's hands. This study showed that supplementary

tactile feedback help novice subjects reduce grip force during the laparoscopic training task but did not offer improvements for the four expert subjects. This indicates that tactile feedback may be beneficial for laparoscopic training but has limited long-term use in the non-robotic setting.

Panait L et al (2009) tested the haptic feedback effect on a laparoscopic simulation training of laparoscopic novices. Each performed two tasks, analogous to the fundamentals of laparoscopic surgery drills, on the Laparoscopy Virtual Reality at 3 levels of difficulty. Participants completed the drills both with and without force feedback. Data on completion time, instrument path length, right and left hand errors, and grasping tension were analysed. The scores in the haptic-enhanced simulation environment were compared with the scores in the non-haptic model. In the more advanced tasks, haptics allowed superior precision, resulting in faster completion of tasks and a trend toward fewer technical errors. In the more basic tasks, haptic-enhanced simulation did not demonstrate an appreciable performance improvement among our trainees. These data suggest that the additional expense of haptic-enhanced laparoscopic simulators may be justified for advanced skill development in surgical trainees as simulator technology continues to improve.

1.2.9.3.2 Self-administered feedback in surgery

Simulation-based training provides minimal feedback and relies heavily on self-assessment. Research has shown that medical trainees are poor self-assessors. MacDonald J et al (2003) studied the self-assessment in simulation-based surgical skills training between medical trainees. Twenty-one medical students performed 10 repetitions of a simulated task. After each repetition they estimated their time and errors made. These were compared with the simulator data. In this study, novices

demonstrated improved skill acquisition using simulation. Their estimates of performance and accuracy of error estimation improved with repetition. Clearly, practice enhances technical skill self-assessment. These results support the notion of self-directed skills training and could have significant implications for residency training programs.

Self-assessment is important to learning but few studies have utilized video self-assessment of basic surgical skills. Hu Y et al (2013) compared a video self-assessment of suturing and knot tying skills by novice trainees to the assessment by a senior attending surgeon. Sixteen senior medical students and 7 beginner surgical interns were video-recorded while performing five suturing and knot tying tasks. The results of this study proved that novice trainees over-estimate their basic technical skills performance compared to the assessment by a senior surgeon. Video self-assessment may be a valuable addition to a pre-residency and surgical internship preparatory curriculum in basic suturing and knot tying.

Development of surgical skills on inanimate models has been popularized by efforts to improve patient safety and efficiency of surgical training. Another study was on the augmentation of the videoscopic suturing skill using self-assessment feedback technique by Jamshidi R et al (2009). They found that the development of videoscopic suturing skill is augmented by independent review of earlier attempts. Knot quality and technique were improved, with a trend toward increased speed. This low-cost method of enhancing skill training for junior trainees parallels the effectiveness of video review in fields such as aviation and athletics.

Can surgeons judge how well they are learning new skills? That was a question asked by Sidhu RS et al (2006) who studied self-assessment of surgeons during a 2-day laparoscopic colectomy course. The objectives of this study were to establish the utility of an assessment tool for participants in a laparoscopic colectomy course, and to determine the accuracy of technical skill self-assessment in this group.

Twenty-two surgeons enrolled in a 2-day course participated. During the animal laboratory, each participant's operative performance was videotaped. Participants completed a global rating scale (GRS) instrument to self-assess their performances. By using the same GRS, 2 trained raters independently assessed each performance by videotape reviews. Surgeons consistently overestimated their performance during a laparoscopic colectomy course as measured by reliable GRS. This finding highlights the issue of credentialing and the importance of preceptorship for surgeons completing such courses.

The ability of surgeons to assess their own performance is essential for training and self-regulation. Another study by Moorthy K et al (2006) was on self-assessment of performance among surgical trainees during simulated procedures in a simulated operating theatre. Unlike other studies on self-assessment, this study found that senior surgical trainees are accurate in their self-assessment of technical skills.

After this analysis, none of the previous researchers tended to study the effect of intra-procedural feedback, but they worked on correcting the errors after the task performance in the form of post-procedural evaluation.

1.2.9.3.3 Workplace based assessment

Workplace-based assessment (WPBA) is the assessment of a trainee's professional skills and attitude and should provide evidence of appropriate everyday clinical competences. It has the advantage of high content validity through assessing actual performance in the workplace. WPBA should be promoted as an integral part of curriculum design and educational planning, in which teaching, learning, assessment and feedback are closely integrated.

In addition, WPBA is a source for providing evidence of satisfactory progress and achievement as well as identifying areas needing further development and discussing and agreeing means of addressing them. Trainees are judged against the standard that they are expected to reach by the end of their current stage of training. Workplace-based assessment tools include: Mini-Clinical Evaluation Exercise, Clinical Encounter Cards, Clinical Work Sampling, Blinded Patient Encounters, Direct Observation of Procedural Skills, Case-based Discussion, and Multisource Feedback.

Multisource Feedback is a method of obtaining feedback in a structured form from staff associated with the trainee who has the opportunity to observe their practice. Staff may be supervisors and may also include those that the trainee themselves supervise. The respondents are asked to rate the trainee by filling in a standard form listing a number of qualities or behavioural characteristics with a rating scale. The trainee also provides their own assessment of how they think they are doing. It provides reasonable feedback on the trainee's behaviour and competence in clinical situations which may not be directly observed by the supervisor.

1.3 Medical errors

1.3.1 Definition

There are three possible definitions for an error:

- Something incorrectly done through ignorance or inadvertence.
- A failure to complete a planned action as intended.
- The use of an incorrect plan of action to achieve a given aim.

The most precise definition of error, and most in accord with everyday usage, is one that ties it to observable behaviours and actions. John Senders and Neville Moray (1991) proposed that an error means that something has been done which:

- Was not desired by a set of rules or an external observer,
- Led the task or system outside acceptable limits, or
- Was not intended by the actor.

Jeffery K Aronson (2009) mentioned that a medication error can be defined as ‘a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient’. The use of the term ‘failure’ signifies that the process has fallen below some attainable standard. The ‘treatment process’ includes treatment for symptoms or their causes or investigation or prevention of disease or physiological changes.

‘Harm’ in the definition also implies ‘lack of benefit’, a form of treatment failure. The definition does not specify who makes the error. Therefore, it could be a doctor, a nurse, a pharmacist, a carer, or another; nor does it specify who is responsible for preventing errors.

1.3.2 History of error in medicine

Twenty years ago medical error was hardly mentioned in the medical literature let alone discussed publicly. Lucian Leape (1994), a surgeon from Harvard, published a prescient and seminal paper which addressed the question of error in medicine. He mentioned that medical and nursing students have been taught Florence Nightingale's dictum—first, do no harm. Yet evidence from a number of sources, reported over several decades, indicates that a substantial number of patients suffer treatment-caused injuries while in the hospital.

Schimmel (1964) reported that 20% of patients admitted to a university hospital medical service suffered iatrogenic injury and that 20% of those injuries were serious or fatal. Steel et al (1981) found that 36% of patients admitted to a university medical service in a teaching hospital suffered an iatrogenic event, of which 25% were serious or life threatening. More than half of the injuries were related to use of medication. Bedell et al (1991) reported the results of an analysis of cardiac arrests at a teaching hospital and they found that 64% were preventable.

1.3.3 Classification of medical errors

There are many taxonomies for classifying medical errors.

1.3.3.1 Arronson classification of errors

Jeffery K Aronson (2009) found that the best way to understand how medication errors happen and how to prevent them is to consider their classification, which can be contextual, modal, or psychological. Contextual classification deals with the

specific time, place, medicines, and people involved. Modal classification examines the ways in which errors occur (e.g. by omission, repetition, or substitution).

However, classification based on psychological theory is to be preferred, as it explains events rather than merely describing them. Its disadvantage is that it concentrates on human rather than systems sources of errors. Psychologists consider an error to be a disorder of an intentional act, and they distinguish between errors in planning an act and errors in its execution. If a prior intention to reach a specified goal leads to action, and the action leads to the goal, all is well. If the plan of action contains some flaw, that is a 'mistake'. If a plan is a good one but is badly executed, that is a failure of skill.

This approach yields four broad types of medication error (numbered 1–4 in Figure 7). Mistakes can be divided into:

- Knowledge-based errors and
- Rule-based errors.

Failures of skill can be divided into:

- Action-based errors ('slips', including technical errors) and
- Memory-based errors ('lapses').

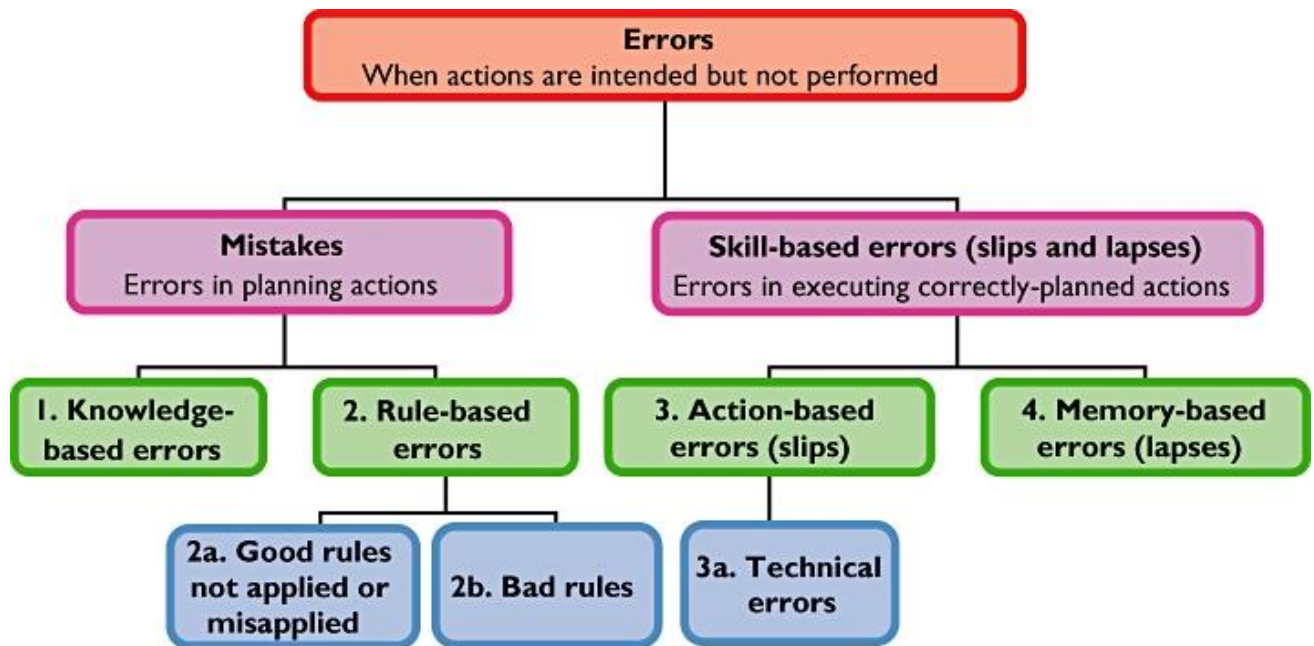


Figure 7 Classification of medication errors based on a psychological approach

1.3.3.2 Ramisson classification of errors

Rasmisson (1983) classification of errors is particularly applicable in medicine. He classified errors into:

- Skills-based level, which relates to faulty execution of a task. An example is when an experienced doctor administers the wrong medication by picking up the wrong syringe.
- Rule-based level, which consists of misclassification/misdiagnosis leading to the application of the wrong rule. An example is when a doctor is proceeding with extubation before the patient is able to breathe independently, because of incorrect application of guidelines.

- Knowledge-based level, this arises from incomplete or incorrect knowledge.

An example is when a doctor is prescribing the wrong medication because of incorrect knowledge of the drug of choice.

1.3.3.3 Reason classification

James Reason (1990) also classified errors, but into two broad categories: active and latent. In general, active errors are enacted by frontline operators and have an immediate effect, e.g. surgeon inflicts an injury to the aorta during the creation of a closed pneumoperitoneum for laparoscopic surgery. Latent errors may lie unnoticed without carrying any adverse effect until they create a major disaster. This is mainly related to bad decision making, bad management, faulty practice or inadequate maintenance.

In his book *Human Error*, James Reason (1990) has done an analysis of the active errors and divided them into two broad types (Figure 8). Slips and lapses, are errors of action, while mistakes are broadly speaking, errors of knowledge or planning.

- Slips and lapses:

Slips and lapses occur when a person knows what they want to do, but the action does not turn out as they intended. Slips relate to observable actions and are associated with attentional failures (such as picking up the wrong syringe), whereas lapses are internal events and associated with failures of memory (such as forgetting to give the drug altogether).

- Mistakes:

Slips and lapses are errors of action; the person intends to do something, but it does not go according to plan. However, with mistakes, the actions may go entirely as planned but the plan itself deviates from some adequate path towards its intended goal. Here the failure lies at a higher level; with the mental processes involved in planning, formulating intentions, judging, and problem solving. If a doctor treats someone with chest pain as if they have a myocardial infarction, when in fact they do not, then this is a mistake. The intention is clear, the action corresponds with the intention, but the plan was wrong.

In daily life errors are frequently attributed to carelessness, forgetfulness, recklessness and other personal defects. The implication is that the person who makes an error has certain characteristics which produce the error and, furthermore, that these characteristics are under their control and they are therefore to blame for the errors they make. This is error seen from the individual perspective; when applied to understanding accidents, Reason refers to this as the 'person model'.

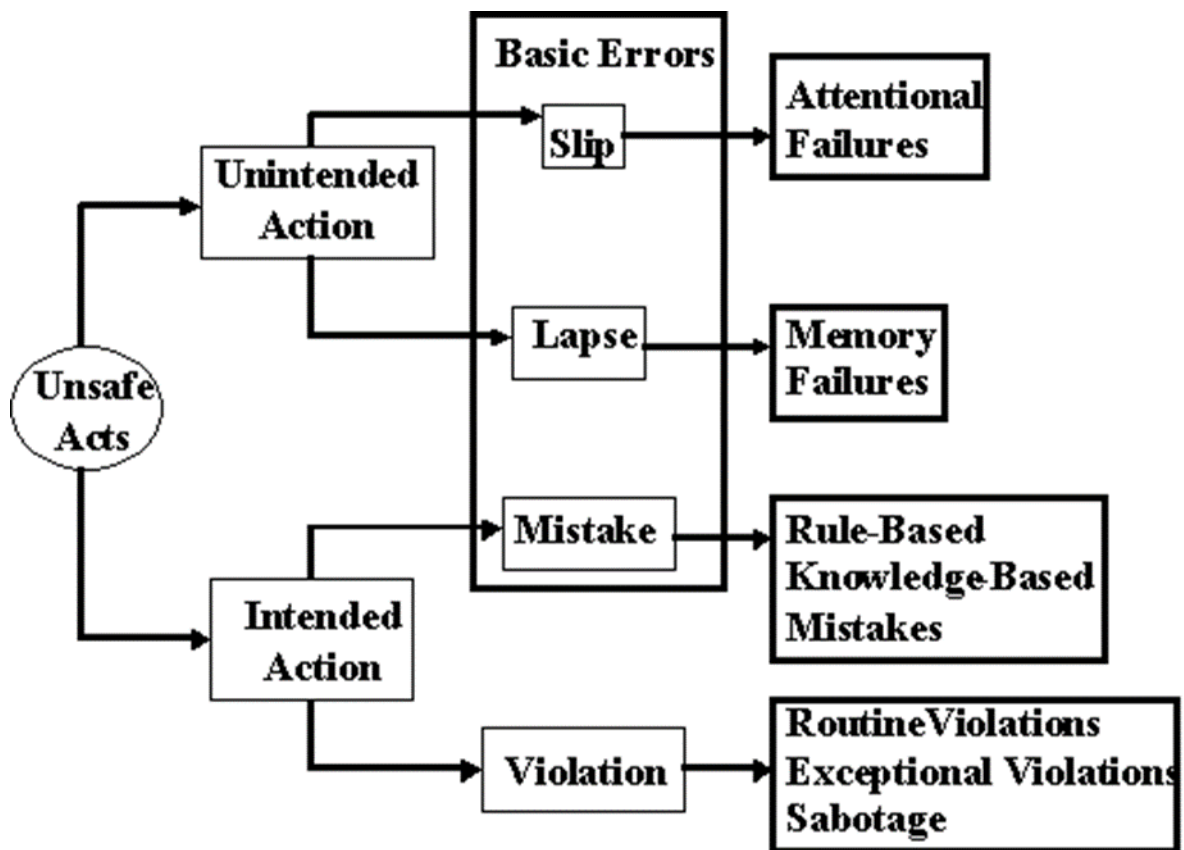


Figure 8 James Reason's classification of errors

1.3.4 Preventing errors through classification

Arronson psychological classification can help understand how errors can be prevented. Knowledge-based errors can obviously be prevented by improving knowledge, e.g. by ensuring that students are taught the basic principles of therapeutics and tested on their practical application and that prescribers are kept up to date. Computerized decision-support systems can also train prescribers to make fewer errors.

Mistakes that result from applying bad rules, or misapplying or failing to apply good rules (rule-based errors), can be prevented by improving rules. Training can help in

preventing technical (action-based) errors. Memory-based errors are the most difficult to prevent. They are best tackled by putting in place systems that detect such errors and allow remedial actions.

Medication errors, which can lead to adverse drug reactions, require clear and unambiguous definitions, so that patients, prescribers, manufacturers, and regulators can all understand each other. The classification of medication errors on the basis of the underlying psychological mechanisms, based on how errors occur, can suggest strategies that help to reduce their occurrence.

1.3.5 Medical errors and the essentials of patient safety

Lucian Leape (1994) began by noting that a number of studies suggested that error rates in medicine were particularly high, that error was an emotionally fraught subject and that medicine had yet to seriously address error in the way that other safety critical industries had. He went on to argue that error prevention in medicine had characteristically followed what he called the 'perfectibility model'. If physicians and nurses were motivated and well trained then they should not make mistakes. If they did make mistakes then punishment in the form of disapproval or discipline was the most effect remedy and counter to future mistakes. Leape summarised his argument by saying: "the professional cultures of medicine and nursing typically use blame to encourage proper performance. Errors are caused by a lack of sufficient attention or, worse, lack of caring enough to make sure you are correct" (Leape 1994 p1852).

Drawing on the psychology of error and human performance, Leape rejected this formulation on several counts. Many errors are often beyond the individual's conscious control; they are precipitated by a wide range of factors, which are often also beyond the individual's control. Systems that rely on error-free performance are doomed to failure. In addition, error prevention that relies exclusively on discipline and training is also doomed to failure.

Least implied and accepted in that environment, there must be some kind of failure or 'performance shortfall'; the person involved did not intend this and must, at least potentially, have been able to act in a different way. All three of these criteria can be challenged, or at least prove difficult to pin down in practice. Much clinical medicine for instance is inherently uncertain and there are frequently no guidelines or protocols to guide treatment. The failure is not necessarily easy to identify; it is certainly not always clear, at least at the time, when a diagnosis is wrong or when at what point blood levels of a drug become dangerously high.

In brief, the notion of intention, and in theory acting differently is challenged by the fact that people's behaviour is often influenced by factors, such as fatigue or peer pressure, which they may not be aware of and have little control over. So, while the working definition is reasonable, we should be aware of its limitations and the difficulties of applying it in practice.

1.3.6 Examples of errors in clinical practice

Errors in diagnosis are common in clinical practice. A previous meta-analysis (McDonald et al 2009) identified the five most commonly misdiagnosed diseases as:

infection, neoplasm, myocardial infarction, pulmonary emboli, and cardiovascular disease.

Other examples of misdiagnosis are when sensitivities to foods and food allergies risk being misdiagnosed as the anxiety disorder Orthorexia. Also, female sexual desire sometimes used to be diagnosed as female hysteria. Bipolar disorder has often been misdiagnosed as major depression. Its early diagnosis necessitates that clinicians pay attention to the features of the patient's depression. The misdiagnosis of schizophrenia is also a common problem. There may be long delays of patients getting a correct diagnosis of this disorder.

Other examples of medical errors include delayed diagnosis, administration of the wrong drug to the wrong patient or in the wrong way, giving multiple drugs that interact negatively, and failure to take the correct blood type into account or incorrect record-keeping.

1.3.7 Errors in surgery

1.3.7.1 Incidence of adverse events in surgical patients

Healey et al (2002) studied the complications of errors in surgical patients. This study reported that 30% of deaths were attributed to errors and authors concluded that the recognition of errors enacted by provider contributed significantly to adverse events presenting significant opportunities for improving patient outcomes. Another study by Calland et al (2002) investigated 30-day postoperative death rate at an academic medical centre and found that errors and adverse events were associated with 12.6% and 19.3% of deaths, respectively. Leape et al (1991) mentioned that nearly half of adverse events (48%) are associated with operations. Another study by

Gawande et al (1999) found that 66% of all adverse events were surgical and almost half of these were caused by provider error.

1.3.7.2 Types of adverse events in surgical practice

Leape et al (1991) and Calland et al (2002) proved that the largest number of adverse events is enacted during surgery in the operating room and technical errors are the most common class of error observed. Healey et al (2002) concluded that the incidence of adverse events resulting from errors varied from 26.9% to 42.4% between surgical procedures.

Technique-related complications, wound infection and postoperative bleeding are the commonest surgical adverse events (24.2%, 11.2% and 10.8 respectively), Gawande et al (1999) and Brennan et al (1991). Gawande et al (2003) reported from 800,000 operations in Massachusetts over a 16 year periods, that 61 items of surgical equipment or consumables were left inside 54 patients. Based on these data, the authors of this study estimated that at national level in USA, misappropriation of instruments and/or consumables occurs in 1,500 patients per year. Examples of the most common surgical errors are operating the wrong patient, operating the wrong site of surgery, injuring a nerve during surgery and retained surgical equipment inside the patient, e.g. sponges or instruments.

1.3.7.3 Causes of surgical adverse events

Couch et al (1981) mentioned that in two thirds of the cases, adverse events are attributed to an error of commission: unnecessary, defective or inappropriate operative procedure. Healey et al (2002) and Gawande et al (1999) mentioned that nearly half of adverse events are preventable. Calland et al (2002) reported that

65.2% of patients deaths were not attributable to their primary diseases and had at least one error identified in their records. Thomas et al (2000) also reported that 22.3% of surgical adverse events are associated with negligence. Carter (2003) regarded the surgeon as a risk factor affecting the clinical outcome of the patient after surgery.

Couch et al (1981) conducted a one-year prospective survey to identify adverse outcomes due to error during care in general surgery. They identified 36 cases among 5612 surgical admissions, but in 23 cases the initiating mishap had occurred in another hospital before transfer. In two thirds of the cases the mishap was due to an error of commission: an unnecessary, defective or inappropriate operative procedure. Twenty of these patients died in the hospital, and in 11 death was directly attributable to the error. Five of the 16 survivors left the hospital with serious physical impairment. A satisfactory outcome was achieved in only 11 cases (31%). The average hospital stay was 42 days, with the duration ranging from one to 325 days; and the total cost for the 36 patients was \$1,732,432.

1.4 Task performance

1.4.1 Definition

This can be defined as the accomplishment of a given task which is measured against known standards of accuracy, completeness and speed.

1.4.2 Factors affecting the task performance

These include:

1.4.2.1 Goal clarity

The performers must have in mind a clear picture of any end or goal they are to achieve. If this picture does not exist, they cannot tell if they are making progress or when they have attended the objectives of the task. Therefore, it is important for a trainer to spend some time in developing and clarifying the goals for the performer (Anderson *et al* 2015). They must be able to engage in whatever behaviours to obtain the goal despite changing circumstances and environmental disturbances

1.4.2.2 Knowledge of structures

Figuring out what to do in a particular situation requires knowledge of the structure of that situation. People must understand the elements that make up the situation, how those elements are connected to one another and the relationships that exist between and among these elements. The knowledge of the structure of the situation allows people to say how the actions they take will lead to the result they seek. It also allows them to say, for a given result, the actions that will lead to it.

1.4.2.3 Feedback

Feedback informs progress, enables corrections and signals attainment of the objective. As previously discussed, feedback is known to have a great effect on the improvement of task performance (Jack Ende, 1983).

1.4.2.4 Motivation

Motivation can be defined as the driving force behind all the actions of an individual (Harackiewicz *et al* 1997). The influence of an individual's needs and desires both have a strong impact on the direction of their behaviour. Motivation is based on the emotions and achievement-related goals. There are different forms of motivation including extrinsic, intrinsic, physiological, and achievement motivation. Achievement motivation is the need for success or the attainment of excellence. Individuals will satisfy their needs through different means, and are driven to succeed for varying reasons both internal and external. Self-satisfaction and incentives are also counted as two great motivators.

1.4.2.5 Environment

Even if all the above factors influencing the task performance are present, performance might still not occur if the environmental conditions are not suitable. As examples, missing tools and equipment, competing priorities, a repressive climate and other environmental factors can interfere with the ability to perform a task well.

1.5 Assessment in surgical education

1.5.1 Principles of assessment

Assessment is a measure of trainee's learning. There are three components of assessment process:

- Input (Information).
- Process (Instructions).
- Output (Performance).

Harden (1979) advocated that "many of the problems encountered in assessment arise from inadequate consideration of what it is one is trying to assess". He proposed the concept of educational objectives and classified them into three main areas:

- Knowledge:

It includes all the cognitive development from the understanding of a process to an ability to solve problems.

- Skills:

Different psychomotor skills that are required by the clinician.

- Attitudes:

Personal qualities of students and their attitude towards medicine, patients and peers. Bloom BS et al (1971) attempted to produce a systemic classification of objectives and classified this into three main domains:

- Cognitive, relevant to the intellectual processes.
- Affective, relevant to the attitudinal and emotional processes.
- Psycho-motor, relevant to the process of physical skills.

1.5.2 Roles of assessment

Assessment process in surgical training is utilised to achieve several objectives:

- As a part of learning process, trainees are shown their mistakes and how to achieve excellence in their work.
- To indicate progress and to set objectives for every level of training.
- To certify a standard of surgical performance.
- To measure the effectiveness of educational program, organisation or institution in order to allocate future resources.

1.5.3 Formative and summative assessment

Formative assessment is a concept utilised to keep track of a trainee's progress through a period of learning in a specified program. "It involves using assessment information to feedback into the teaching/learning process" (Gipps, 1994). Sadler (1989) viewed feedback as a component of formative assessment process, however, there is no guarantee that the improvement in task performance will be achieved within a valid and reliable assessment. Sadler further advocated that understanding the levels of achievement by the trainee is a key towards improvement in task performance. Currently achieved levels need to be compared by a trainee with the required standard for acquiring better performance.

Summative assessment is usually conducted at the end of a program or course and is designed to understand whether the desired instructional objectives have been achieved or not. In this method of assessment, a trainee is provided with a grade and the intention is to discover what has been learnt. Summative assessment has less role in improvement of performance when compared to formative assessment.

1.5.4 Rules of assessment

Harden (1979) explained that "there are three rules that apply to selecting an assessment procedure"

- The method should be valid i.e. it should measure what you wish it to measure.
- The method should be reliable and consistent.
- The method should be practical in terms of resources available and numbers of students to be examined.

On the other hand, high reliability is no guarantee for validity. It is always necessary to keep the need for validity in mind and to effect, if necessary, a compromise in favour of validity even if the level of reliability should fall.

1.5.5 Validity of assessment process

Validity is defined as the extent to which the assessment process measure what it was supposed to measure. There are many key types of validity:

- 1) Content validity:

This relates to the degree to which the assessment process measures the construct of interest. Content validity is determined by 'expert judgement'. It is a rational analysis of the assessment process by the experts who are familiar with the area of interest.

2) Face validity:

Face validity is a component of content validity and is established when an individual reviewing the assessment process concludes that it measures the characteristics of interest. Good face validity can establish rapport and trust between the assessor trainees. There is a degree of subjectivity about face validity but it is not without its importance in literature.

The best way establishing face validity is by asking trainees about the fairness of assessment process and whether the assessment test could test laparoscopic skills?

3) Construct validity:

This relates to the extent to which a test measure the trait or theoretical construct that is intended to measure. For example if it is hypothesised that higher efficiency and fewer errors are achieved by any particular assessment process in a task performance then if less errors or high efficiency was really achieved, it would represent construct validity. Construct validity is an ongoing process as one refines a theory, if required, in order to make predictions about processes.

4) Concurrent validity:

This validity relates is the degree to which the results of assessment are related to the results on an established assessment process. For example, if a new method of

assessment in laparoscopic surgery is compared with an already established process in terms of results and the results in new methods show high positive correlation then there is a clear evidence of concurrent validity.

5) Criterion-related validity:

This validity is assessed when one is interested in determining the relationship of scores on a test to specific criteria. For example, an assessment process designed for laparoscopic surgery should be able to relate to the relevant criteria such as established grades or completion of the program.

6) Predictive validity:

It is the degree to which a test can predict future performance. It is required by laparoscopic assessment process to have strong predictive ability. It is however important that no test has perfect predictability so it is better to have outcome decisions based on more than one predicting indicators.

1.5.6 Surgical task analysis

Surgical operative performance can be assessed by audit of morbidity, mortality and, especially in patients with cancer, in terms of long-term outcome. This works on the identification of problems and sub-optimal results by surgeons and hospitals.

However, Goldman (1992), Green et al (1995), Rigby et al (2001) and Martin et al (2002) proved that morbidity and mortality data extracted from medical records are very often inaccurate and the reliability of the reports is often poor. Morbidity and mortality provide no means of identifying the factors responsible for specific complications. These could be due to errors enacted during the preoperative, intra-

operative and post-operative period. In addition, morbidity and mortality data do not correlate specific complications with particular technical errors and are unable to isolate and evaluate the exact role of technical skills of the surgeon on clinical outcome. Therefore, Cuschieri (2000) argued that audit is simply not enough for improvement of surgical performance. He suggested that the Human reliability assessment (HRA) can be translated into clinical practice and should be modified, researched and developed to improve surgical performance.

HRA technique is an example of surgical task analysis which involves the use of qualitative and quantitative methods to assess the human contribution to risk or error. It was established in high risk industries to reduce errors related with human factors. It has been used in high-risk industry (e.g. nuclear and aerospace) to prevent accidents, whose consequences would be catastrophic. It differs from audit used in surgical practice in that it is both prospective and prescriptive from the start, e.g. the system is designed to identify what may go wrong, the probability of this happening, the consequence were it to happen, and the necessary defence systems that should be in place to ensure that the risk is as low as possible.

Kirwan (1994) outlined HRA for use in high-risk industries in 10 steps:

- 2) Problem definition, 2) Task analysis, 3) Human error analysis, 4) Representation, 5) Screening, 6) Quantification, 7) Impact assessment, 8) Error reduction, 9) Quality assurance and 10) Documentation.

Joice et al (1998) adapted these generic HRA steps to operative surgery with some needed modifications in laparoscopic surgery and used to study errors enacted during 20 laparoscopic cholecystectomies.

Tang et al (2004) summarised HRA into clinical settings and called it 'Observational clinical human reliability assessment' (OCHRA). With this technique he calculated task and instrument error probabilities and it was suggested that better cognitive training should reduce procedural errors. Cuschieri et al (2010) idealised the concept of proficiency gain curve in laparoscopic surgical training in assessment based on OCHRA principles. Talebpour et al (2009) used OCHRA method to describe quantitatively the proficiency gain curve for a laparoscopic procedure and indicated the plateau stage when individual surgeons attain maximal performance in the execution of a specific procedure.

1.6 Conclusions of literature review

Surgical checklists are in use as means to reduce errors. Checklists are infrequently applied during procedures and have been limited to lists of procedural steps to be used as aid memoires.

Feedback comes in a variety of types and modes of application. Feedback is essential for learning and developing performance in surgical education. Although some papers tended to study the effect of intra-procedural feedback, they studied the task performance in the form of post-procedural evaluation.

The rates of medical errors in medicine are particularly high and errors have to be addressed in a safe way to prevent consequences and harm of the patients.

There are some generic factors that can affect the task performance, these include the goal clarity, the knowledge of structures, structured feedback, motivation and suitable environmental conditions.

The surgical task can be assessed using the Human Reliability Assessment technique by assessing the human contribution to enact errors.

1.7 Study hypothesis

A checklist applied during a standardised laparoscopic procedure can improve the task performance.

1.8 Aims of the thesis

- 1) To develop a checklist to be applied during laparoscopic procedures in order to improve the surgical task performance.
- 2) To compare between the effect of a trainee-self-administered and trainer-administered checklist on the laparoscopic task performance.
- 3) To study the effect of the checklist on the surgical task performance during a simulated routine task.
- 4) To study the effect of the checklist on the surgical task performance during simulated emergency scenario.
- 5) To clinically evaluate the effect of the checklist on the surgical performance of the trainees during routine laparoscopic procedures in operating theatres.

Chapter 2

2 The development of a performance based checklist

Chapter 2

2.1 Introduction

Surgical checklists are introduced by WHO in order to reduce errors and improve patients' safety. Checklists are infrequently applied during surgical procedures and have been limited to lists of procedural steps to be used as aid memoires.

2.2 Aims

In this lab-based study, we aimed to develop a simple performance based checklist to be applied during laparoscopic procedures as a way of error reduction mechanism.

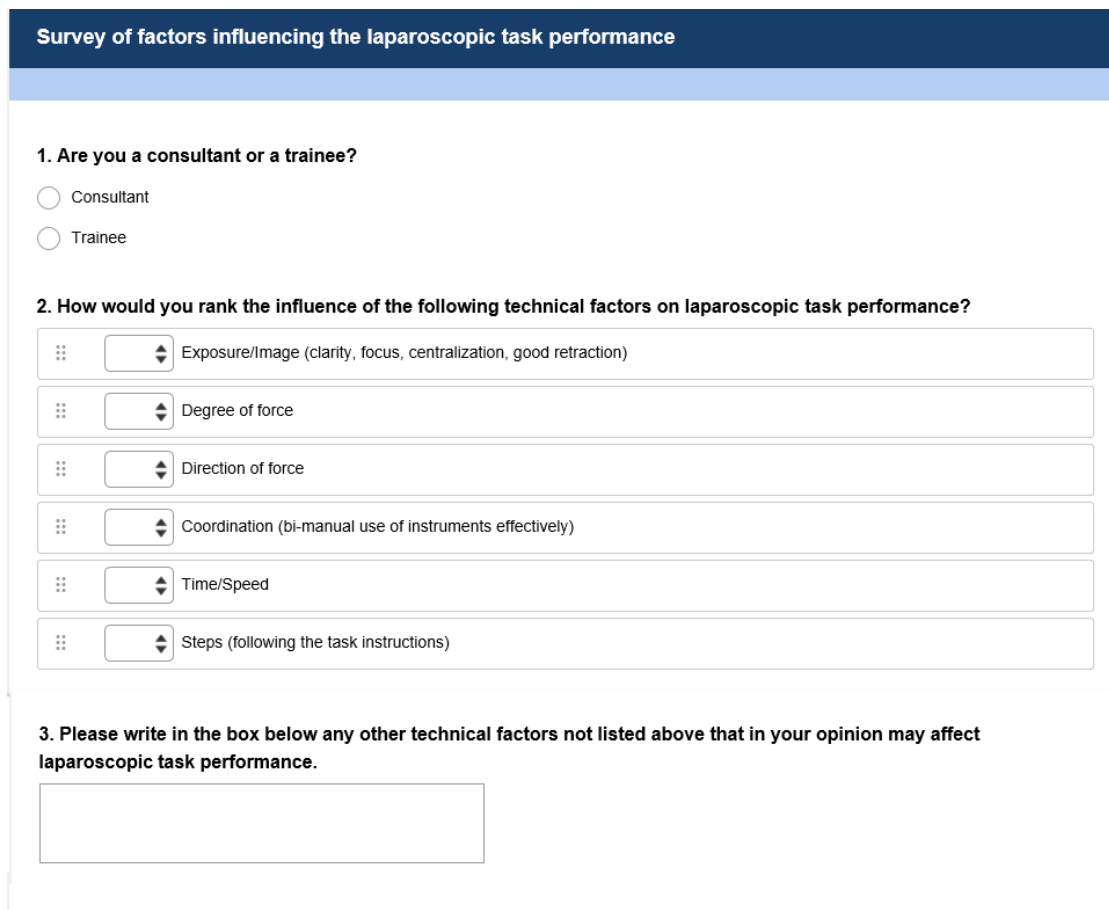
As the best method of administering the checklists is still unknown, we also aimed to compare the effects of trainee self-administered versus trainer-administered checklist on the laparoscopic task performance of novice surgeons, and to pilot the best method on a standardized task.

2.3 Methods

2.3.1 Formulation of the performance based checklist

We used the Survey Monkey website to create a survey on the technical factors influencing the laparoscopic task performance. We began with the survey design, then created a collector to distribute it.

A link via an online questionnaire (Figure 9) was sent per email to a number of 8 local consultants and 6 registrars at the Ninewells Hospital and Medical School. Survey responses were then recorded directly in our created account.



Survey of factors influencing the laparoscopic task performance

1. Are you a consultant or a trainee?

☐ Consultant

☐ Trainee

2. How would you rank the influence of the following technical factors on laparoscopic task performance?

⋮ [Ranking Scale] Exposure/Image (clarity, focus, centralization, good retraction)

⋮ [Ranking Scale] Degree of force

⋮ [Ranking Scale] Direction of force

⋮ [Ranking Scale] Coordination (bi-manual use of instruments effectively)

⋮ [Ranking Scale] Time/Speed

⋮ [Ranking Scale] Steps (following the task instructions)

3. Please write in the box below any other technical factors not listed above that in your opinion may affect laparoscopic task performance.

[Text Box]

Figure 9 Online questionnaire on technical factors influencing laparoscopic task performance

2.3.2 Pilot studies

2.3.2.1 Trainer-administered vs trainee-administered methods in applying the checklist-comparative study

2.3.2.1.1 Task setup

The participants were randomised into two equal groups, five participants in each group. Every participant had to perform the task in two separate stages, first stage with no checklist, then a second stage with the developed performance based checklist. The first group with the trainee-administered intra-procedural checklist, while the second group with the trainer-administered intra-procedural checklist.

2.3.2.1.2 Location and task selection

The surgical task was standardised laparoscopic double square knots (Figure 10) performed in the dry lab at the Cuschieri Skills Centre on a synthetic material.

The task of laparoscopic double square knots formation was selected due to certain measurable standards:

- Measurability standards when divided into subtasks and further subdivision into steps.
- Reproducibility.
- Possibility to calculate enacted errors and number of completed knots.



Figure 10 Double square knots

2.3.2.1.3 Inclusion criteria of the participants

Medical students were included in this study according to their interest in the concept of laparoscopic surgery and their availability.

2.3.2.1.4 Invitation of the participants

Invitation leaflets (Appendix) were also displayed in Ninewells Hospital and University of Dundee Medical School notice boards. Each medical student received an email invitation to participate in every phase.

20 declared their interest. 15 candidates were interviewed on the basis of their background understanding, enthusiasm.

2.3.2.1.5 Exclusion criteria of the participants

Any student with previous laparoscopic suturing experience was excluded from the study.

2.3.2.1.6 Randomisation and blinding

Participants were randomised into two groups using an online 'Research Randomiser software'. The primary and secondary assessors were blinded for testing the reliability of the assessment.

2.3.2.1.7 Materials

Laparoscopic setup was kept ready before the start of each task performance. SZABO-BERCI-SACKIER laparoscopic trainer (Figure 11) was chosen for the task due to the good working space it provides for the standardization of the different laparoscopic angles (Figure 12).

- Manipulation angle: The angle between the axis of the right and left hand instruments. This angle was kept equal to 60° to allow comfortable movement within visual field.
- Azimuth angle: the angle between optical axis and instruments. It was kept equal (30°) to allow comfortable movement within the visual field.
- Elevation angle: The angle between the target, and the axis of the instrument. It was kept equal to 60°. Ideally this angle should be between 45-60 degrees and allow comfortable movement within visual field.
- The optical axis-to-target view angle was standardized at 90°, by elevating the suturing base material on a slope and using a 30° scope.



Figure 11 SZABO-BERCI-SACKIER laparoscopic trainer

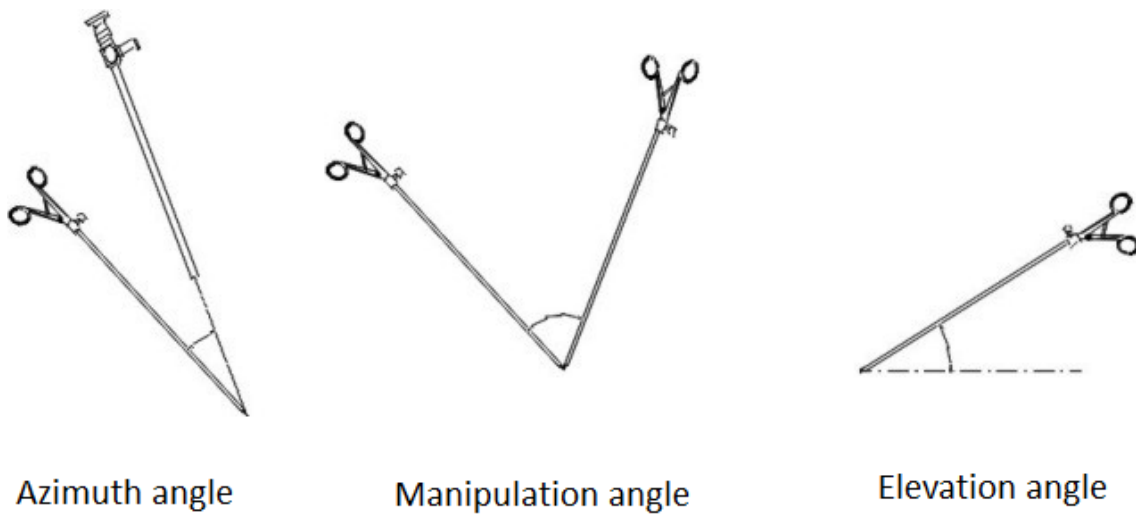


Figure 12 Ergonomic angles

The Distance between the participant and the TV-monitor (19" TFT flat screen monitor) was standardized at 100 cm, regarding El Shallaly et al (2006):

" For most surgeons operating from a 14-in. diagonal CRT monitor, both the maximal and minimal (close-up) view distances are individually variable, but the surgeon should never be farther than 3 m (10 ft) or less than 0.9 m (3 ft) from the monitor. However, within limits, the maximal view distance increases with increasing monitor size. The limit for close-up distance is 0.9 m, irrespective of monitor size."

Suture material:

Polyglycolic acid (Vicryl®, Ethicon ©, a division of Johnson & Johnson Medical Ltd, New Jersey, USA) (Figure 13) is a synthetic absorbable suture which is widely used during laparoscopic surgery procedures. Its tensile strength and memory also makes it a suture of choice for laparoscopic knot formation in laboratory settings. In the study settings, the thickness of 2 0 Vicryl material was standardized with 20 cm length which was passed through the suturing base 'neoprene sheet'.



Figure 13 Vicryl suture material

Telescope: 26003BA, Hopkins ®, 30 degree, 10mm diameter, 31 cm length, Karl Storz (Figure 14).

Needle holders: 26173KAF, KOH Macro Needle Holder, 5mm diameter, 3cm length, Karl Storz (Figure 15).



Figure 14 Telescope, Hopkins ®



Figure 15 KOH Macro Needle Holder

TV monitor:

19" TFT flat screen monitor, Desktop version, code 9419N, Colour System PAL/NTSC, Resolution max. 1280 x 1024, SDI, Composite, S-Video, RGB, DVI and S-XGA Input, Brightness: 450cd/m², Contrast: 650:1, Power Supply: 100-240 VAC, 50/60 Hz, Karl Storz.

Light source:

KARL STORZ Cold Light Fountain XENON NOVA 175, code 20131501, with one 175 Watt XENON lamp and one, KARL STORZ light outlet. Power Supply: 100-125/220-240 VAC, 50/60 Hz, consisting of: 20131520 XENON NOVA 175, 400A Mains Cord (Figure 16).

Camera control unit (CCU):

CCU with integrated SDI-Module, integrated KARL STORZ communication Bus SCB and integrated image processing module, Colour system: PAL/NTSC, Power Supply: 100-240 VAC, 50/60 Hz (Figure 16).

Three-chip camera head, colour system Pal, with integrated Parfocal Zoom Lens $f = 14 - 28\text{mm}$ (2x), Karl Storz.



Figure 16 Light source and Camera Control Unit

Light cable:

Fibre Optic Light Cable, code 495NA, with straight connector, diameter 3.5 mm, length 230 cm, Karl Storz.

Video cable and software:

ClimaxDigital VCAP303 USB 2.0 Video capture cable was used to connect between the TV-Monitor to the Laptop (Figure 17).

Recording was done using Arcsoft ShowBiz 3.5 software.

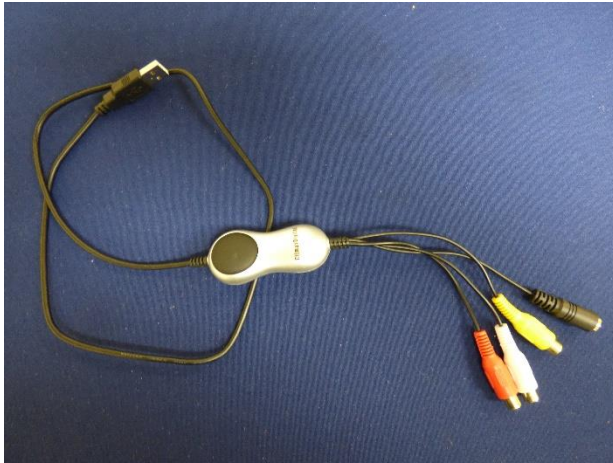


Figure 17 ClimaxDigital VCAP303 USB video capture

Neoprene sheet:

Significant success was made by identifying the qualities of commercially available neoprene. Neoprene is an extremely versatile synthetic rubber and is produced by forming a raw mass through mechanical kneading and rolling process. Surface treatment of neoprene is in the form of lamination using 'nylon', dependant on the intended purpose (Figure 19).

Red surface neoprene was chosen because of the colour contrast it provides with the violet Vicryl suture material (Figure 18), making the suture material clearly detectable. Nylon surface of the neoprene sheet was also found excellent for suturing, as it allowed a needle to take a bite and did not allow a grip by a macro needle holder unless a conscious strong effort was made to grip it. It also allowed a lifting movement which was reversible like human tissue when significant traction was applied to the knot. Traction on tissue (base) was considered an error which

could be detrimental for a human tissue while performing a knot on a vessel or delicate tissue.

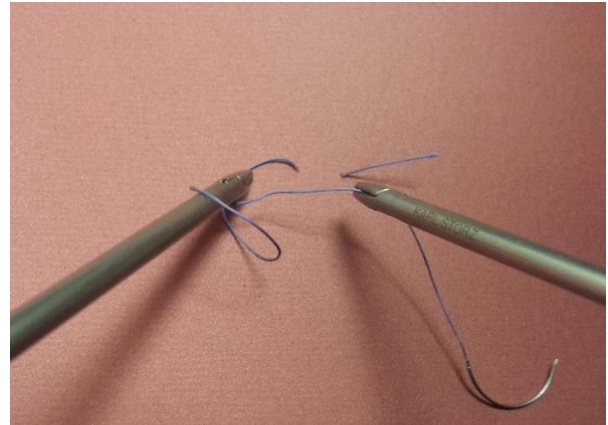
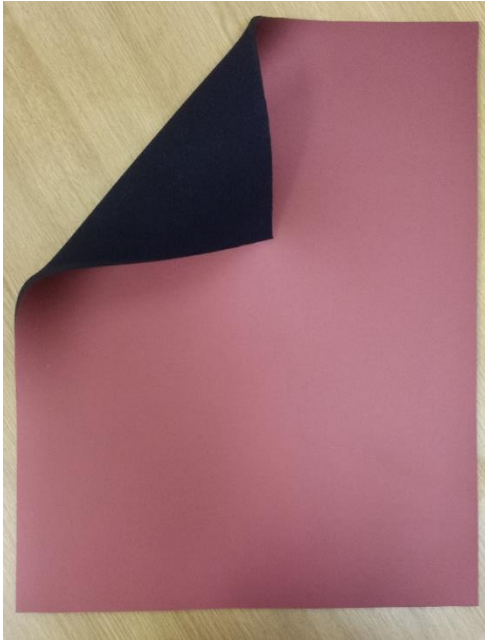


Figure 18 Red Neoprene sheet with the blue Vicryl suture material

Figure 19 Nylon surface of neoprene sheet

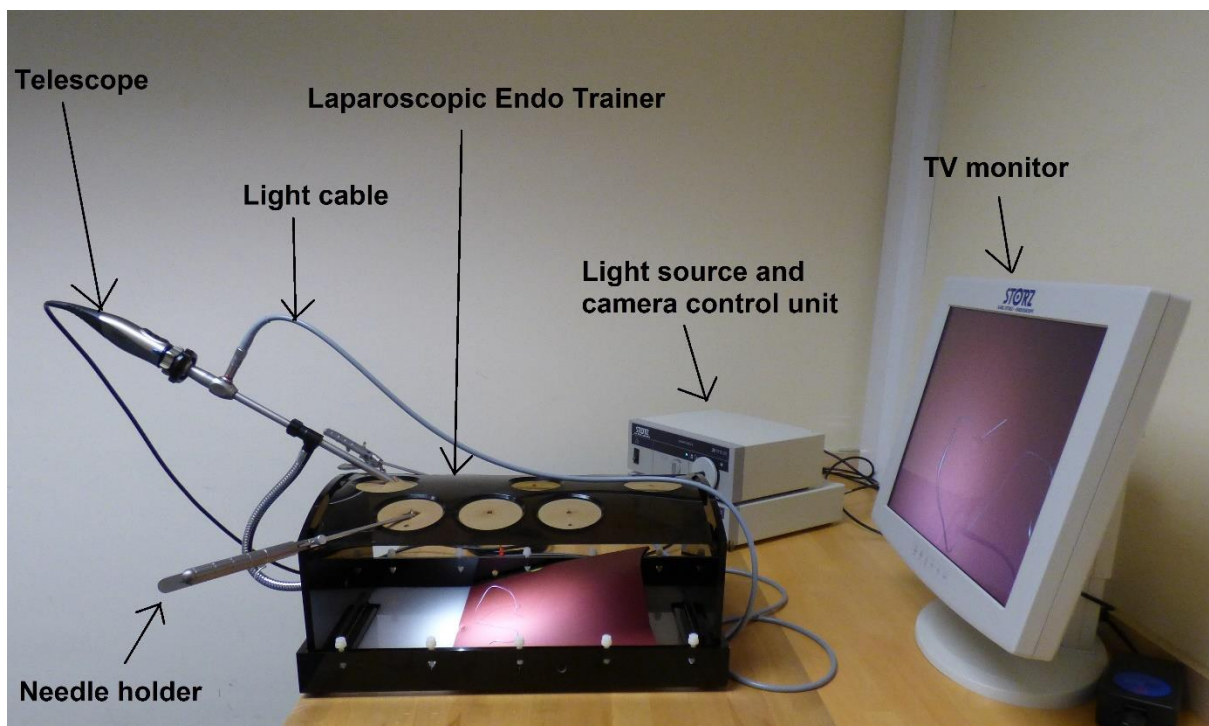


Figure 20 The whole laparoscopic kit

2.3.2.1.8 Induction process

An induction session was conducted prior to the stage one of the study:

- 5 min presentation about basics of laparoscopy.
- 5 min to watch a video of the laparoscopic task.
- 5 min task explanation by the trainer.
- 10 min introduction to the study setup and handling of instruments by the trainer.
- 30 min training on the Laparoscopic Endo Trainer” setup (Figure 10).
- 5 min answering any questions.

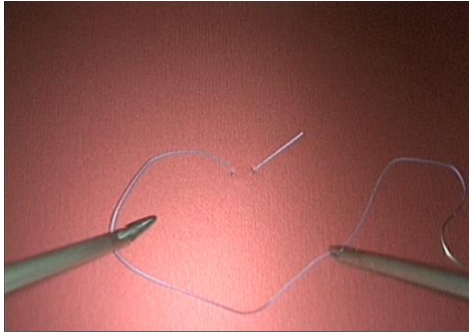
2.3.2.1.9 Study protocol of the first pilot study

Laparoscopic task was divided into 4 subtasks and further subdivided into 26 steps in order to be easily explained to the participants.

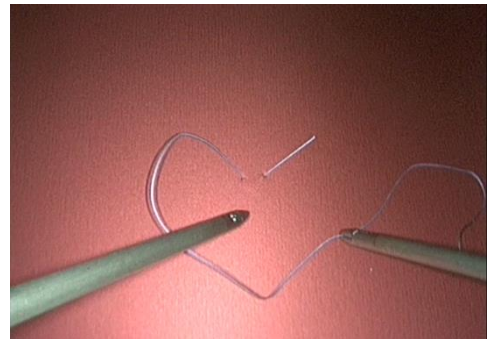
In this phase, all candidates were asked to perform the same laparoscopic surgical task in 2 stages, first one with no checklist and the second one with the checklist.

Each subtask is explained below in picture format along with its steps (Figure 21 to Figure 24).

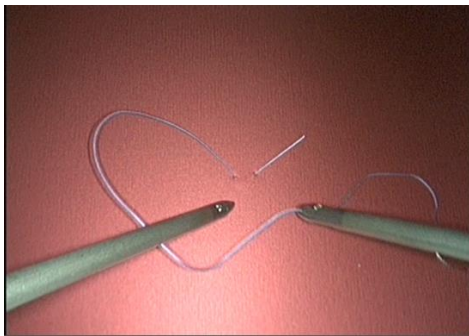
Figure 21 Subtask 1, (C) curve formation (3 steps)



Grip appropriate end of suture

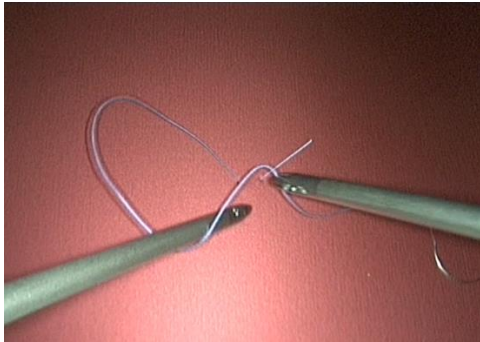


Left instrument positioning



Spatial orientation of both instruments

Figure 22 Subtask 2, double knot configuration (10 steps)



Right instrument supination



Left instrument shifts forward



Right instrument's first throw



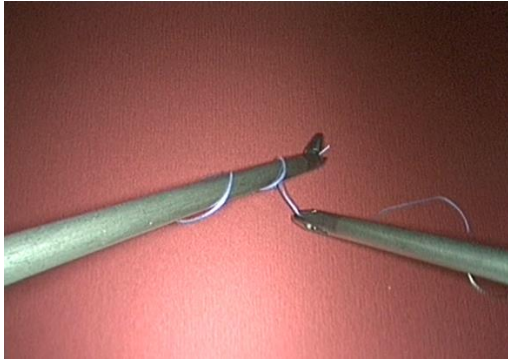
Left instrument shifts forward



Right instrument's second throw



Left instrument shifts forward



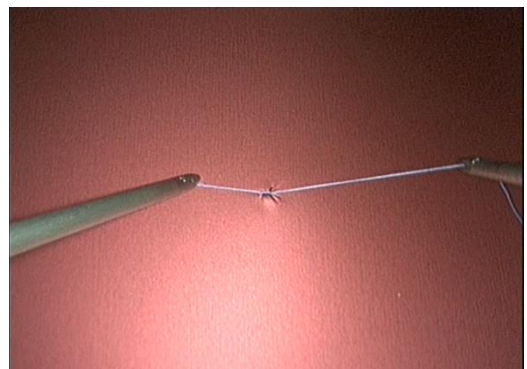
Left instrument approaching suture end



Left instrument gripping suture end

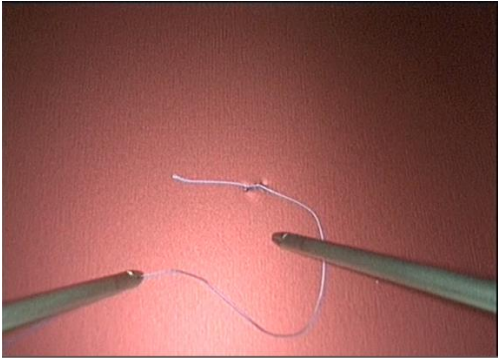


Left instrument pulling backwards

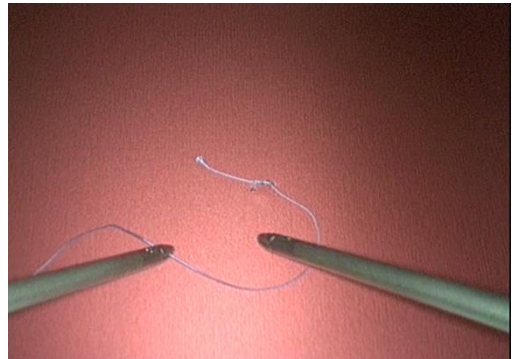


Balanced pull with both instruments

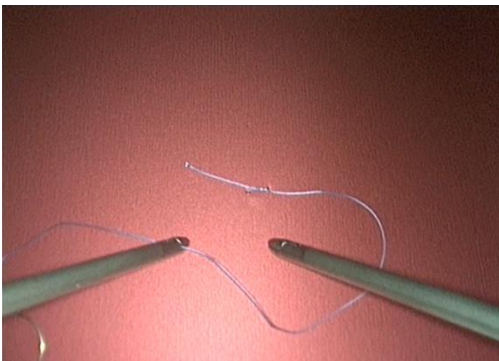
Figure 23 Subtask 3, reverse (C) curve formation (3 steps)



Grip appropriate end of suture

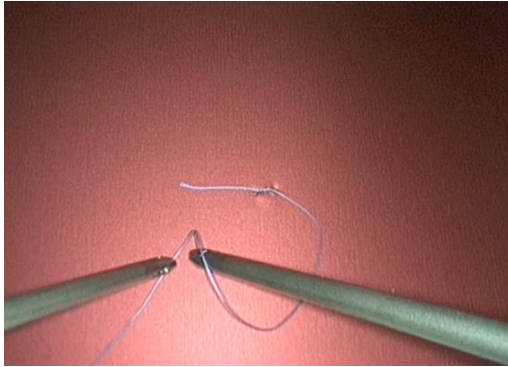


Right instrument positioning

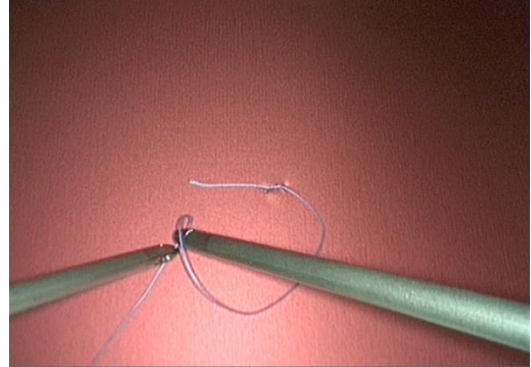


Spatial orientation of both instruments

Figure 24 Subtask 4, Reverse double knot configuration (10 steps)



Left instrument supination



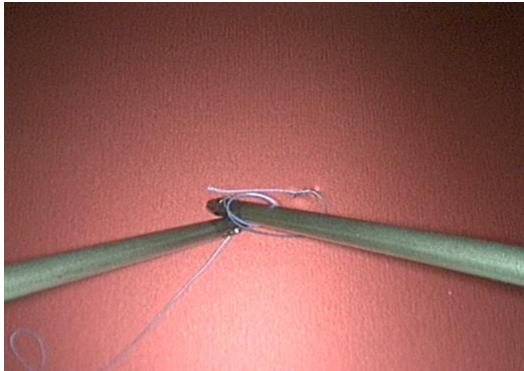
Right instrument shifts forward



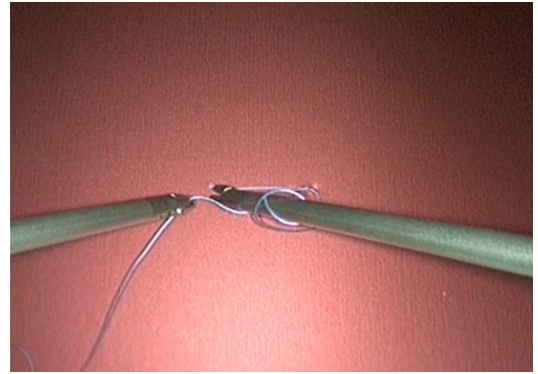
Left instrument's first throw



Right instrument shifts forward



Left instrument's second throw



Right instrument shifts forward



Right instrument approaching suture end



Right instrument gripping suture end



Right instrument pulling backwards



Balanced pull with both instruments

2.3.2.1.10 Application of performance based intra-procedural checklist

- Trainee self-administered checklist:

In the first group, the components of the checklist were displayed beside the TV monitor. Every 20 seconds, the trainer sounded a soft beeping sound in order to remind the trainee to apply the checklist. The beeping sound was generated by AVS audio editor software version 8 (Online Media Technologies Ltd., UK). The frequency of standard beep tones was of 44.1 kHz running at an intensity of 50db for 120 milliseconds.

- Trainer-administered checklist:

In the second group, the trainer was reading the checklist at 20 seconds intervals.

2.3.2.1.11 Task process

All tasks were video recorded to study the number of errors in both stages. The unedited videos were analysed for surgical task performance with the main assessor who was blind to the categorisations of the groups.

Two randomly selected videos were assessed by a second blind assessor and compared to the analysis of the first assessor, as a test of reliability of the results. Agreements and disagreements between both assessors were studied. Disagreements were looked at and analysed again, than consensus was made.

2.3.2.1.12 Endpoints

- a) Number of errors. Eight type of errors were identified and studied in each task (Table 4).

b) Number of completed knots.

1. Inappropriate Instrument positioning.
2. Lack of supination.
3. Missed step.
4. Inappropriate placement of the bite with the needle holder.
5. Instrument out of endoscopic view.
6. Inappropriate grip of the suture material.
7. Inappropriate degree of force.
8. Wrong direction of force.

Table 4 Error types identification

2.3.2.1.13 Survey questionnaire to rank factors influencing the task performance

A survey in form of post-procedural paper feedback (Figure 25) was obtained from the participants of the first pilot study to rank the factors that influenced their laparoscopic task performance.

Post-procedural survey:

Do you agree with the order of the applied checklist:

Yes

No

If no, how would you rank the following factors that affected your performance from the most to the least effective?

- ☐ Bimanual coordination
- ☐ Degree of force
- ☐ Steps of the task
- ☐ Speed

Please choose only one answer.

Was the beep/the trainer:

- ☐ Distracting you from concentrating on your performance.
- ☐ Reminding you to follow the checklist.

Figure 25 Survey questionnaire to rank factors that influenced task performance

2.3.2.1.14 Statistical analysis

The statistical package for the Social Sciences software (version 22, SPSS Chicago, IL, USA) and Excel (Microsoft ® Excel ® for Windows 8 ®, Microsoft Corporation, Redmond, WA) were used for data analysis.

Data for number of errors and number of completed knots showed non parametric distribution and were presented as median (IQR) and (Wilcoxon test) was used for statistical analysis. P-value was defined as statistically significant when $p < 0.05$, and statistically highly significant when $p < 0.01$.

2.3.2.2 Study of the effect of the developed checklist on laparoscopic task performance of surgical trainees

2.3.2.2.1 Task setup

The participants were randomised into two equal groups, four participants in each group. Every participant had to perform the task in one 5-minute stage, the control group with no checklist, and the study group with the trainee-self-administered performance based checklist.

2.3.2.2.2 Location and task selection

The surgical task was standardised laparoscopic double square knots (Figure 10) performed in the wet lab on porcine intestine at the Cuschieri Skills Centre.

2.3.2.2.3 Inclusion criteria

National and international surgical trainees at registrar level (ST3 level or above) who attended the 'Intermediate Laparoscopic Skills Course' at the Cuschieri Skills Centre, at Ninewells Hospital and Medical School.

2.3.2.2.4 Randomization and blinding

Participants were randomized into two equal groups. They were blinded to the nature of the study.

First group performed the task with no checklist, while the second one with the trainee self-administered performance based intra-procedural checklist.

2.3.2.2.5 Materials

The tasks were performed in a Laparoscopic Endo trainer (26348 SZABO-BERCI-SACKIER laparoscopic trainer) (Figure 11).

Angles: are kept the same as the first study.

Monitor: 24" HD monitor, code 9524NB, colour systems PAL/NTSC, max. screen resolution 1920 x1200, image format 16:10, power supply 100 - 240 VAC, 50/60 Hz, Karl Storz.

Light source: Cold Light Fountain XENON 300 SCB, code 20133101-1, with integrated anti-fog pump, 300 Watt Xenon bulb and KARL STORZ light connection, Power supply 100-125/220-240 VAC, 50/60 Hz. consisting of: 20133120-1 Cold Light Fountain XENON, 300, with integrated SCB, power supply, 100 - 125/220 - 240 VAC, 50/60 Hz, 400 A Mains Cord, 610 AFT Silicone Tubing Set, length:250 cm, 20090170 SCB Connecting Cable, length 100 cm.

Light cable: Fibre Optic Light Cable, code 495NCS, with straight connector, diameter 4.8 mm, length250 cm, Karl Storz.

Camera Control unit (CCU): HD hub, Max resolution 1920x1080Pixel. Chip HD camera head. Max resolution 1920x1080Pixel, focal length $f = 14\text{-}30\text{mm}$ (2x), Karl Storz.

IMAGE 1 H3-Z Three-Chip Full HD Camera Head: 50/60 progressive scan, soakable, gas- and plasma-sterilizable, with integrated Parfocal Zoom Lens, focal length $f=15\text{-}31\text{ mm}$ (2x), 2 freely programmable camera head buttons, Karl Storz.

Telescope: 26003BA, Hopkins ®, 30 degree, 10mm diameter, 31 cm length, Karl Storz (Figure 14).

Needle holders: 26173KAF, KOH Macro Needle Holder, 5mm diameter, 3cm length, Karl Storz (Figure 15).

Suture materials: were standardized in type, colour and length, using 20 cm blue 2 0 Vicryl ®, Ethicon ©, Johnson & Johnson Medical Ltd, New Jersey, USA) (Figure 13).

Animal tissue: the task was performed on porcine intestine instead of the synthetic material as a suitable suturing medium and more realistic for the high surgical registrars' level (Figure 26).



Figure 26 Laparoscopic double square knot on porcine intestine

2.3.2.2.6 Induction process

Due to the previous laparoscopic experience of the participants of this pilot study, a shorter introduction of 10 minutes was conducted.

- 5 min to watch the video of the task.
- 3 min task explanation by the trainer.
- 2 min answering any questions.

2.3.2.2.7 Study protocol of the second pilot study

The laparoscopic double square knot task was also divided into 4 subtasks and further subdivided into 26 steps as the previous study (Figure 21 to Figure 24). In this study, all candidates were asked to perform the laparoscopic tasks in a single stage of 5 minutes, the control group with no checklist and the study group with the checklist.

2.3.2.2.8 Application of performance based intra-procedural checklist

The checklist was displayed beside the TV monitor. The trainer used to sound a soft beeping sound at 20 seconds intervals in order to remind the participants to follow the checklist.

2.3.2.2.9 Task process

All tasks were video recorded to study the number of errors in both groups. The unedited videos were analysed for surgical task performance with the main assessor who was blind to the categorisations of the groups.

A randomly selected number of videos were assessed by second blind assessor as a test of reliability of the results when compared to the first assessor analysis.

2.3.2.2.10 Endpoints

- a) Number of errors in each task.

b) Number of completed knots in each task.

2.3.2.2.11 Survey questionnaire to rank factors influencing the task performance

A survey in form of post-procedural paper feedback (Figure 25) was collected from the participants on factors included in the checklist that effectively influenced their performance.

2.3.2.2.12 Statistical analysis

Data for number of errors and number of completed knots showed non parametric distribution and were presented as median (IQR) and (Mann-Whitney U test) was used for statistical analysis. P-value was defined as statistically significant when $p < 0.05$, and statistically highly significant when $p < 0.01$.

2.4 Results

2.4.1 Online questionnaire

Six consultants and five higher surgical trainees answered the questionnaire (Figure 27). The 6 factors influencing the laparoscopic task performance as ranked in order of importance (Figure 28):

1. Exposure, including good retraction, image clarity, focus and centralization.
2. Bi-manual coordination, or use of both instruments effectively.
3. Degree of force and
4. Direction of force were equally ranked.
5. Steps, follow the task instructions.
6. Speed.

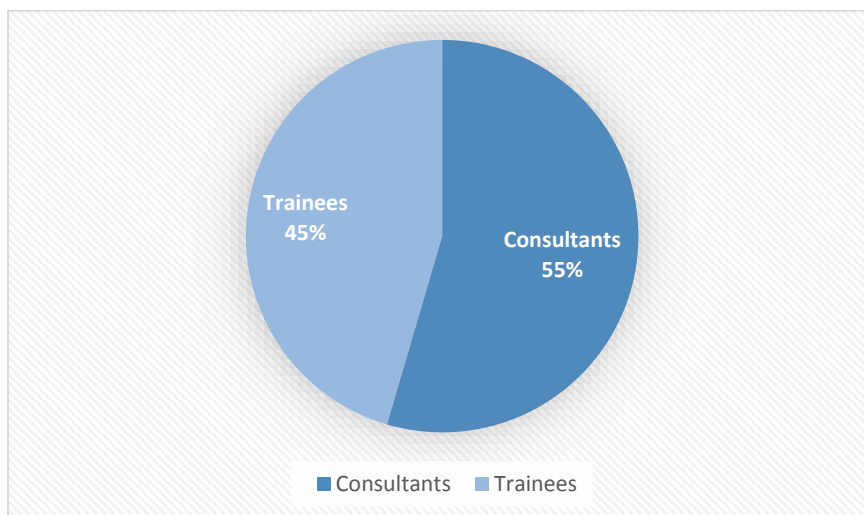


Figure 27 Responses of the online questionnaire

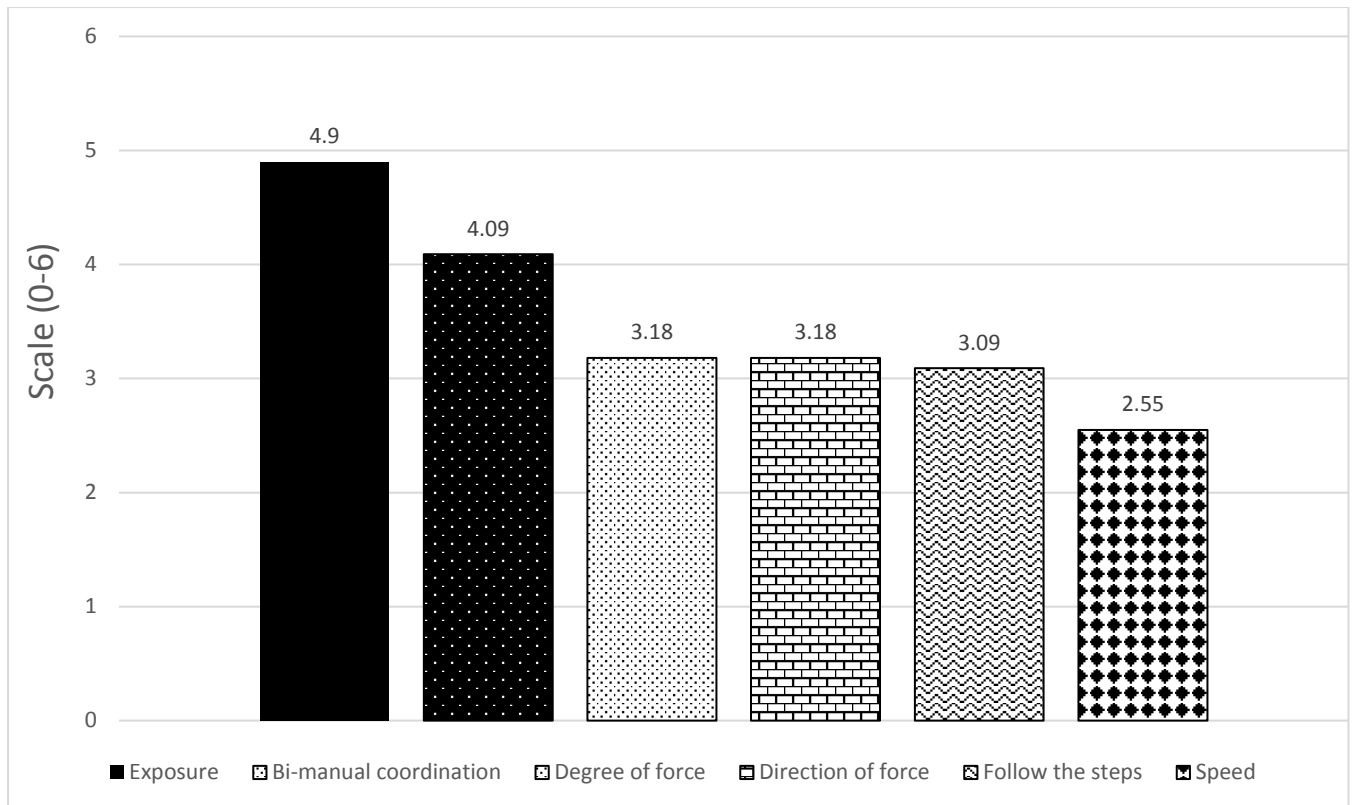


Figure 28 The ranked factors influencing the laparoscopic task performance

2.4.1.1 Excluded factors that affect the laparoscopic task performance

Due to the nature of our lab-based study, some factors were excluded based on the following causes:

Exposure, was excluded in the lab-based study due to the standardisation of the optical view.

Direction of force, could not be taught to novices with no previous laparoscopic experience.

2.4.1.2 Included factors that affect the laparoscopic task performance

Four technical factors were included in the checklist in the lab-based study. They were introduced to the participants and translated into simple words in order to make it easily understood.

- 1) Bimanual coordination, was worded to the participants as “use both hands together”
- 2) Degree of force, was worded as “be gentle”
- 3) Steps of the double knot task were clearly determined and explained during the induction session.
- 4) Speed, was worded as “slow down”.

2.4.2 Trainer-administered vs trainee-administered methods in applying the checklist-comparative study

2.4.2.1 Selection of the participants

11 participants were selected from medical students and junior doctors. Only one medical student was excluded after performing the whole task because he/she refused to follow the instructions of the trainer and preferred to practise on the knot tying with his/her own way. Ten participants were included for the study, 4 Females and 6 Males. All participants in this study were right handed.

2.4.2.2 Number of errors

Results were collected as number of errors in every subtask and total number of knots. The results were statistically analysed in every group to compare between the first stage (with no checklist) and the second stage with the checklist.

2.4.2.3 Trainee-administered checklist group

During the first stage, 154 errors were detected and 3 knots were successfully performed. While, 84 errors were detected and 4 knots were performed during the second stage with the use of the checklist.

Total number of errors was significantly different between the first and the second stage, $p < 0.01$.

2.4.2.4 Trainer-administered checklist group

During the first stage, 131 errors were detected and 4 successful knots were performed. During the second stage, 106 errors were detected and 5 knots were performed.

2.4.2.5 Results of the survey questionnaire to rank factors that influenced the task performance

A number of 7 out of 10 participants in the first pilot study mentioned that "Speed" was the most influencing factor in the checklist, while 3 participants agreed with the used order of the checklist.

In the second group, 2 out of 5 participants mentioned that the instructions received from the trainer were sometimes distracting.

2.4.3 Study of the effect of the developed checklist on the laparoscopic task performance of surgical trainees

2.4.3.1 Selection of the participants

All the participants who attended the 'Intermediate Laparoscopic Skills Course' at the Cuschieri Skills Centre, at Ninewells Hospital and Medical School were recruited.

Eight national and international surgical trainees at registrar level (ST3 level or above). All participants were right handed.

2.4.3.2 Number of errors

Total number of errors that were detected in the 2 groups was 427. The no checklist group committed 281 errors, while 146 were detected during the performance of the checklist group.

A total number of 44 successful knots was performed. The checklist group performed 24 knots, while the control group only performed 20 knots.

2.4.3.3 Survey questionnaire to rank factors influencing the task performance

Three out of 4 participants in the checklist group of this study mentioned "Speed" as the most influencing factor in the checklist and one participant agreed with the order of the checklist.

2.5 Discussion

The main aim of the lab-based research was to develop a performance based intra-procedural checklist and to find the best method of its application. This is the first study to look at a surgical checklist that is simple to be applied, mainly performance based, and used at a cyclical basis during surgical tasks.

The introduction of a Surgical Safety Checklist by the WHO has significantly reduced the morbidity and mortality of surgery. The 19 items surgical checklist ensures that essential information such as patient identity, the type of procedure, its risks and other patient factors are brought to the team's attention. This synchronization of essential information is accompanied by an introduction of all team members by name and role in the operating theatre. The WHO surgical checklist may prevent avoidable human error, however, it is only limited to pre-and post-procedural evaluation.

There are only few previous studies that have looked at the effect of checklist during routine surgical procedures. Intra-procedural checklist has been loosely defined by different authors. Robb WB et al (2012) studied the effect of an intraoperative surgical aid memoire on the reduction of conversion rates from laparoscopic to open cholecystectomy. The subdivision of the procedure into 10 standardized stages was temporally related to the reduced conversion rates to open cholecystectomy. In this study, the checklist was used as an indirect measure of error reduction, limited to parts of a specific procedure (cholecystectomy) and was only used as aid memoire for procedural steps.

Ziewacz JE et al (2012) studied the design, development, and implementation of a checklist for intraoperative neuro-monitoring changes. The purpose of this study was to provide an evidence-based algorithm for the design, development, and implementation of a new checklist for the response to an intraoperative neuro-monitoring alert during spinal surgery. The algorithm highlighted the specific roles of the anaesthetist, surgeon, and neuro-monitoring personnel and encouraged communication between teams. The use of this checklist was only limited to neuro-monitoring changes and its clinical efficacy is not known.

Our checklist is short and simple, made of four factors making it easy to remember and quick to apply by novices repeatedly. The simplicity of the checklist minimizes its potential interference as a distraction during the procedure. Performing the procedure in a step wise fashion in a correct order has been the focus of previous studies with checklists applied preoperatively. Our checklist included this important factor but critically also included additional factors influencing the task performance itself. The factors of the checklist are based on generic factors which makes it applicable to most surgical procedure. The application of a mainly performance based checklist will result in error reduction rather than error correction, i.e. minimizes the occurrence of errors.

The performance of laparoscopic surgery is often more difficult for novices when compared to open procedures. There are potentially several reasons which may include image quality and its magnification, depth perception and the interpretation of 2D image into 3D. Instruments' fulcrum effect, lack of haptic sensation, and unfamiliarity with the angular view might also make laparoscopic surgery more difficult than open.

Novices tend to operate at the same speed regardless the high and low risk zones. Therefore, it is important to highlight slowing down the performance for novices with little laparoscopic experience. During the intensive concentration required for performing laparoscopic tasks, novices often ignore their non-dominant hand at the expense of the dominant one. A typical scenario arises when novice surgeons fail to adequately retract the tissue using the instrument in their non-dominant hand resulting in poor exposure for the dissection performed through the instrument in their dominant one. Reminding the novice to use both hands optimally has the potential advantage of making the surgeons operate bimanually.

An important independent factor for the performance in laparoscopic surgery is the degree of force applied to the tissue using the instrument with too little force often results in repeated actions or too much force giving rise to errors with consequence, such as bleeding or tissue tear. The novices need guidance throughout the procedure over time to understand the appropriate degree of force required to achieve the task. For a novice, it is safer to be gentle in order to minimize any errors with consequence.

Experts tend sometimes to apply our simple four component checklist at regular intervals often unknowingly, however, it takes time and practice for the novices to be able to apply these components automatically when appropriate. For the sake of standardization, we used a beeping sound to remind novices to apply the checklist.

In this study, we used the HRA technique for analysing the task performance objectively on error assessment sheet.

Slowing down was the most influencing factor that improved the laparoscopic task performance of the participants in both studies without prolonging the task execution. As in general the accuracy of a movement tends to increase when its speed decreases above a threshold. Our interpretation is that slowing down could give the participants more time for visual feedback.

The trainee-self-administered method in applying the checklist appears to have a significant accelerating effect on the acquisition of technical skills when compared to the trainer-administered method. Participants felt that the trainer-administered method in applying the checklist was more distracting rather than helpful.

Three different methods were studied and piloted for reminding participants of applying the checklist. These included auditory, visual and haptic methods. Visual method (flashing lights) was excluded because of its distracting effect. The haptic method (vibrating device in the participants' pockets) was found to be impractical because it frequently went unnoticed by the participants. Auditory method was applied in this study and was found easily to be noticed, reproducible and least distracting.

Development of error assessment sheet facilitated the assessment process of the laparoscopic double knot tying tasks. Neoprene suture base was chosen in the first study because it was found to be cheap, commercially available, with right degree of elasticity and was easily modelled into different structures i.e., intestine, skin etc.

Porcine intestine was chosen in the second study as a suitable suturing medium for the participants' laparoscopic experience. Our small sample size showed significant

difference between both groups. A bigger sample size could have the advantage of potentially reducing the probability of finding significant results purely by chance.

An attempt was made to send the questionnaire to other European institutions but no reply was received. Survey Monkey ® was used to formulate the checklist among master surgeons at the Ninewells Hospital and Medical School via an online questionnaire. The website offers a free plan with limited features and several pro plans with more advanced features. We used the free “BASIC plan”. It is possible to create and send a survey with up to 10 questions or elements and safely store up to 100 responses per survey. A previous study by Hohwü et al (2013) found that web-based questionnaires could replace traditional paper questionnaires with comparable response rates, lower costs and less liability to damage or loss.

2.6 Conclusions

A standardised format of the performance based checklist was developed (Figure 29). The trainee self-administered method of applying a surgical checklist had a significant accelerating effect on the acquisition of technical skills during a standardised lab-based laparoscopic task when compared to the trainer administered method.

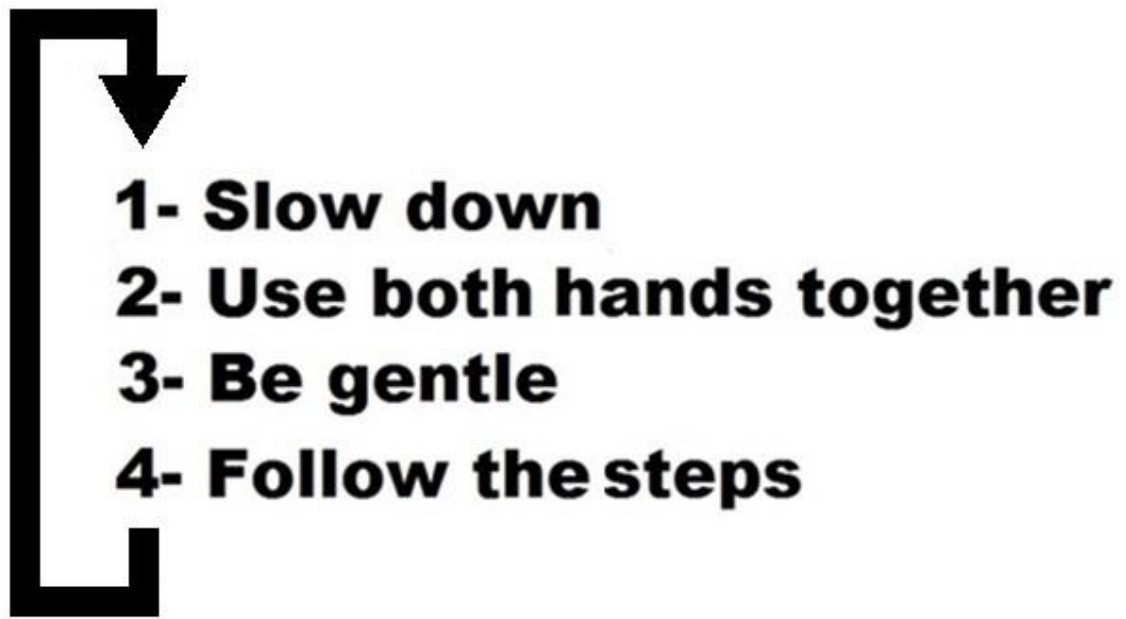


Figure 29 The performance based intra-procedural checklist loop for laparoscopic routine task

Chapter 3

3 The application of the checklist in a routine task

Chapter 3

3.1 Introduction

The current gold standard format for training feedback and error reduction is post-procedural paper feedback, however the main limitation of paper feedback is its retrospective post-procedural nature requiring the information being retrieved from memory, often resulting in the loss of finer aspects to feedback.

In the previous studies (chapter 2), we developed a performance based intra-procedural checklist and piloted its effect on the laparoscopic task performance when self-administered by the surgical trainees.

3.2 Aims

We aimed to study the effect of the previously developed self-administered intra-procedural checklist on the laparoscopic performance of novice surgeons when applied during a standardised laparoscopic task.

3.3 Methods

3.3.1 Task setup

This study consisted of 2 equal groups. Control group: received a standardised post-procedural paper feedback alone with no checklist. Checklist group: received the standardised trainee self-administered performance based intra-procedural checklist in addition to the post-procedural paper feedback.

Every participant performed laparoscopic double square knots in 5 separate stages. The duration of every stage was 3 minutes, and was followed by a 3-minutes rest.

3.3.2 Paper feedback

The paper feedback was included in every arm of this study, as the current gold standard in order to study the effect of the checklist (Table 5).

PAPER FEEDBACK OF LAPAROSCOPIC DOUBLE KNOT TASK				
Performance Stage:		Participant: Checklist/no checklist		
Performance Date:				
Please Note: 1 means errors, means no errors.				
Please follow comments section for detailed description of error in each subtask.				
(C) curve Formation		Comments:		
Grip appropriate end of suture	Left Instrument positioning above 'C'	Right Instrument Lift Up		
Double knot Configuration		Comments:		
Right Instrument Supination	Left instrument shift	Right instrument 1 st throw	Left instrument shift	Right instrument 2 nd throw
Left instrument shift	Left instrument approach	Left instrument grip	Left instrument pull	Both instrument grip and pull
Reverse (C) curve formation		Comment:		
Grip appropriate end of suture	Right Instrument positioning above 'C'	Left Instrument Lift up		
Reverse Double knot configuration		Comment:		
Left Instrument supination	Right instrument shift	Left instrument 1 st throw	Right instrument shift	Left Instrument 2 nd throw
Right Instrument shift	Right instrument approach	Right instrument grip	Right Instrument Pull	Both instruments grip and pull

Table 5 Paper feedback form

3.3.3 Location, tasks, instruments and materials

The location, task and materials were kept the same as the first study (see 2.2.1).

3.3.4 Inclusion criteria of the participants

Medical students and junior doctors who are interested in the concept of laparoscopic surgery were included in this study.

3.3.5 Invitation of the participants

Invitation leaflets were displayed again in Ninewells Hospital and University of Dundee Medical School notice boards again after the summer holidays. Each medical student received an email invitation to participate in this phase.

3.3.6 Exclusion criteria of the participants

Any participant with previous laparoscopic experience or has participated in the previous phase of the study was excluded.

3.3.7 Randomisation and blinding

All participants were randomised into 2 equal groups using an online 'Research Randomiser Software'. The primary and secondary assessors were blinded for testing the reliability of the assessment.

3.3.8 Induction process

An induction session was conducted prior to the stage one of the study:

- 5 min presentation about basics of laparoscopy.

- 5 min to watch a video of the laparoscopic task.
- 5 min task explanation by the trainer.
- 10 min introduction to the study setup and handling of instruments by the trainer.
- 30 min training on the Laparoscopic Endo Trainer” setup (Figure 10).
- 5 min answering any questions.

3.3.9 Study protocol of the routine task

Participants have performed the task in 3 minutes, repeated over 5 stages, every stage was followed by 3-minutes rest.

3.3.10 Application of checklist

The checklist was displayed on a separate paper beside the TV monitor. The trainer used to sound a beep at 20 seconds intervals in order to remind the participants to follow the checklist.

3.3.11 Task process of the routine task

All tasks were video recorded to study the effect of the paper feedback and the checklist on the task performance of the novices.

The unedited videos were analysed for surgical task performance with the main assessor who was blind to the categorisations of the groups.

A randomly selected number of videos were assessed by second blind assessor as a test of reliability of the results when compared to the first assessor analysis.

3.3.12 End points of the routine task

- a) Total number of errors during each task.
- b) Error probability for each task (total number of errors per total number of knots).
- c) Error types (Table 4).
- d) Number of knots in each task.

3.3.13 Assessment process

It was alleged that an assessment method for the selected task should be developed that could justify the 'near gold standard' assessment process. The task of laparoscopic double knot formation was studied in detail.

3.3.14 Task, subtasks and steps

The task of laparoscopic double knot was divided into 4 subtasks and 26 individual steps (Figure 21 to Figure 24).

3.3.15 Error assessment sheet

Subtasks and steps were incorporated into a newly designed assessment method which was named 'Error assessment' sheet (Table 6).

Development of this sheet was the fundamental step in this study for the design process of the assessment to be similar to the 'current gold standard' in national training program. Candidates from both groups were assessed similarly and results were noted on the developed error assessment sheets.

PROCEDURAL ERROR ASSESSMENT SHEET

 Participant:
 Date:

[Done by the trainer]

(C) curve formation		Comment: Time:		
Grip appropriate end of suture	Instrument positioning	Correct instrument spatial orientation		
Double knot Configuration		Comment:		
Right instrument supination	Left instrument shift	Right instrument 1 st throw	Left instrument shift	Right instrument 2 nd throw
Left instrument shift	Left instrument approach	Left instrument grip	Left instrument pull	Both instrument positioning and pull
Right (C) curve formation		Comment:		
Grip appropriate end of suture	Instrument positioning	Correct instrument spatial orientation		
Single Rev. knot configuration		Comment:		
Left instrument supination	Right instrument shift	Left instrument 1 st throw	Right instrument shift	Left instrument 2 nd swing
Right instrument shift	Right instrument approach	Right instrument grip	Right instrument pull	Both instrument positioned and

Table 6 Procedural error assessment sheet

3.3.16 Statistical analysis

Data for number of errors, error probability, number of complete double square knots and error types; showed non parametric distribution and were presented as median (IQR) and (Mann-Whitney U test) was used for statistical analysis. P-value was defined as statistically significant when $p < 0.05$, and statistically highly significant when $p < 0.01$.

In order to study the learning curve in the number of errors and number of completed knots (to compare between stage 1 vs the later stages in each group), Wilcoxon test was used for data analysis. Error rate was excluded because of the constant value of the time/minute in this study.

3.4 Results

3.4.1 Exclusion of the participants

One medical student was excluded from this study because he/she showed no further interest to continue the task after the second session and decided to leave.

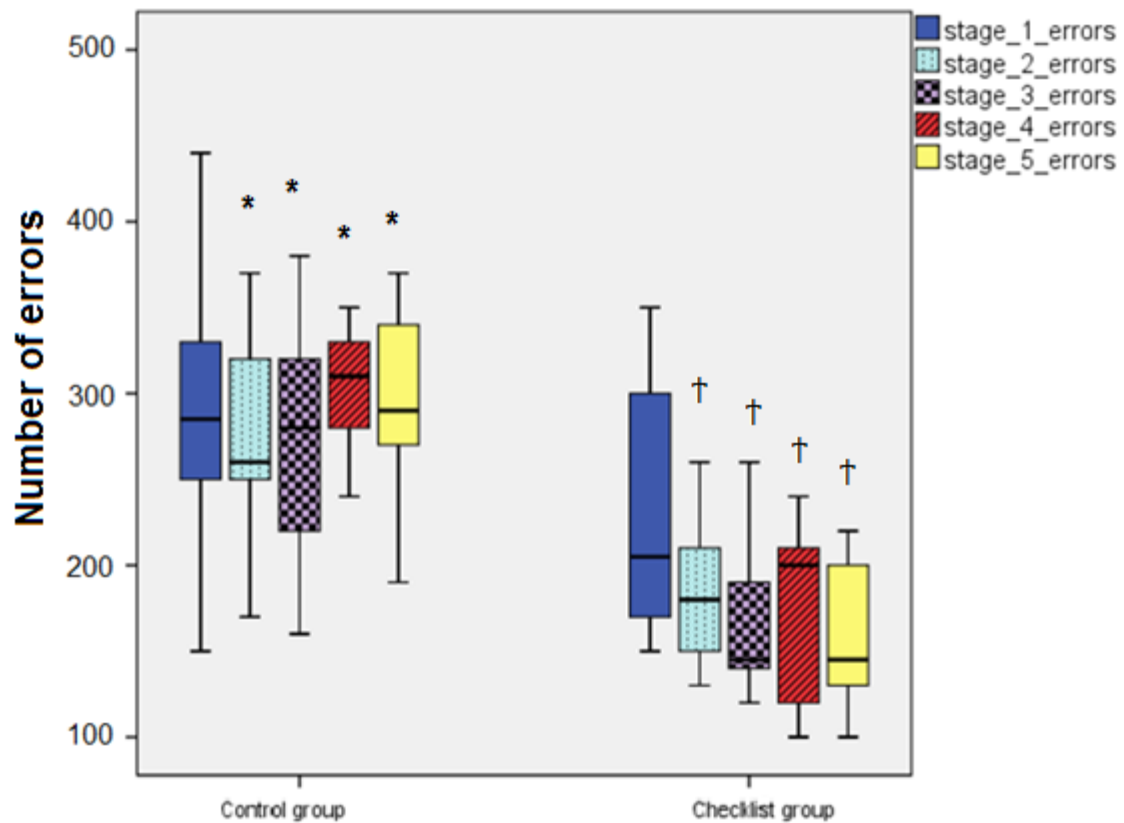
3.4.2 Selection of the participants

Twenty-one medical students and junior doctors were selected for the study. Twenty were included: 18 right handed and 2 left handed participants, 12 Females and 8 Males.

3.4.3 Number of errors

2341 errors were detected during the observation 141 tasks, 408 subtasks and 2249 steps during all stages. There were 1422/2341 errors (60.75 %) in the control group (those who received only the paper feedback); as compared to 919/2341 errors (39.25%) in the checklist group (those who received our checklist and the paper feedback) (Figure 30).

The checklist group had an enhanced learning curve as the last 4 stages showed significant fewer errors compared to the first stage ($p < 0.05$). The control group showed no improvement (Figure 30).



Control group received the paper feedback only.

Checklist group received the checklist and the paper feedback.

* $p < 0.01$ vs errors in corresponding stages in checklist group.

† $p < 0.05$ vs errors in stage 1 of the checklist group.

Figure 30 Median (IQR) of number of errors in the 2 groups during the 5 stages

3.4.4 Number of successful knots

There was no statistically significant difference in the number of completed knots between the two groups.

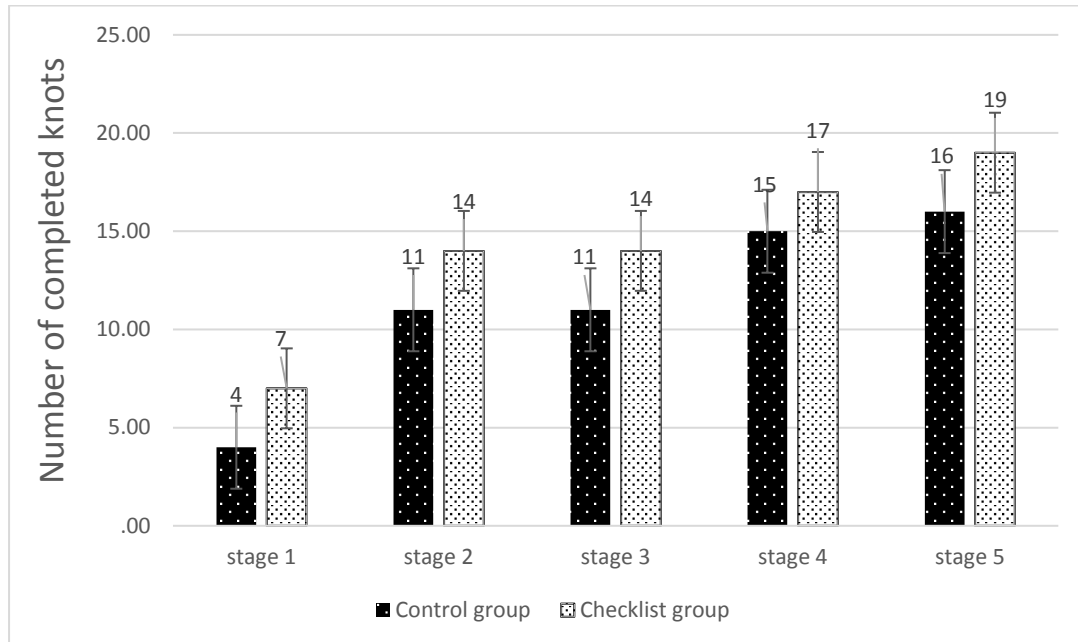


Figure 31 Number of knots in the 2 groups during the 5 stages

Learning curve:

Both groups showed an enhanced learning curve, as the comparison of the number of completed knots between stage 1 and all the later 4 stages was significant in each group ($p < 0.05$).

3.4.5 Error probability

Error probability= Total number of enacted errors in a task per total number of knots.

It was not possible to count the error probability separately in every stage, as some participants did not perform any successful knots. Error probability was counted in the total 5 stages to compare between the Median of the 2 groups (Figure 32).

There was a highly significant difference between both group ($p < 0.01$).

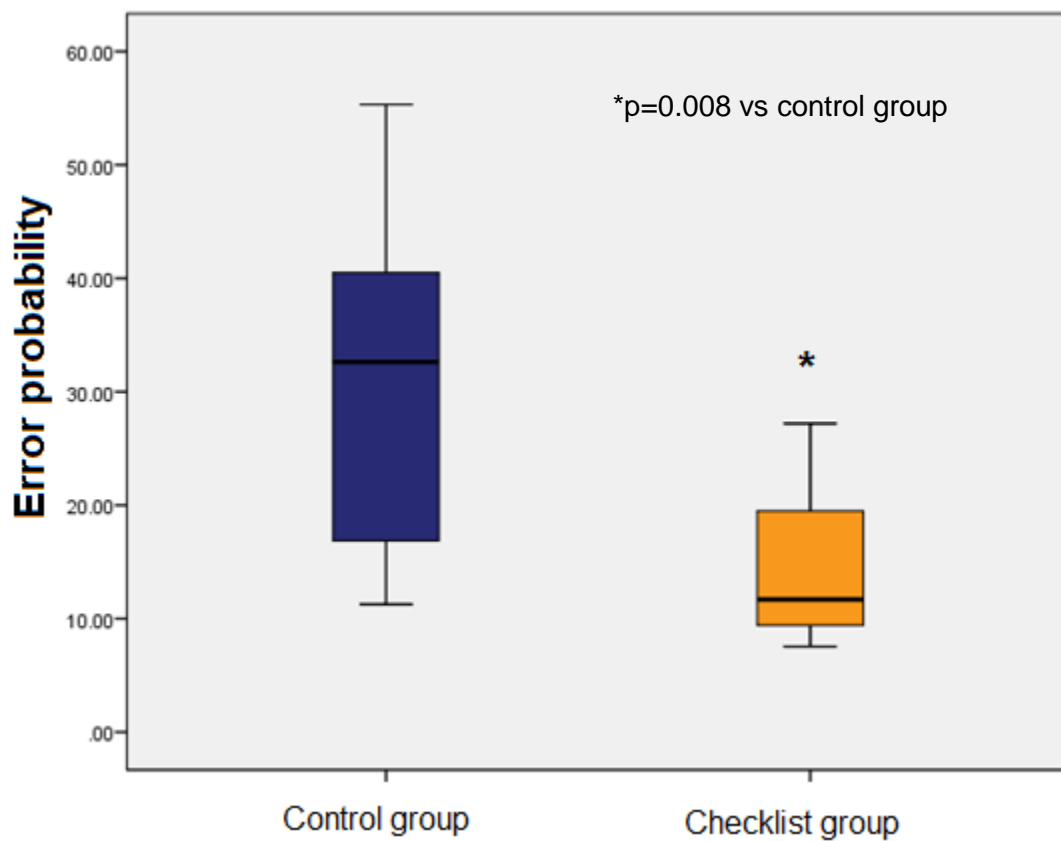


Figure 32 Median (IQR) of error probability in the 2 groups

3.4.6 Error types

Individual errors during each step of the laparoscopic task were identified (Table 7).

The checklist group performed better with fewer number of errors for all the error types. However, there was no significant difference in each of 'the lack of supination', 'Inappropriate placement of the bite with the needle holder' and 'Instrument out of endoscopic view'; the differences in the rest of error types were highly significant ($p < 0.01$).

Error types	control group	checklist group
Inappropriate degree of force	303	157
Inappropriate instrument positioning	254	119
Inappropriate grip of suture material	214	163
Wrong direction of force	196	149
Missed step	76	37
Lack of supination	180	120
Inappropriate placement of the bite with the needle holder	96	85
Instrument out of endoscopic view	103	89

Table 7 Analysis of error types in routine task

3.5 Discussion

The simple performance based intra-procedural checklist appears to have a significant accelerating effect on the acquisition of technical skills when applied by novices during a standardised lab-based laparoscopic task.

Paper feedback was applied to both arms of the trial in order to standardize the effect of the checklist in the checklist group. Studies have shown that feedback has the ability to enhance trainees' performance and learning ability. Another study regarded feedback as crucial to improving knowledge and skill acquisition. The main limitation of paper feedback is its retrospective post-procedural nature requiring the information being retrieved from memory, often resulting in the loss of finer aspects to feedback, unlikely the nature of the performance based checklist.

In the first stage of our study, novices showed no statistically significant difference between the two groups in the total number of errors. This may simply indicate that the baselines for the error rates in both groups were similar. In retrospect, it would have been better if both groups were compared for errors without being exposed to the checklist as true baselines. In the later 4 stages, the use of the checklist resulted in committing fewer number of errors which shows the significant effect of the checklist in error reduction and error prevention.

Although novices were asked to perform the tasks slowly, they managed to successfully complete the same number of knots with fewer errors. In addition, participants performed the task more accurately when they tended to slow down, as in general the accuracy of a movement tends to decrease when its speed increases above a threshold. Our interpretation is that slowing down could give the participants more time for visual feedback. However, there was a measureable improvement in

the checklist group in regards to the performance; nevertheless, there was no compromise on time.

The fact that there is no statistically significant difference in the number of completed knots per time may indicate that either the sample size was not big enough or participants indeed chose not to slow down. It is possible that participants interpreted slowing down as being more careful.

Error probability is often taken as a measure of how errorless the procedure is being conducted at different stages during surgery. In our study, error probability was defined as total number of errors per total number of successfully performed knots. Our definition was pragmatic application for the concept of error probability because some participants could not perform any successful knots during the first stages.

The checklist group performed better in five out of eight error types. Although the link between the individual error types and the checklist components was not the focus of this study, there appears to be a relationship between the individual checklist items and certain error types. For example, being asked to be gentle resulted in committing fewer errors defined as “inappropriate degree of force” and “wrong direction of force”. There were significant improvements in the checklist group for “inappropriate instrument positioning” and the “inappropriate grip of suture material”. This could have been corrected by the two components of the checklist, “slowing down” and “using both hands together”. Being asked to follow the steps could be resulted in committing fewer “missed steps”.

The duration of the task was standardized (3 minutes per stage), therefore error rate and time execution were not applicable as assessment points in this study. All components of the checklist have been translated in practice to careful execution of

the task. It is difficult to deduce the percentage share of each component of the checklist on the task performance. This may be the subject of future studies.

In our study, the beep eventually became associated with an unconditioned stimulus (application of checklist), which reminded the trainee to apply the checklist subconsciously, without the need of reading the checklist every 20 seconds. Only two participants were left handed and they were randomised one in each group, which did not influence the results of this study.

3.6 Conclusion

The performance based intra-procedural checklist significantly enhanced the laparoscopic performance and the learning curve of novice surgeons in a routine knot tying laparoscopic task.

Chapter 4

4 The application of the checklist in a simulated emergency task

Chapter 4

4.1 Introduction

Checklists are applied routinely in aviation industry in operations, technical maintenance and repair, as well as training for pilots and other personnel. Aviation checklist for unexpected events (DECIDE checklist) is common in use for simulated training to prepare aircraft personnel to handle emergencies during flights. However, there is no study to date that has looked at the effect of a surgical checklist on the task performance during simulated laparoscopic emergency scenarios.

The previous studies (see chapter 2 and 3) showed that the simple intra-procedural checklist can improve the laparoscopic task performance of novices and the acquisition of new technical skills during routine knot typing tasks.

4.2 Aims

We aimed to adopt a simple self-administered performance based checklist to study its effect on the surgical task performance when applied during a simulated emergency scenario.

4.3 Methods

4.3.1 Task setup

This study consisted of the application of the checklist on a standardised emergency surgical scenario. Participants were randomised into 2 equal groups. Every participant performed the urgent laparoscopic clipping task once. The control group: received no checklist, and the checklist group received the standardised trainee self-administered performance based intra-procedural.

4.3.2 Location and task selection

Unexpected bleeding vessel requiring urgent clipping for haemostasis using the LapSim Virtual Reality Simulator (Figure 33) at the Cuschieri Skills Centre.

4.3.3 Inclusion criteria

Medical students and junior doctor who are interested in the concept of laparoscopic surgery and who have no previous laparoscopic experience were included in this study.

4.3.4 Invitation

Participants were invited to participate in this study via an email invitation.

4.3.5 Randomization

Participants were randomised into two equal groups using an online 'Research Randomiser software'.

4.3.6 Induction process

A short induction session was conducted prior to the study. The Session included the following points for familiarisation:

- Introduction to the setup and handling of the Virtual Reality Simulator.
- Performance of a bimanual coordination task.
- Watching a video clip of a laparoscopic clipping exercise.
- Performance of the clipping task once.
- Answering any questions.

4.3.7 Conditions of the laparoscopic clipping task

- The configuration of the task was on easy level.
- The camera is controlled by the computer.
- Both instruments are graspers when the task starts.
- To change instrument (grasper, clip applier, scissors or suction device) the novices have to pull back the handle towards them until they can see a menu on the screen.

Grasp the handle to highlight the instrument they need, push the handle back down, and they will see the selected instrument.

- When the clip applier is in use, a box in the upper corner of the screen tells how many clips are left in the cartilage.
- When the vessel is over-stretched, it turns red initially to symbolize injury and if more force is applied it will start bleeding.
- The task was to clip the bleeding vessel.

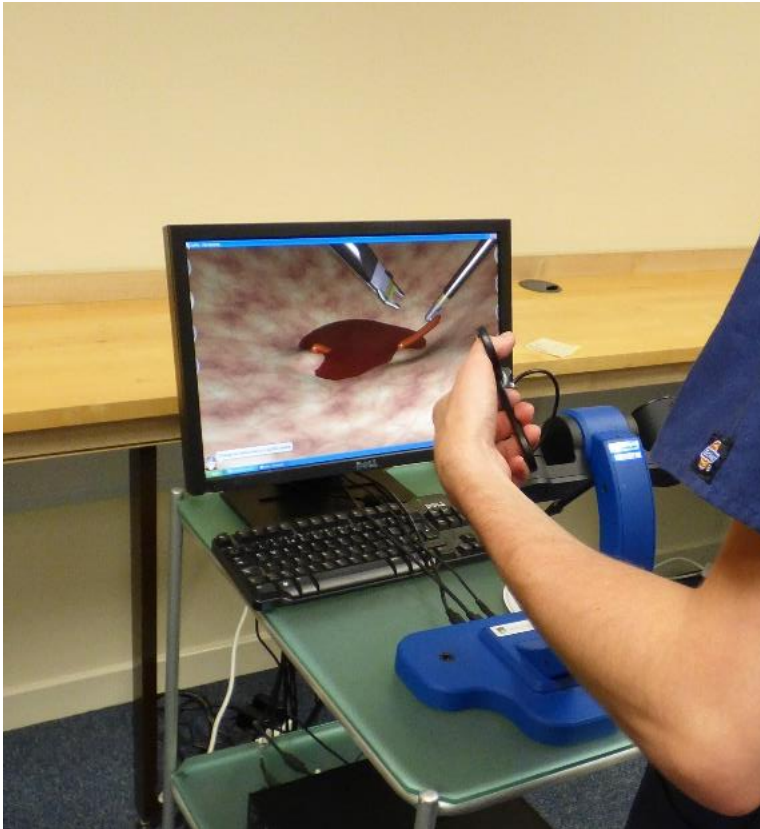


Figure 33 Lapsim Virtual Reality Simulator

4.3.8 Creating an emergency situation

The trainer began the task by tearing the vessel and immediately asked the participant to take over. The participant was unaware of the potential emergency scenario he/she was to encounter.

In order to stop the bleeding, the participant had to grasp both ends of the vessel and apply laparoscopic clips separately on each end (Figure 34 and Figure 35). The task ended when haemostasis was complete and the suction device was used to clear the occurred bleeding (Figure 36).

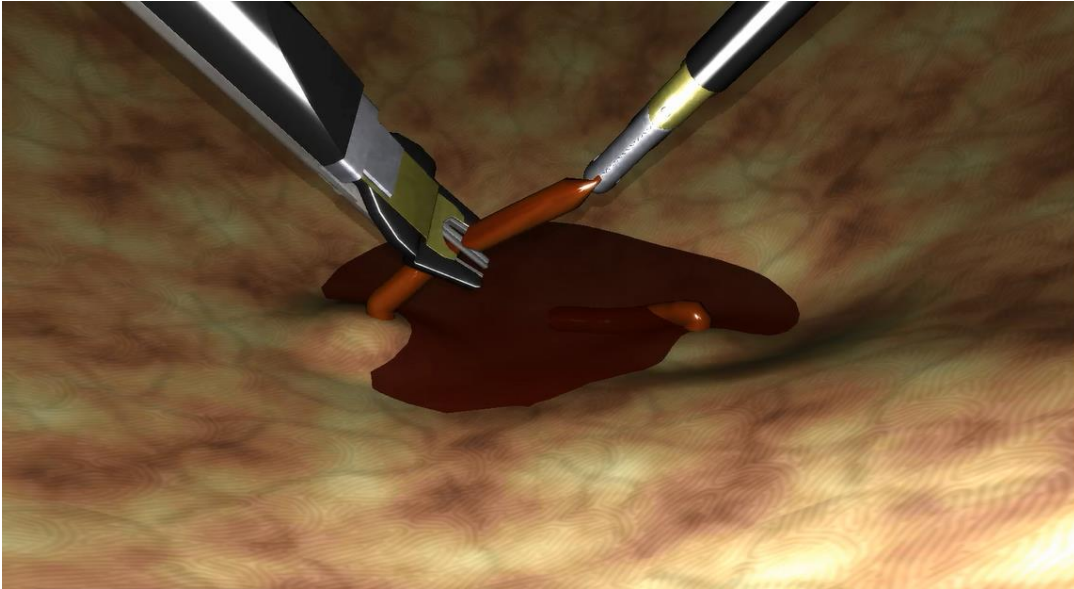


Figure 34 Clip applying on the left end of the bleeding vessel

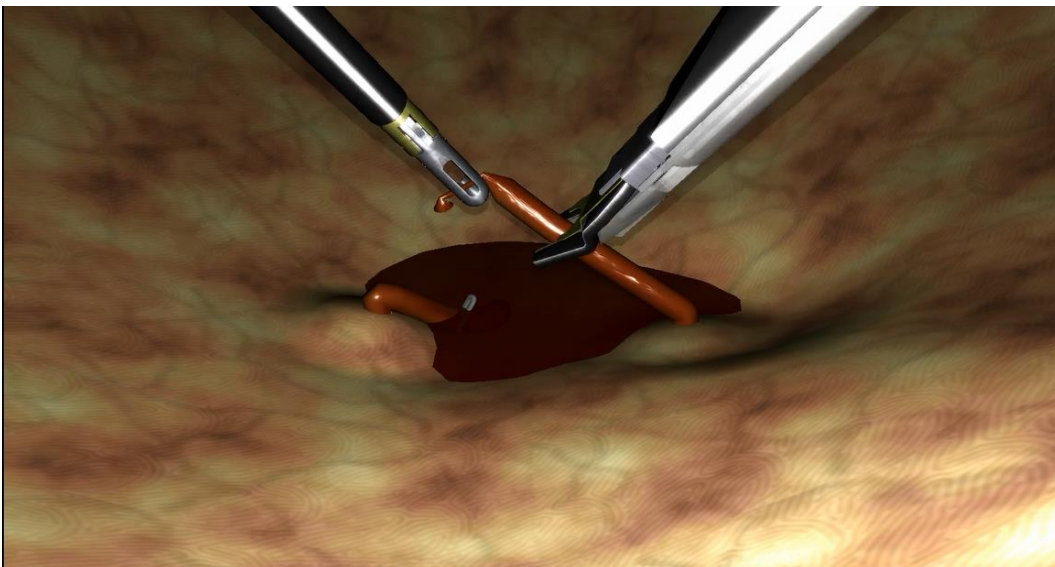


Figure 35 Clip applying on the right end of the bleeding vessel

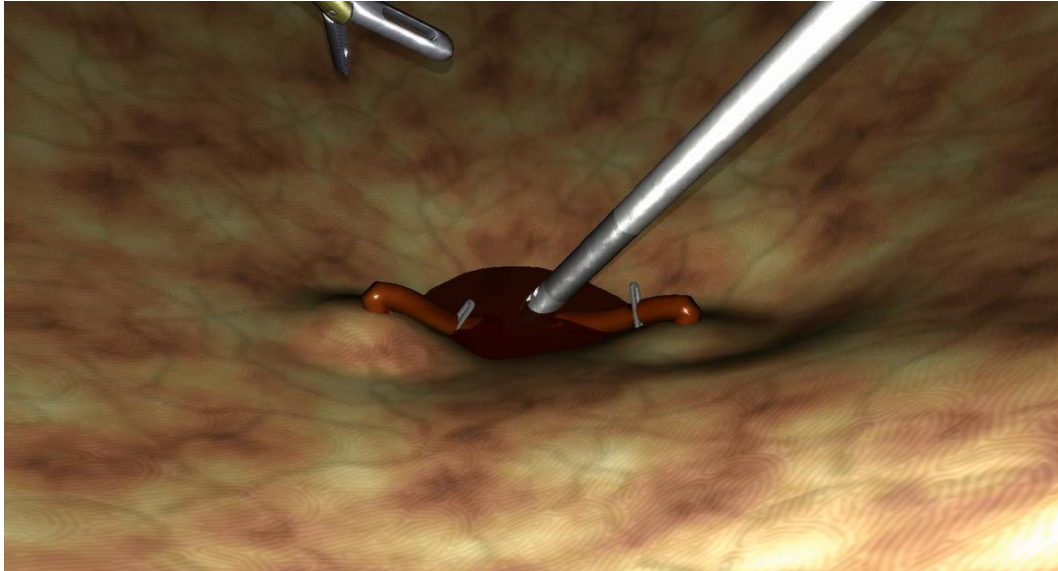


Figure 36 Draining the blood using the suction device and the pedal

4.3.9 Randomisation

The participants were randomised in two equal groups. The first group performed the task with no checklist and the second group with the trainee self-administered performance based intra-procedural checklist.

4.3.10 Application of emergency intra-procedural checklist

The aviation checklist for unexpected events (Table 2) was adopted with the previously developed performance based checklist (Figure 29) to formulate a new intra-procedural checklist to be used during simulated emergency scenarios (Figure 37).

The checklist was displayed on the wall in front of the Virtual Reality simulator. For the sake of standardization, the trainer used to sound a beep at 20 seconds intervals in order to remind the participants to apply the checklist.

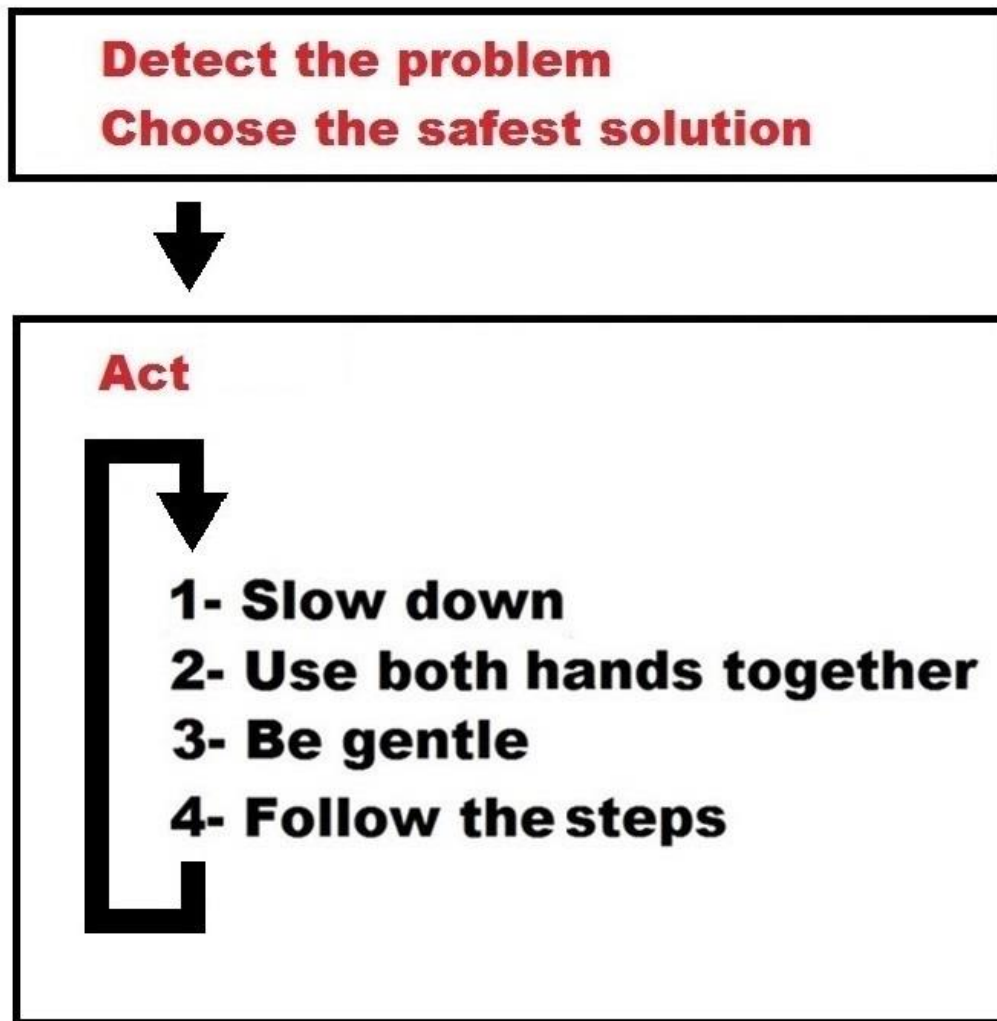


Figure 37 The performance based intra-procedural checklist for laparoscopic emergency task

4.3.11 End points and assessment

The task was computer-assessed, based on the value of 8 factors:

1. Number of badly placed clips.

The number of clips placed incorrectly, or outside designated target areas.

2. Number of dropped clips.

3. Right instrument path length (m).

The length of the path swept by the tip of the right instrument as a measure of the economy of movements.

4. Left instrument path length (m).

The length of the path swept by the tip of the left instrument as a measure of the economy of movements.

5. Right instrument angular path (degree).

Pivotal rotation of the right instrument. This is a measurement of how much the participant wiggled the instrument. It does not take into account for axial rotations.

6. Left instrument angular path (degree).

Pivotal rotation of the left instrument. This is a measurement of how much the participant wiggled the instrument. It does not take into account for axial rotations.

7. Total time (sec).

8. Blood loss (lit).

4.3.11.1 Endpoints exclusion

“Number of incomplete/complete target areas”, which is the number of areas where clip placement failed; and “the percentage of maximum stretch damage” were both excluded because the nature of this study; as the vessel had to be torn by the trainer in order to create an emergency scenario. Also at least 2 clips had to be placed at each end of the torn vessel in order to achieve haemostasis.

4.3.12 Statistical analysis

The statistical package for the Social Sciences software (version 22, SPSS Chicago, IL, USA) and Excel (Microsoft® Excel® for Windows 8®, Microsoft Corporation, Redmond, WA) were used for data analysis.

Data was not normally distributed and non-parametric statistics were used for data analysis. Data was presented as median (IQR), calculated by (Mann-Whitney U test) to study the statistical difference between the 2 groups in each of the 8 assessment points. P-value was defined as statistically significant when $p < 0.05$, and statistically highly significant when $p < 0.01$.

4.4 Results

4.4.1 Selection of the participants

Thirty medical students with no previous laparoscopic experience were selected to this study. Fourteen males and 2 left handed.

4.4.2 Assessment points

The median of each assessment point was analysed, showing a significant difference between the 2 groups in 6 out of 8 assessment points.

4.4.2.1 Number of badly placed clips

There was a highly significant difference between the 2 groups concerning the number of badly placed clips (Figure 38).

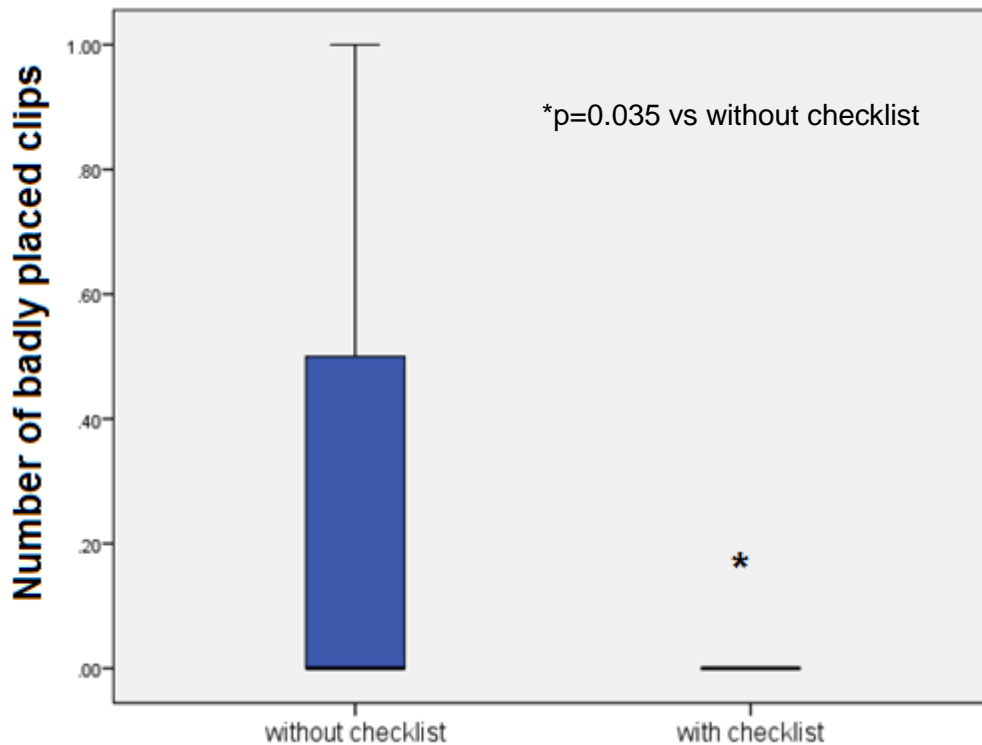


Figure 38 Median (IQR) of number of badly placed clips

4.4.2.2 Number of dropped clips

There is a highly significant difference between the 2 groups concerning the number of dropped clips (Figure 39).

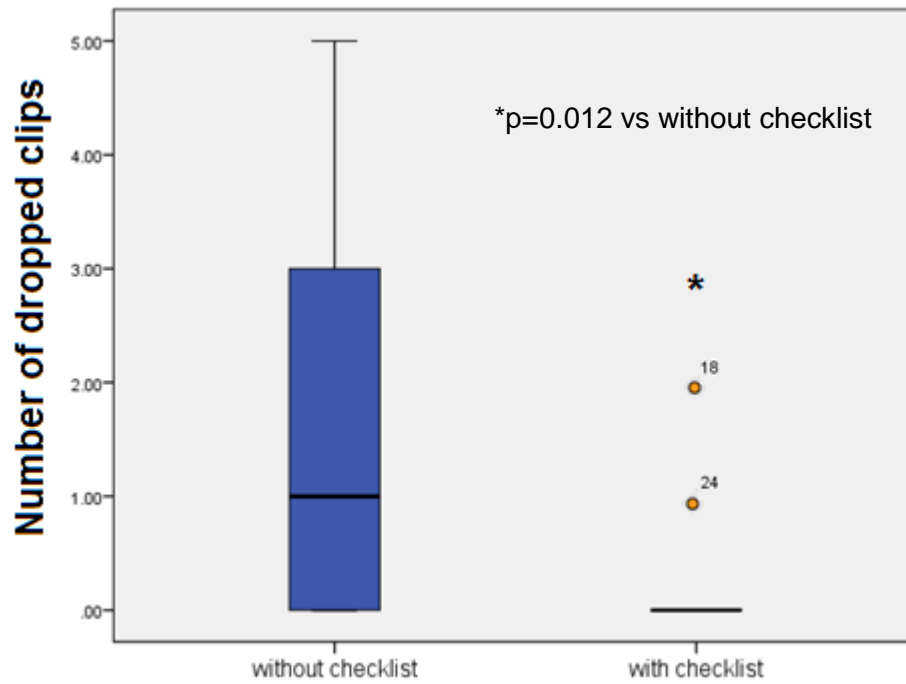


Figure 39 Median (IQR) of number of dropped clips

4.4.2.1 Right instrument path length

There was a significant difference between the 2 groups concerning the right instrument path length (Figure 40).

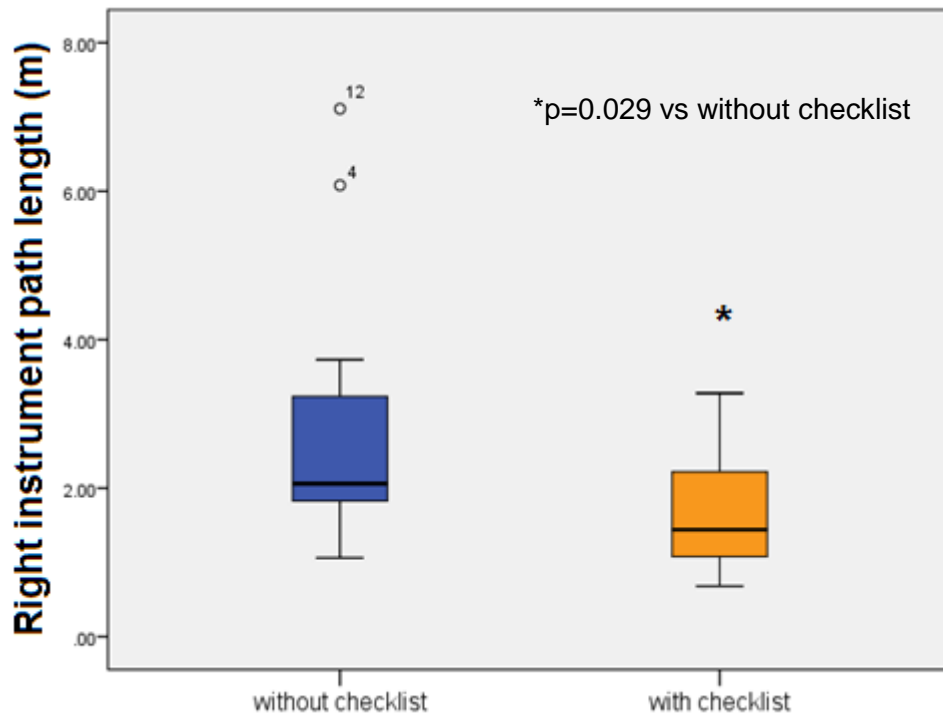


Figure 40 Median (IQR) of right instrument path length

4.4.2.2 Left instrument path length

There was a significant difference between the 2 groups concerning the left instrument path length (Figure 41).

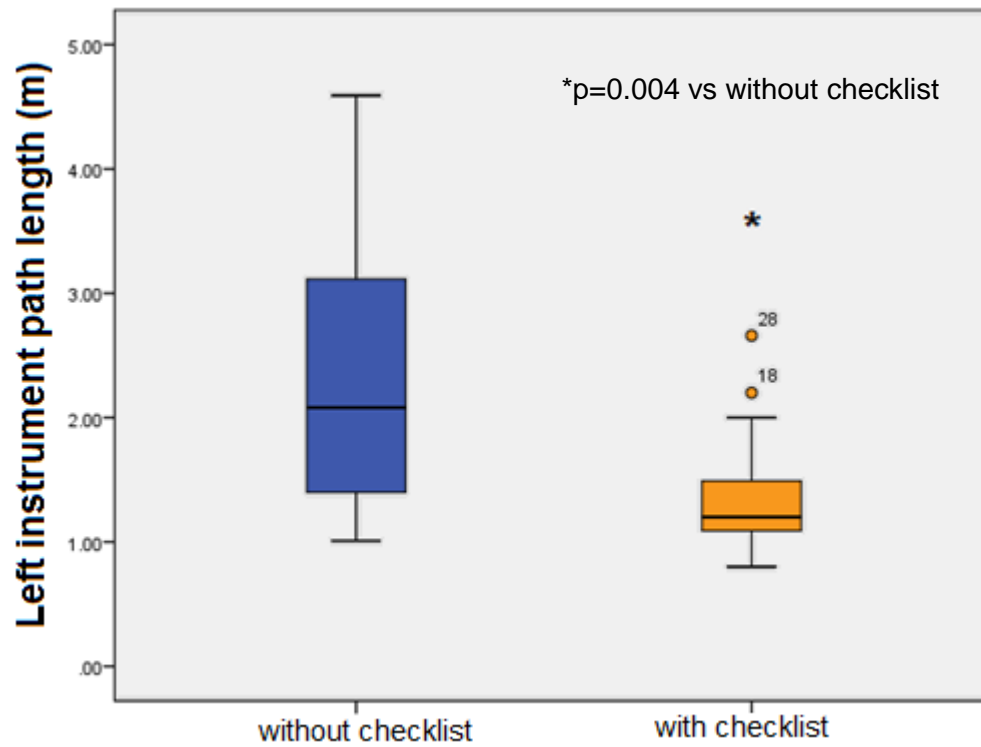


Figure 41 Median (IQR) of left instrument path length

4.4.2.1 Right instrument angular path

There is a significant difference between the 2 groups concerning the right instrument angular path (Figure 42).

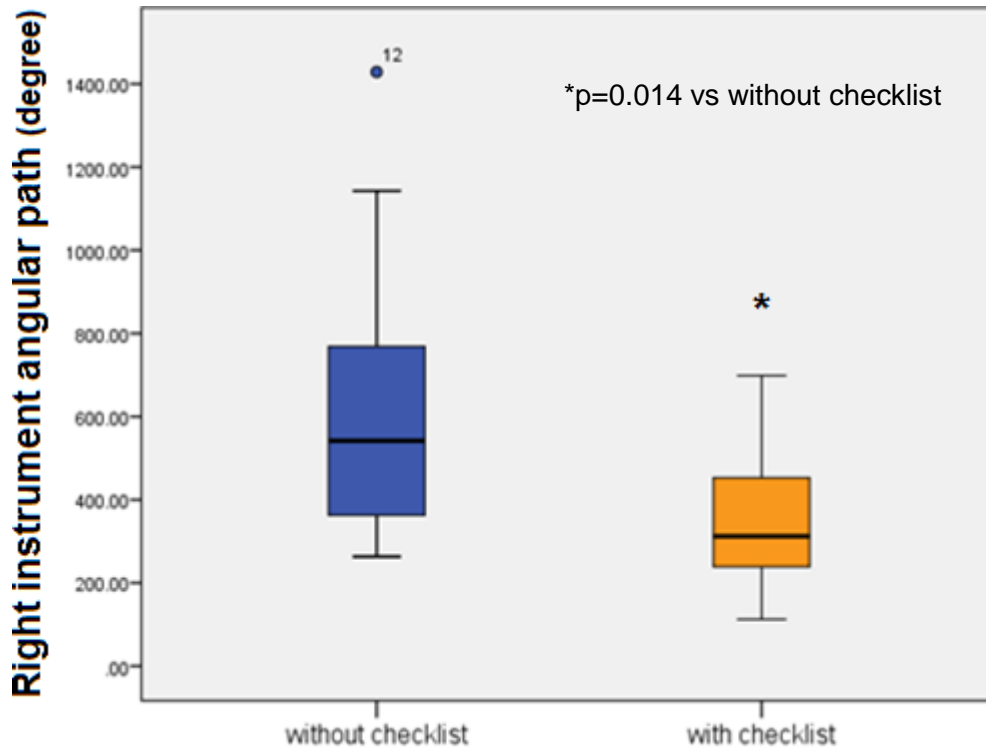


Figure 42 Median (IQR) of right instrument angular path

4.4.2.2 Left Instrument angular path

There was a significant difference between the 2 groups concerning the left instrument angular path (Figure 43).

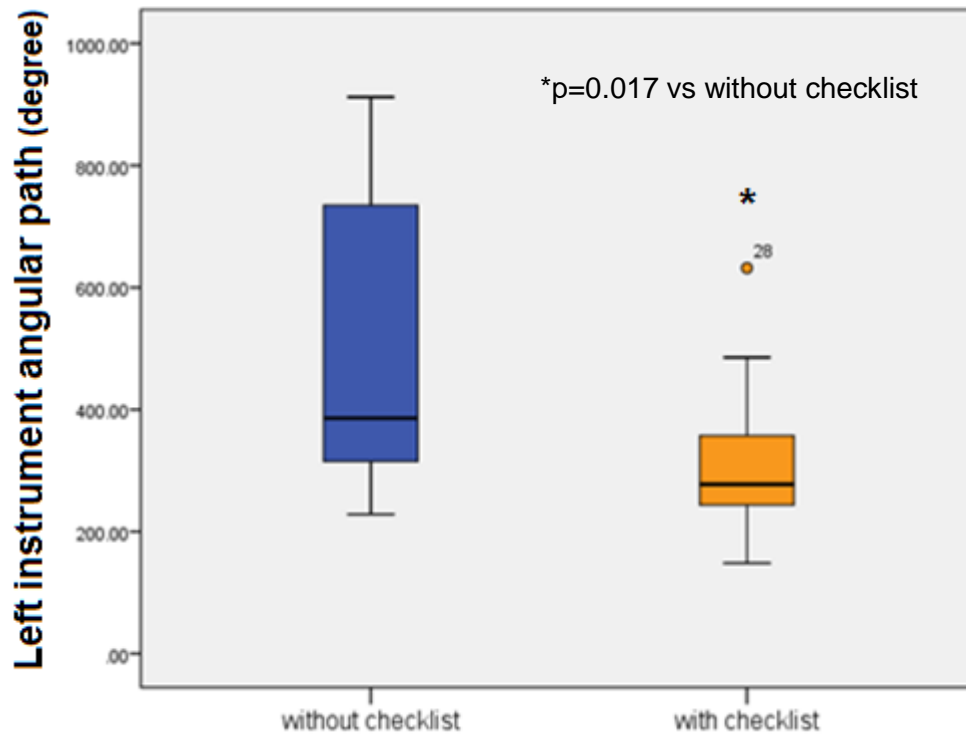


Figure 43 Median (IQR) of left instrument angular path

4.4.2.3 Total time

There was no significant difference concerning the total time (Figure 44).

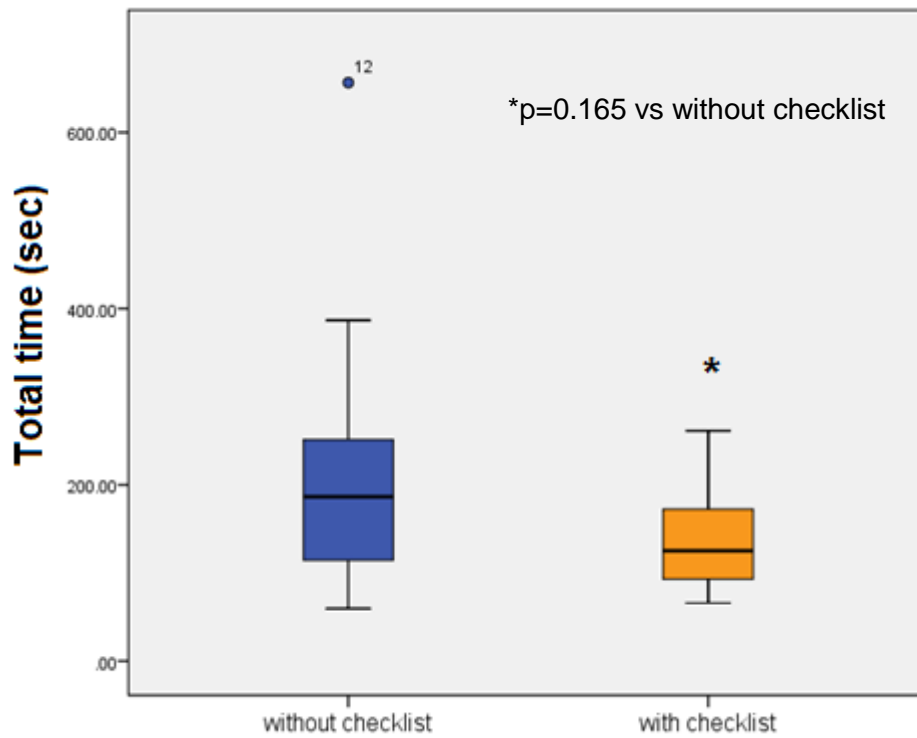


Figure 44 Median (IQR) of total time

4.4.2.4 Blood loss

There was no significant difference between the 2 groups concerning the blood loss (Figure 45).

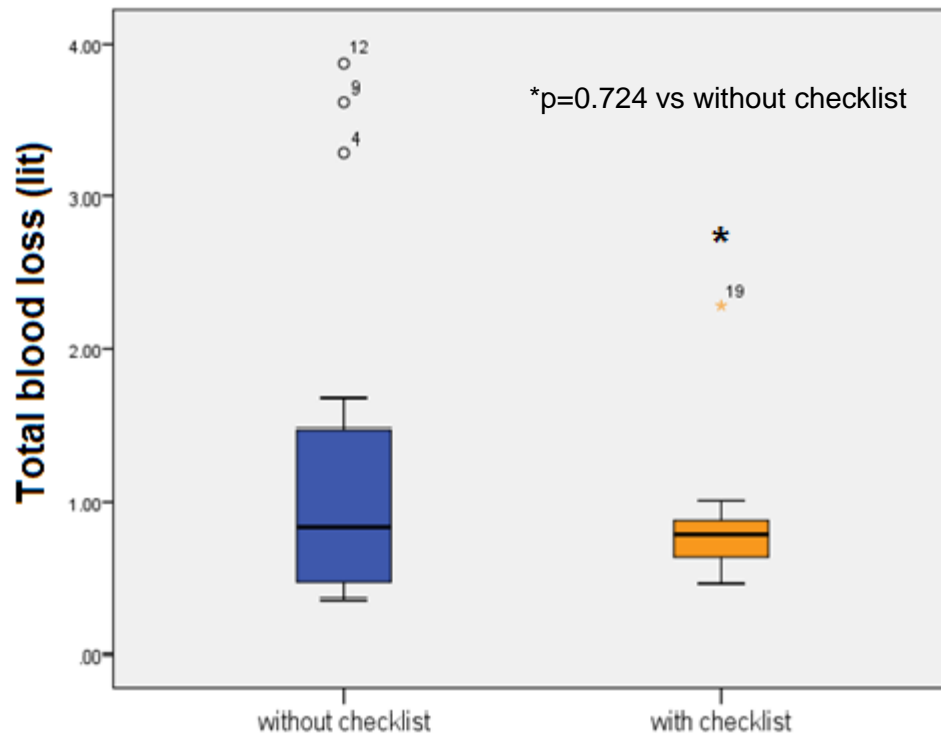


Figure 45 Median (IQR) of blood loss

4.5 Discussion

There is no study to date that has looked at the effect of a surgical checklist on the task performance during surgical emergency scenarios, laparoscopic or open, as a way of error prevention. The main aim of this study is to develop a performance based checklist for unexpected surgical situations and to study its effect in an emergency simulated scenario.

Checklists are applied routinely in aviation industry in operations, technical maintenance and repair, as well as training for pilots, and other personnel. Aviation checklist for unexpected events (DECIDE checklist) is in use for simulated training to prepare aircraft personnel to handle emergencies during flights. The DECIDE checklist was shortened into 3 simple components. These included: Detect the problem, choose the safest solution, and then act. These aim to assist the novice to formulate a solution to the problem. This was then combined with the previously developed 4-component performance based checklist (chapter 3) (Figure 37).

Research has shown that limited capacity of human brain can be exceeded when multiple attention demanding tasks are executed simultaneously. The capacity of the human mind is limited in stressful situations as the experience in the aviation industry shows. This task saturation has been causal to accidents, for example, when unexpected events or distractions disturb the routine so that some tasks are overlooked, leading to disaster. Surgeons can also suffer from task saturation in emergency scenarios when unexpected events and distractions occur. In an emergency scenario, the surgeon firstly needs to be able to detect and define what the problem is. Secondly, to be able to select an appropriate solution to remedy the problem. And thirdly to implement the solution, all executed in a timely manner. This increased demand on mental capacity can result in task saturation, giving rise to a

decline in task performance. Our checklist reminds the novice to define the problem, select a solution and execute the action in a timely manner creating a frame for structural thought process. Once the problem is defined and the solution is selected, the checklist helps the novice in executing his/her actions with fewer errors through a series of performance based checklist components (slowing down, using both hands together, being gentle and following the steps).

Our checklist is short and simple, made of seven factors making it easy to remember and quick to apply by novices repeatedly. The simplicity of the checklist minimizes its interference as a distraction during the procedure. The checklist is based on generic factors which makes it potentially applicable to most surgical procedures. The application of a mainly performance based checklist will result in error reduction rather than error correction, i.e. minimizes the occurrence of errors. Experts tend to apply our simple seven component checklist during emergency situations often unknowingly. To study the effect of the checklist on experts, we don't envisage a marked improvement. However, it takes time and practice for the novices to be able to apply these components automatically when appropriate.

The capacity of the human mind is limited in stressful situations as experience in the aviation industry shows. This task saturation has been causal to accidents, for example, when unexpected events or distractions disturb the routine so that some tasks are overlooked, leading to disaster. Surgeons can also suffer from task saturation in a routine operation when unexpected events and distractions occur. Therefore, it is an important factor to remind the surgeon where and what the problem is. Then, he has to think about the right solution with the safest option before he acts. Performing the procedure in a step wise fashion in a correct order

has been the focus of previous studies. Our checklist included this important factor but critically also included additional factors influencing the task performance itself.

Translation of a motor skills training from vitro settings to actual theatre is always unpredictable, especially when addressing the issue of 'virtual reality' (VR). Adam's (1996) approach dictated that arbitrary relations developed during motor skill training will cause the reappearance of errors when these relations exist. Training on a virtual reality simulator has been shown to improve the performance in the operating rooms.

The use of LapSim virtual reality simulator was helpful to create an emergency situation. The 8 computed predetermined technical assessment factors were very specific, giving precise results to compare between the 2 groups.

Although novices were asked to perform the tasks slowly, they managed to successfully complete the same task with fewer errors over the same period of time. Participants performed the task more accurately when they slowed down. This could be because the accuracy of a movement decreases when its speed of execution increases above a threshold. Our interpretation is that slowing down could give the participants more time for visual feedback.

The checklist appears to have improved the task performance by improving the economy of movements. It also appears that this improvement has been translated into a significant reduction in the number of errors committed during the application of haemostatic clips. However the extent of the blood loss is an example of the consequence of errors committed during the clip application. Task performance has a more direct relationship with the error itself (e.g. clip application) than its consequences (e.g. blood loss). Often there are other confounding variables that

result in the development of consequences and complications when errors are committed.

The emergency scenario of a bleeding vessel was selected for this study because it is a common encounter in clinical environment often requiring quick thinking and rapid corrective actions executed with as few errors as possible. Virtual reality simulator was selected for the purpose of this study because it allowed full participation of complete novices in an emergency surgical task. This would not be ethically and practically possible in a clinical setting. However, the criticism of using virtual reality simulators in emergency tasks is the lack of real life fear, consequence and uncertainty. In real life, errors with consequence may lead to severe harm to the patient.

Due to the nature of the emergency task, two of the computed technical assessment factors were excluded. These included number of the incomplete/complete target areas, which is the number of areas where clip placement failed and the second one is the percentage of maximum stretch damage. These assessment points were both excluded because the vessel had to be torn by the trainer in order to create an emergency scenario.

During the emergency task, the trainer torn the vessel and asked the participants to take over immediately. However, it took some participants few seconds more to realize the situation they were exposed to. This caused some delay and more bleeding, which can be our interpretation for the non-significant differences in the total time and total blood loss between the two groups.

4.6 Conclusion

The performance based checklist for emergency surgical scenarios improved the performance of laparoscopic novices when applied during a standardised unexpected bleeding task.

Chapter 5

5 The application of the checklist in a clinical environment

Chapter 5

5.1 Introduction

This study consists of the application of the developed performance based self-administered intra-procedural checklist (see chapter 3) in operating theatres during elective procedures as a way of error reduction and error prevention.

5.2 Aims

We aimed to study the effect of the performance based self-administered intra-procedural checklist in elective laparoscopic procedures in the operating theatres of the Tayside NHS trust, as a way of error reduction mechanism and improvement of patient safety.

5.3 Methods

5.3.1 Task selection and grading of difficulty

Each gall bladder was graded (1 to 3) anatomically as an indication for the potential procedural difficulty as seen in Table 8.

<p>Grade 1:</p> <p>No adhesions to the gall bladder</p> <p>Cystic duct seen on retraction of gall bladder</p> <p>No obvious ductal or vascular anatomy</p> <p>Unobstructed view of Calot's triangle.</p>
<p>Grade 2:</p> <p>Obese patient</p> <p>Fat-laden falciform</p> <p>Hypertrophied liver: quadrate lobe partially obstructing view and/or right hepatic lobe making retraction difficult.</p> <p>Filmy/loose areolar adhesions to the gall bladder</p> <p>Fat over Calot's triangle.</p>
<p>Grade 3:</p> <p>Dense omental adhesions to the gall bladder</p> <p>Duodenal adhesions to the gall bladder</p> <p>Difficult, obscure, abnormal anatomy</p> <p>Contracted, inflamed, or densely adherent gall bladder</p> <p>Stone impacted in neck or Hartmann's pouch</p> <p>GB neck adherent to bile duct.</p>

Table 8 Grading the difficulty of laparoscopic cholecystectomy

5.3.2 Participants' inclusion criteria

Higher surgical trainees in general surgery at Tayside were included in this study and required the attendance of a trainer during the procedure as per routine practice. Only two trainers were included in this study for standardisation. The training level of the participants and their previous experience on laparoscopic cholecystectomy were noted.

5.3.3 Participants' recruitment

Surgical trainees were invited to this study by an email invitation from the secretary of the surgical department. A clinical research fellow at the University of Dundee was responsible for the trainees' recruitment, using participant information sheets as the main medium of recruitment.

5.3.4 Location and procedural selection

This part of the study took place in theatres affiliated with Tayside NHS trust (Ninewells hospitals, Perth Royal Infirmary and Stracathro Hospital).

Laparoscopic cholecystectomy was included in this study. Two procedures for each trainee were video-recorded without the use of the checklist, directly followed by 2 further operations after the introduction of the checklist.

The digitalised unedited videos were anonymously stored on the computer at the Cuschieri Skills Centre for error analysis by a blinded assessor using the HRA technique. A randomly selected number of videos were assessed by second blind assessor as a test of reliability of the results when compared to the first assessor analysis.

5.3.5 Application of checklist

Unlike the lab-based study, the optical view was not standardized in this clinical study. Therefore, exposure was added to the checklist (Figure 46). The checklist was displayed in front of every trainee while he/she operates (Figure 47). A clinical research fellow used a soft beeping sound to remind the trainees to apply the checklist at 4-minutes intervals due to the longer duration of the task in the clinical study.



Figure 46 The performance based checklist for elective laparoscopic procedures



Figure 47 The displayed checklist in front of the operating trainee

5.3.6 End points of the clinical study

- Number of errors (consequential and inconsequential).
- Number of instrument movements.
- Time execution of the procedure.
- Error types.
- Number of trainer intervention.
- Trainee satisfaction score.

5.3.7 Measurements

- Total number of errors per total number of instrument movements.
- Total number of errors per time.
- Error types per time.
- Total number of instrument movements per time.
- Number of trainer intervention per time.

5.3.8 Task zones of laparoscopic cholecystectomy

The hierarchal task analysis involved the division of laparoscopic cholecystectomy into 3 component task zones (Table 9).

Task 1: Dissection of cystic duct and artery in Calot's triangle.
Start: grabbing the fundus of the gallbladder (Figure 48). End: insertion of the clip applier (Figure 49).
Task 2: Clipping of the cystic artery and transection of the cystic duct.
Start: insertion of the clip applier End: transection of both the cystic artery and cystic duct.
Task 3: Separation of the gallbladder from the liver bed.
Start: transection of both the cystic artery and cystic duct. End: complete separation of the gallbladder from the liver bed (Figure 50).

Table 9 Hierarchal division of laparoscopic cholecystectomy into 3 task zones

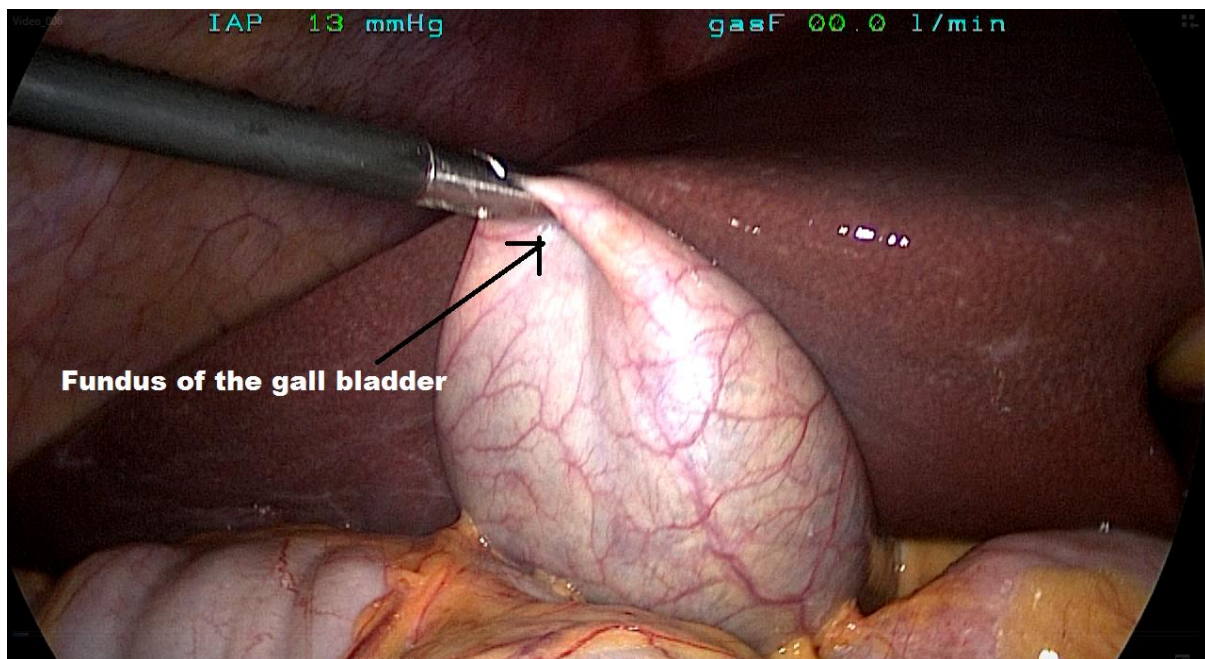


Figure 48 Grabbing the gallbladder fundus with the grasper

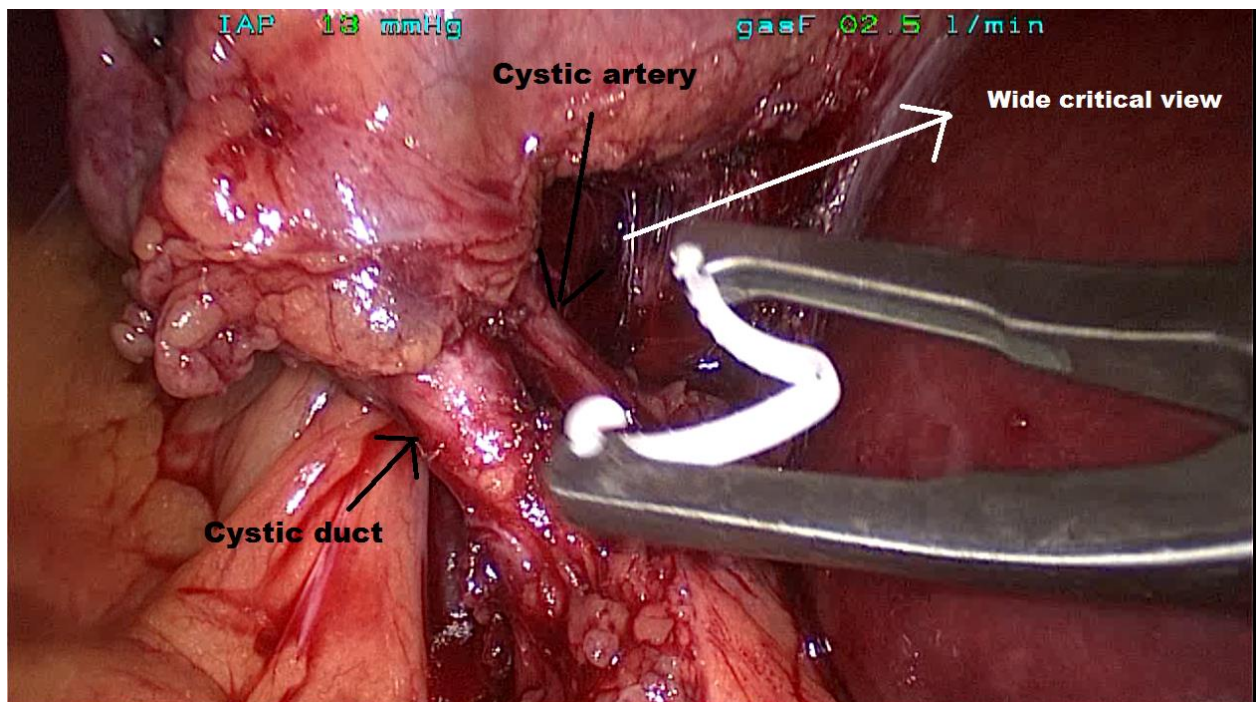


Figure 49 Insertion of laparoscopic clip applicator

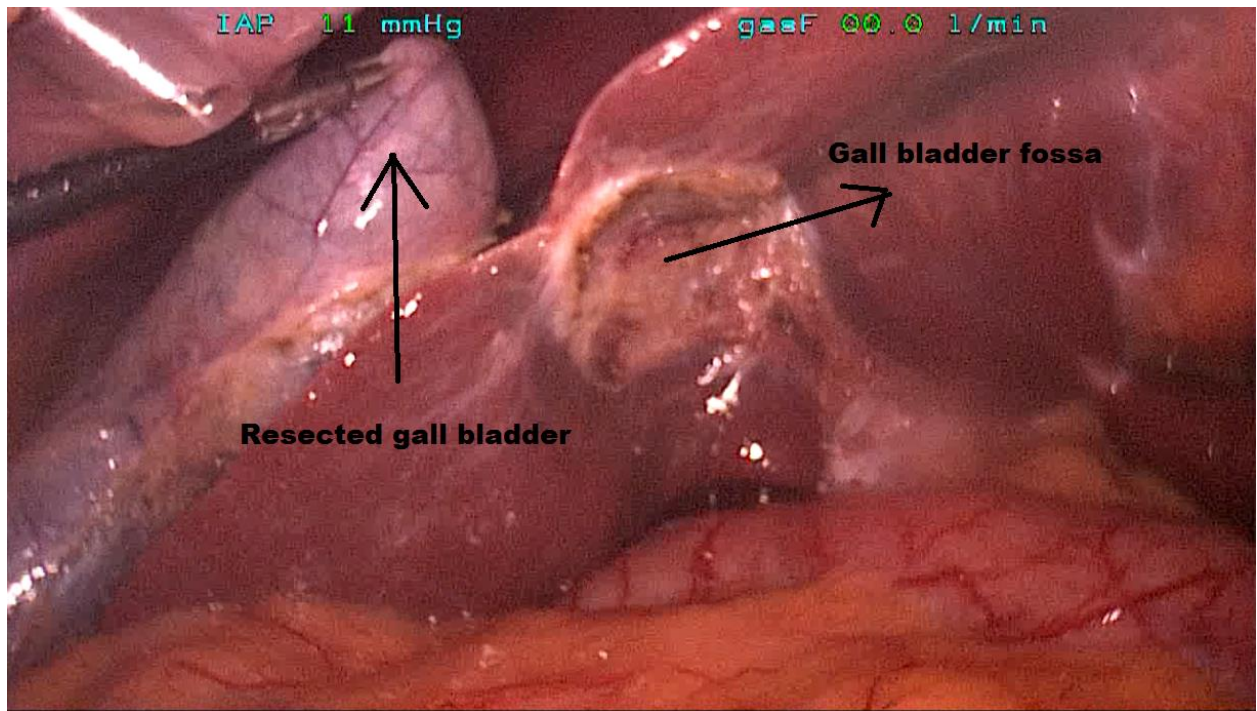


Figure 50 Complete separation of gall bladder from the liver bed

5.3.9 Setup of laparoscopic cholecystectomy

The patient is positioned supine on the bed. The anaesthetist stayed towards the patient's head in order to monitor the vital functions and the ventilation of the patient. The scrub nurse and the instrument table were towards the right limb of the patient. The operating surgeon had to stand on the left side of the patient, as well as the first assistant who was responsible of holding the telescope. The second assistant had to stand on the right side of the patient to hold a grasper to push the gall bladder fundus cephalad to achieve good exposure of Calot's triangle.

The procedure was started by making a 12 mm sub-umbilical incision. A trocar was placed through this incision and was connected to the insufflation tubing. Once the abdomen was insufflated, the scope was inserted through the trocar. Under visualization, one 11 mm trocar sub-xiphoid was placed with one 5 mm trocars in the

right upper quadrant and one 5 mm trocar in the right lumbar region of the abdomen (Figure 51).

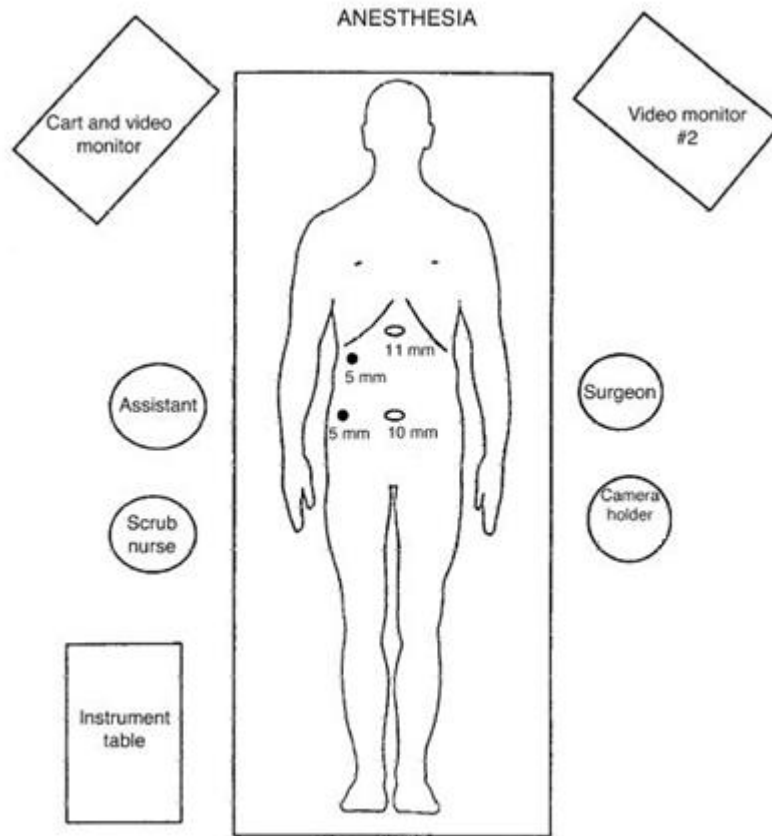


Figure 51 Setup of laparoscopic cholecystectomy

5.3.10 Equipment and instruments

The monitor:

Karl Storz, 26" HD monitor, code 9524NB, colour systems PAL/NTSC, max. screen resolution 1920 x1200, image format 16:10, power supply 100 - 240 VAC, 50/60 Hz.

Telescope:

Karl Storz, 26003BA, Hopkins ®, 30 degrees, 10mm diameter, 31 cm length.

Camera control unit:

Karl Storz, IMAGE 1 HUB HD Camera Control Unit SCB, max. resolution 1920x1080 pixels, color systems PAL/NTSC, power supply 100-240 VAC , 50/60 HZ.

Camera head:

Karl Storz, 22220055 Image1 H3-Z 3-chip HD camera head 1080P, PAL/NTSC 50/60hz.

Light source:

Karl Storz Cold Light Fountain Xenon 300 SCB, with Karl Storz-SCB, with integrated anti-fog pump, 300 Watt Xenon bulb, power supply 100-125/220-240 VAC, 50/60Hz.

Light cable:

Karl Storz Fibre Optic Light Cable, code 495NCS, with straight connector, diameter 4.8 mm, length 250 cm.

THERMOFLATOR-SCB:

Karl Storz, Power supply 100-240 VAC, 50/60 Hz.

Instruments:

The trocars were ENDOPATH® XCEL™ UNIVERSAL SLEEVES, Ethicon ©, Johnson & Johnson Medical Ltd, New Jersey, USA (Figure 52).

CB5LT Stability sleeve, 5mm diameter, 100mm

CB11LT Stability sleeve, 11mm diameter, 100mm

CB12LT Stability sleeve, 12mm diameter, 100mm

Pledget holder/ grasper with ratchet: CLICKLINE Forceps, 33310ME, Karl Storz, single action jaws, with multiple teeth, width of jaws 4.8 mm, for atraumatic and accurate grasping, size 5 mm, length 36 cm, consisting of: 33121 Plastic Handle (Figure 53).

Duckbill grasping forceps: CLICKLINE REDDICK-OLSEN Dissecting and Grasping Forceps, Karl Storz, rotating, dismantling, insulated, with connector pin for unipolar coagulation, with LUER-Lock irrigation connector for cleaning, double action jaws, size 5 mm, length 36cm. Consisting of: 33121 Plastic Handle without ratchet, 33300 Metal Outer Sheath, 33310 KJ Forceps Insert (Figure 54).

Electrocautery dissecting hook: CADIERE Coagulating and Dissecting Electrode, 26775CL, Karl Storz, insulated sheath, with connector pin for unipolar coagulation, L-shaped, with cm-marking, distal tip tapered, size 5mm, length 43 cm (Figure 54).

CLICKLINE Kelly Dissecting and Grasping Forceps, Karl Storz, rotating, dismantling, insulated with connector pin for unipolar coagulation, with LUER-Lock irrigation connector for cleaning, double action jaws, size 5 mm, length 36 cm consisting of: 33121 Plastic Handle, without ratchet, 33300 Metal Outer Sheath, 33310 ML Forceps Insert (Figure 56).

APPLIERL, Laparoscopic Applier for Large Polymer LocaClip, LocaMed Limited, UK. LML003, Large Polymer Ligating LocaClip (6 Clip/Cartridge), LocaMed Limited, UK (Figure 57).

CLICKLINE Hook Scissors, 34321EK, Karl Storz, rotating, dismantling, with connector pin for unipolar coagulation, with irrigation connection for cleaning, single action jaws, tips of jaws not crossing, size 5 mm, length 36cm. Consisting of: 33121 Plastic Handle, insulated, without ratchet, 33300 Outer Sheath, insulated, 34310 EK Scissors Insert (Figure 58).



Figure 52 ENDOPATH® XCEL™ UNIVERSAL SLEEVES, Ethicon trocars



Figure 53 Pledget holder, grasper with ratchet



Figure 54 Electrocautery dissection hook



Figure 55 Kelly dissecting forceps



Figure 56 Duckbill grasping forceps

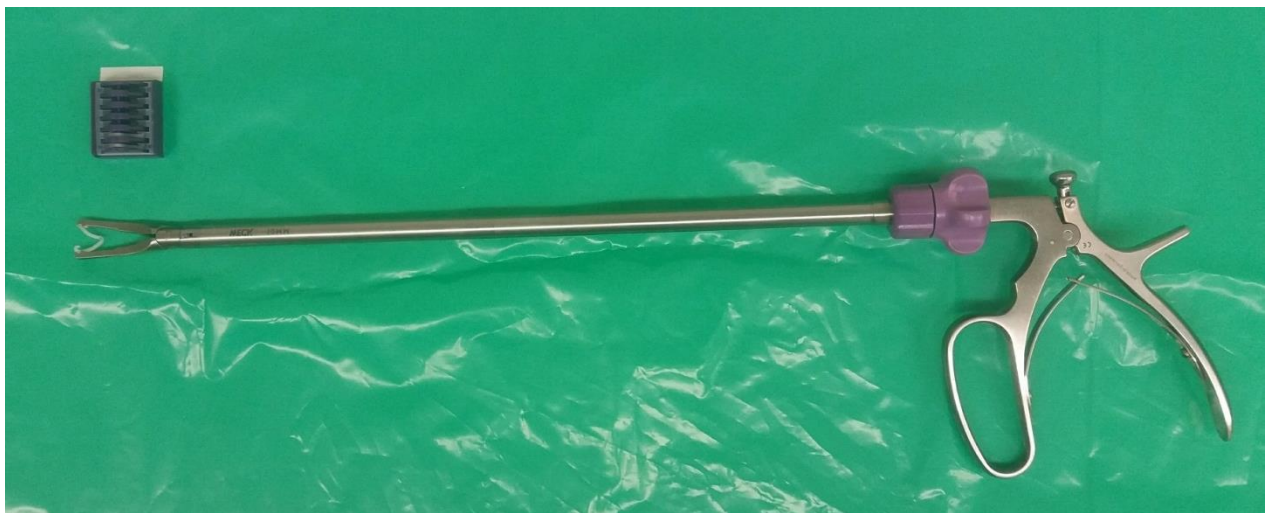


Figure 57 Laparoscopic clip applier



Figure 58 Laparoscopic hook Scissors

5.3.11 Technique of laparoscopic cholecystectomy

Dundee technique for laparoscopic cholecystectomy was used. The fundus of the gall bladder was grasped and retracted towards the right shoulder of the patient. The Hartman's pouch was retracted antero-laterally towards the right anterior superior iliac spine. Dissection of Calot's triangle was made by using the following instruments:

1-The hook diathermy.

2-The pledget.

3-The CLICKline Kelly Dissecting and Grasping Forceps.

The Cystic artery and Cystic duct were clipped using large Polymer Hem-o-lok® clips, then were transacted by the hook scissors. The gallbladder was peeled from the liver bed using the hook diathermy.

5.3.12 Procedural error assessment

The details of the error classification system were described in a study by Joice *et al* (1998). Errors were classified into consequential or inconsequential (Table 10 and Table 11). Purposeless movement of the instrument was regarded as inconsequential error.

Consequential errors	Task 1	Task 2	Task 3
Perforation:			
Of the gall bladder			
Of the small bowel			
Bleeding:			
From the liver injury			
From a cystic artery			
From small vessels			
From an omental injury			
Injury to the cystic duct			
Omitting to coagulate bleeding			
Diathermy burn:			
To the liver			
To the diaphragm			
To the duodenum			
To the abdominal wall			
Broken instrument			
• <i>Total number of errors</i>			

Table 10 Consequential errors classification in laparoscopic cholecystectomy

Inconsequential errors	Task 1	Task 2	Task 3
Overshooting of instrument movement (use of excessive force with instrument traveling a longer distance than optimum)			
Non-visualization of instrument tip during dissection			
Instrument movement out of endoscopic view			
Applying current without visualizing the instrument			
Avulsion of the tissue rather than dissection			
Cutting without lifting tissues from underlying structures			
Inappropriate cutting with instruments			
Insertion of instruments in wrong tissue planes			
Inappropriate grasping of tissues			
Purposeless movement of instrument			
<ul style="list-style-type: none"> <i>Total number of errors</i> 			

Table 11 Inconsequential errors classification in laparoscopic cholecystectomy

5.3.13 Trainee satisfaction survey

A post-procedural paper survey was applied as a feedback from each participant at the end of the last procedural performance using a 5-point Likert scale (Table 12).

Please choose only one answer	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1. I found it easy to apply the checklist					
2. I found the checklist useful					
3. I will consider using the checklist routinely					

Table 12 Trainee satisfaction post-procedural survey

5.3.14 Trainer satisfaction survey

A post-procedural paper survey was applied as a feedback from the two trainers at the end of the last procedural performance using a 5-point Likert scale (Table 13).

Please choose only one answer	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1. I found it easy to apply the checklist					
2. I found the checklist useful					
3. I will consider the trainees to use the checklist routinely					

Table 13 Trainer satisfaction post-procedural survey

5.3.15 Statistical analysis

The statistical package for the Social Sciences software (version 22, SPSS Chicago, IL, USA) and Excel (Microsoft ® Excel ® for Windows 8 ®, Microsoft Corporation, Redmond, WA) were used for data analysis.

Data for number of errors per time, number of errors per number of instrument movements, number of instrument movements per time and number of trainer's interventions per time showed non parametric distribution and were presented as median (IQR) and (Wilcoxon test) was used for statistical analysis.

P-value was defined as statistically significant when $p < 0.05$, and statistically highly significant when $p < 0.01$.

5.4 Results

5.4.1 Participants' demographic data

Six trainees in the general surgery from the Tayside NHS were selected in this study. All the participants were right handed and 3 were male and 3 were female. The level of training and their logbook were noted as follows:

- Two participants at ST6-ST8 registrar level who had previously performed 60-80 laparoscopic cholecystectomies.
- Two participants at ST4-ST5 registrar level with previous experience of 30-40 laparoscopic cholecystectomies.
- Two participants at ST3-ST4 registrar level with previous experience of 10-15 laparoscopic cholecystectomies.

5.4.2 Number and grade of difficulty of procedures

Twenty-four laparoscopic cholecystectomies were enrolled into the study. Six surgical trainees each performed 4 cases, 2 cases without the application of the checklist and directly followed by 2 cases with the checklist.

When comparing the anatomical grades of difficulty of the procedures in the 2 groups with and without the application of the checklist respectively, 5 were graded easy vs 8; 3 graded average vs 3; and 4 graded difficult vs 1.

5.4.3 Total number of errors per total number of instrument movements

There was a statistically significant difference between both arms of the trial concerning the number of errors per number of instrument movement (Figure 59).

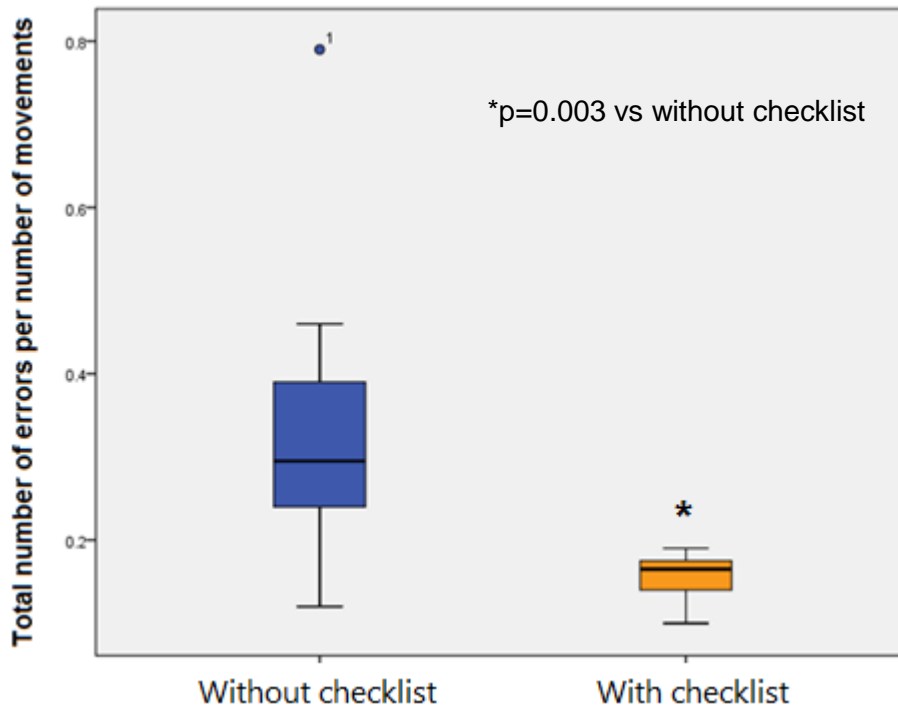


Figure 59 Total number of errors per total number of instrument movements with and without application of checklist

5.4.4 Number of errors per time

There was a statistically significant difference between both arms of the trial concerning the total number of errors per time (Figure 60).

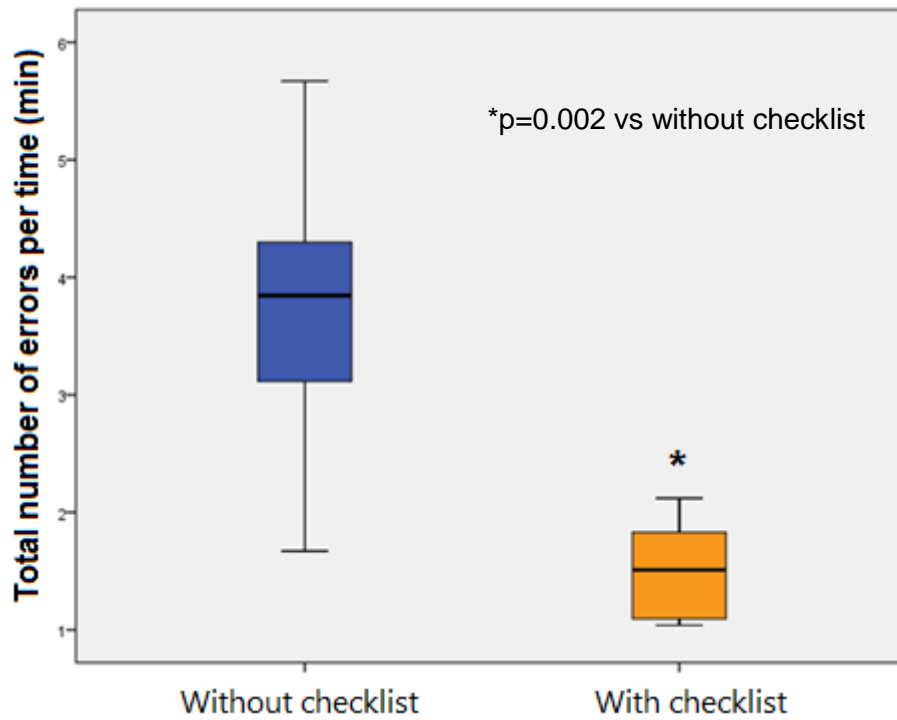


Figure 60 Total number of errors per time with and without application of checklist

There was a statistically significant difference between both arms of the trial concerning the number of consequential errors per time (Figure 61).

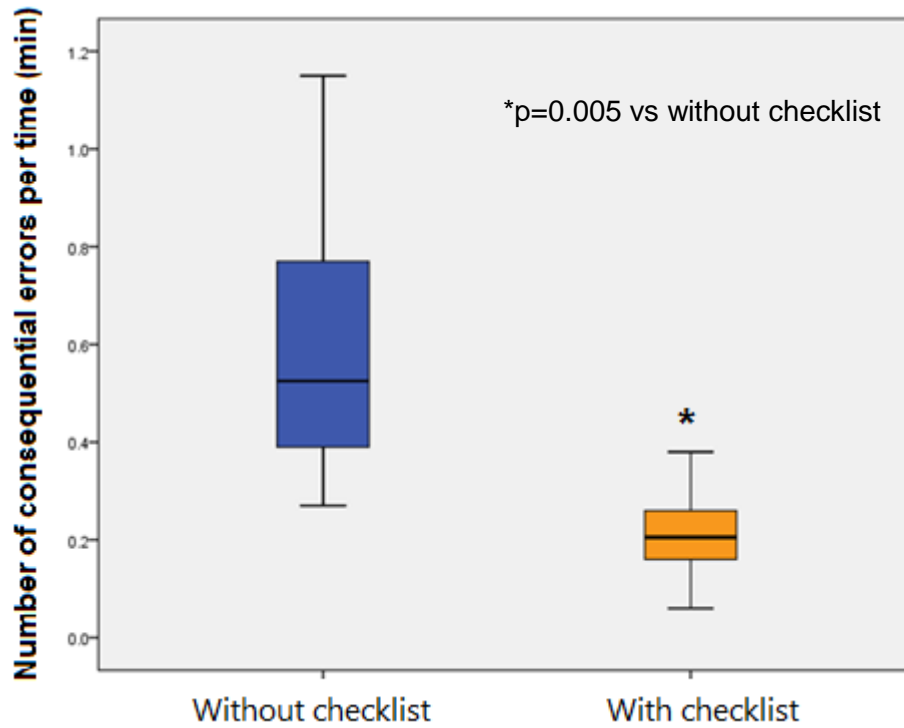


Figure 61 Number of consequential errors per time with and without application of checklist

There was a statistically significant difference between both arms of the trial concerning the number of inconsequential errors per time (Figure 62).

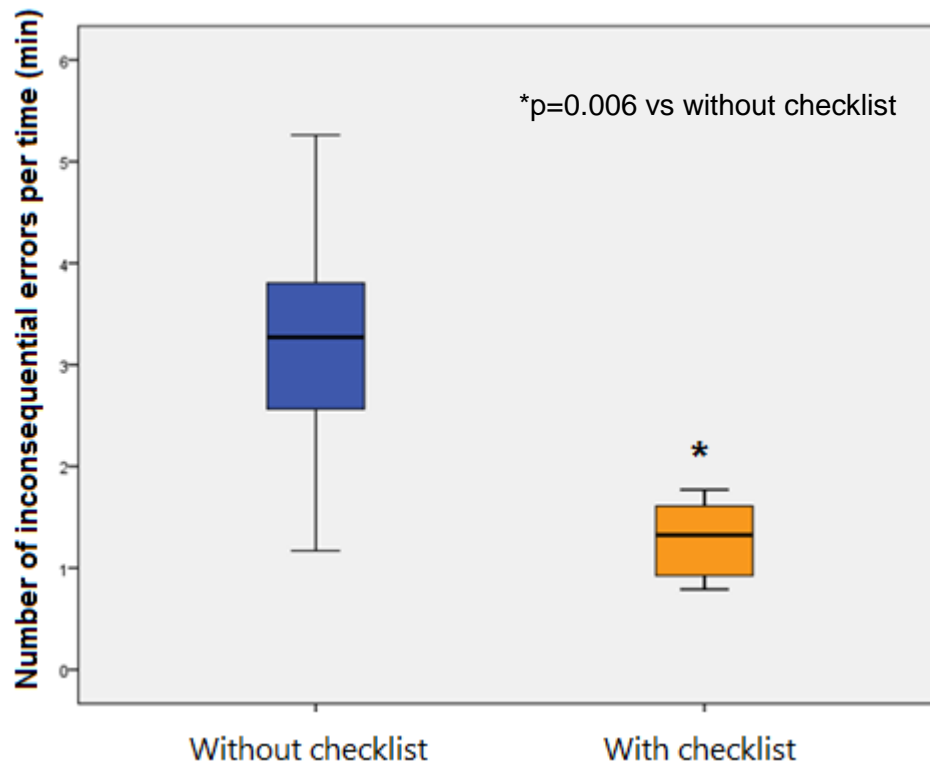


Figure 62 Number of inconsequential errors per time with and without application of checklist

5.4.5 Error types per time

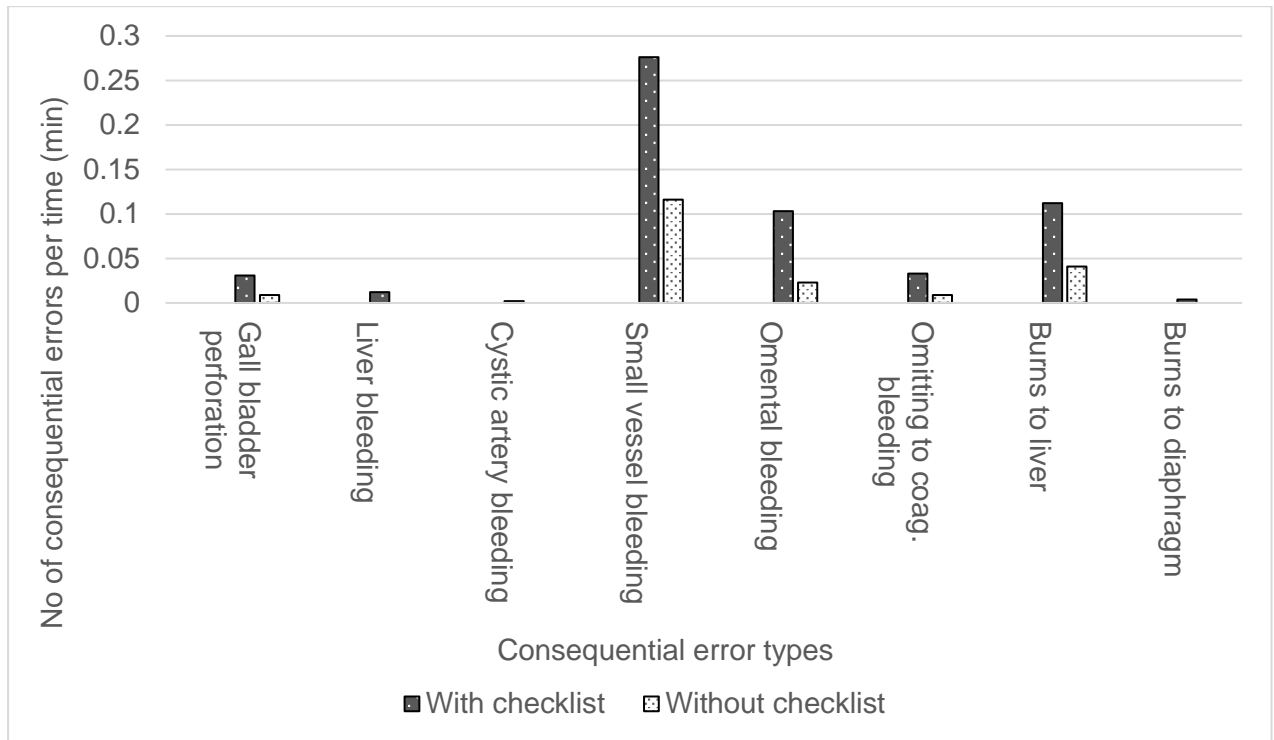


Figure 63 Consequential error types per time with and without application of checklist

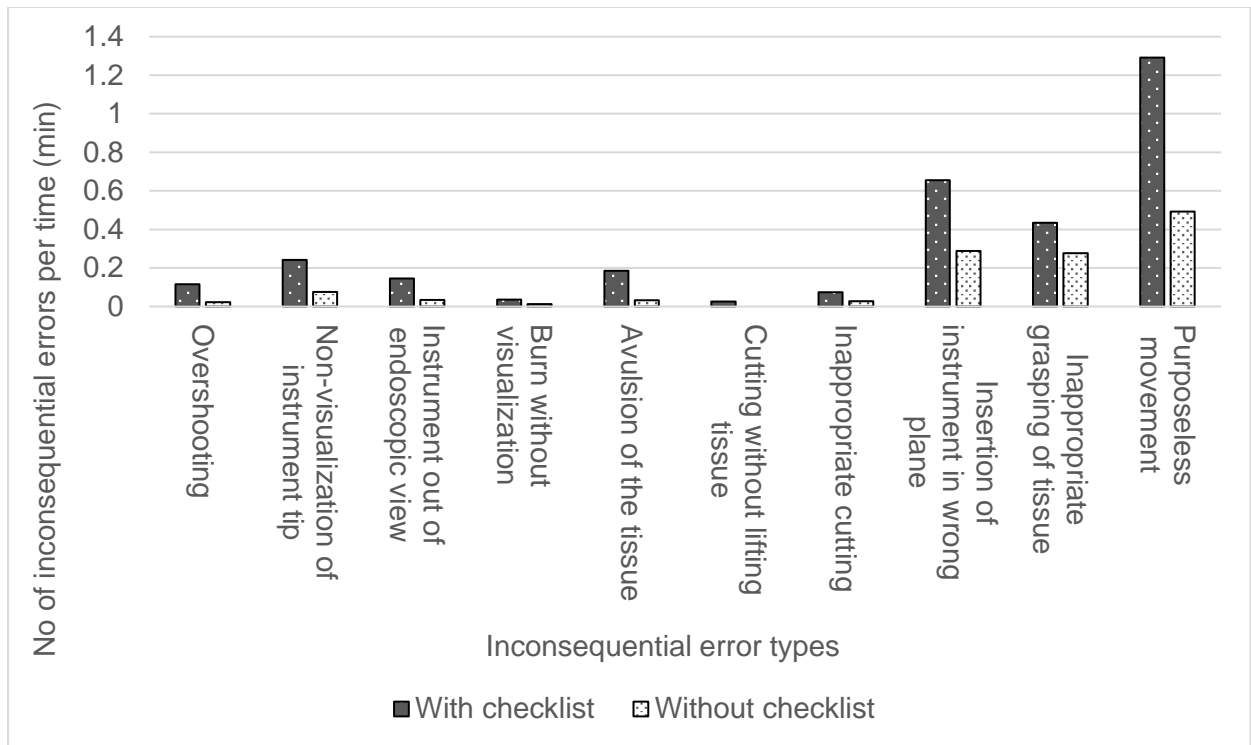


Figure 64 Inconsequential error types per time with and without application of checklist

5.4.6 Number of trainer interventions per time

There was a statistically significant difference between both arms of the trials concerning the interventions of the trainer per time (Figure 65).

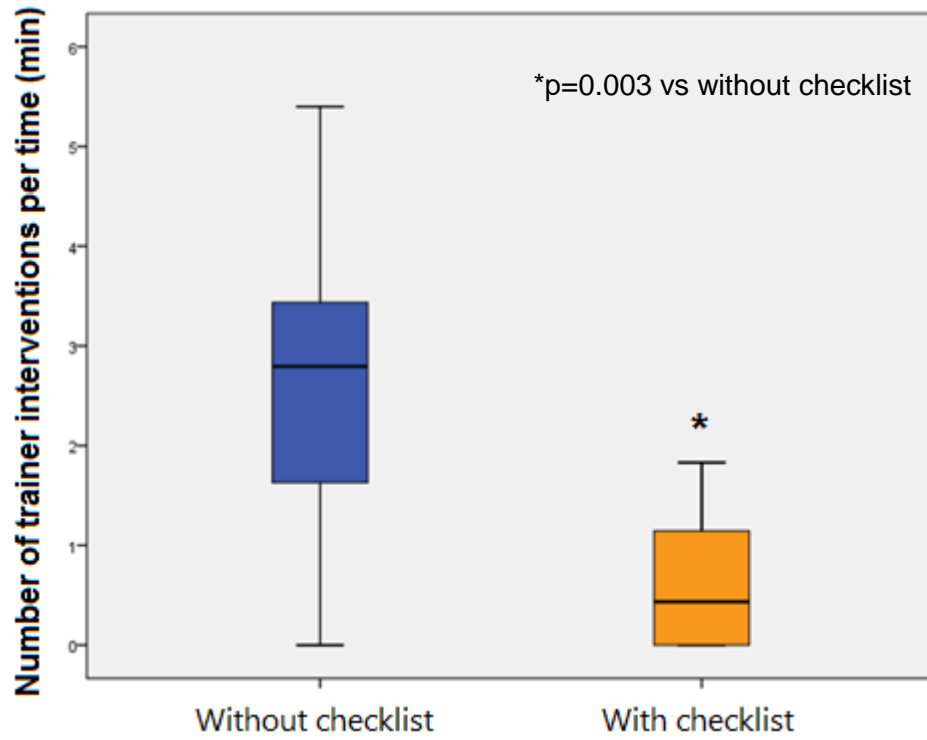


Figure 65 Number of trainer interventions per time with and without application of checklist

5.4.7 Number instrument movement per time

There was a statistically significant difference between both arms of the trial concerning the number of instrument movement per time (Figure 66).

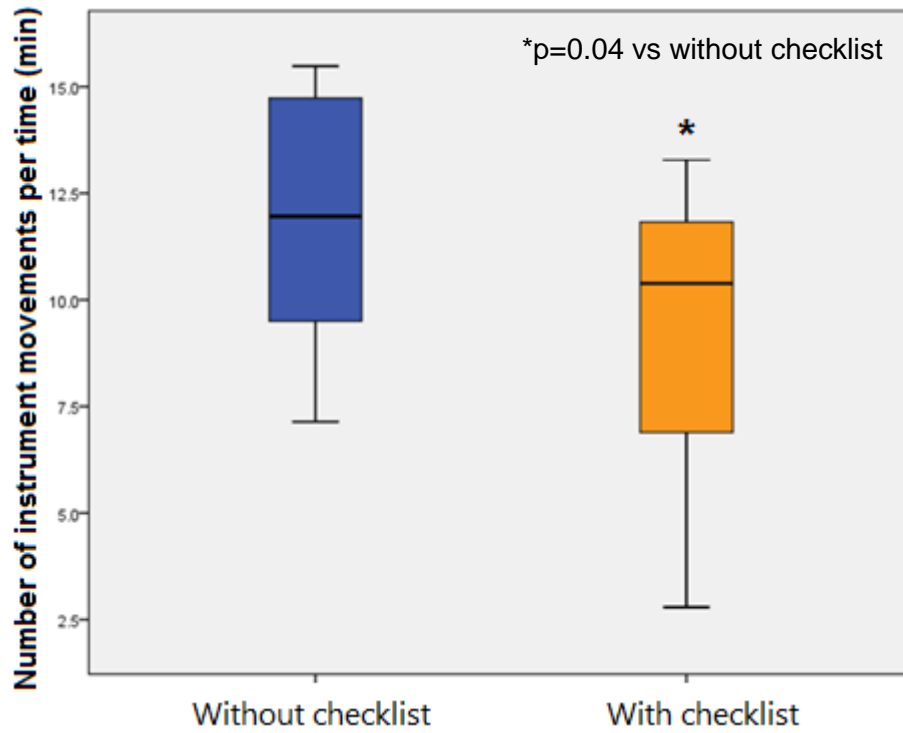


Figure 66 Number of instrument movement per time with and without application of checklist

5.4.8 Trainee satisfaction score

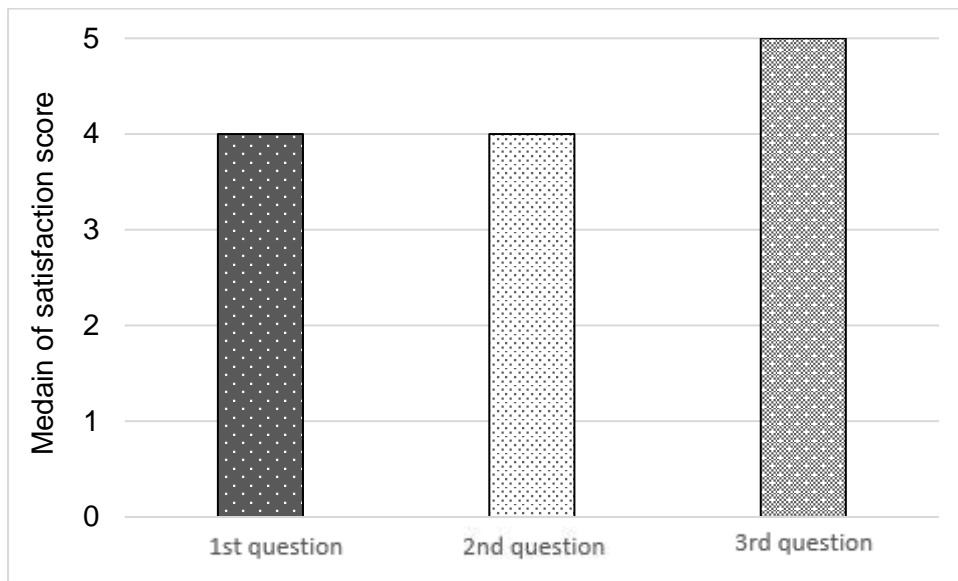


Figure 67 Score of trainee satisfaction survey

5.4.9 Trainee satisfaction score

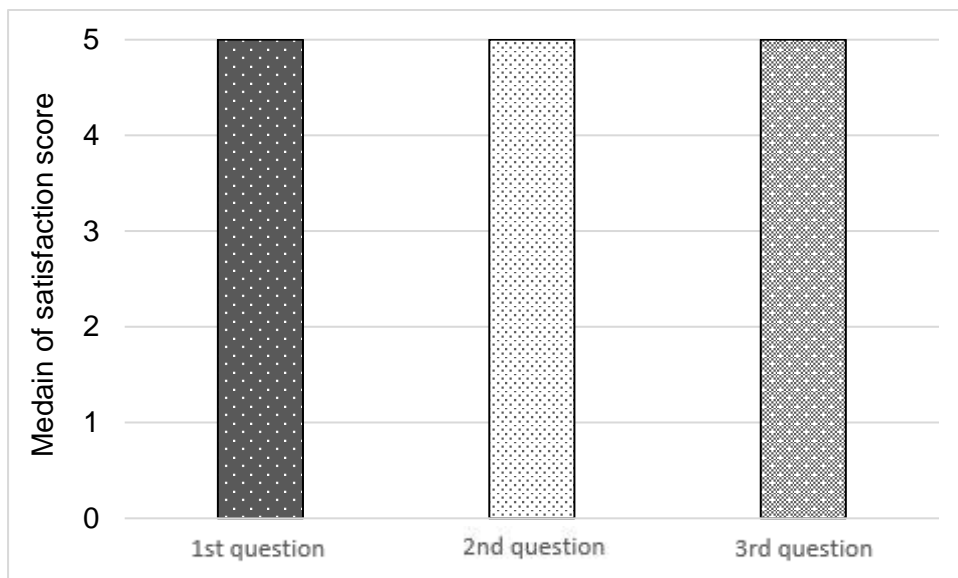


Figure 68 Score of trainer satisfaction survey

5.5 Discussion

The main aim was to study the effect of the previously developed performance based self-administered checklist on the performance of surgical trainees during elective laparoscopic cholecystectomy.

Due to the variation in the duration of each procedure, the number of errors, number of instrument movements, error types and number of trainer interventions were calculated per time and/or per instrument movements.

Number of errors were calculated per both, time and instrument movements. Total number of errors per total number of instrument movements, total number of errors per time, as well as the number of consequential and inconsequential errors per time significantly decreased with the application of the checklist. During the performance of a surgical task, anyone of the three components namely time of execution, number of movements to achieve the task and number of errors committed during the task can either kept constant or increase/decrease in any combination or permutation which results in a variety of outputs for errors over time and errors over movements (Table 14).

One can assume that there appears to be a relationship between the checklist and certain error types. For example, being asked to slow down may have resulted in committing fewer errors defined as “purposeless movement of the instrument” and “insertion of instrument in wrong tissue plane”. There was a significant improvement with the application of the checklist in “overshooting of the instrument” and “avulsion of the tissues”, this could have been due to the checklist asking the trainees to be gentle. “Non-visualization of instrument tip” and “instrument out of endoscopic view” may have been corrected by the component of the checklist “check the exposure”.

One cannot be sure about the relationship between the error types and the checklist components, as we did not study each component individually. Participants also committed fewer number of consequential errors, this mainly was noted in less “gall bladder perforation”, “burns to the liver”, “bleeding from omental injury” and “bleeding from small vessels”.

Number of interventions by the trainer per time significantly decreased during the application of the checklist. The trainer intervention can be seen as a test of external validity for the checklist. Since the trainer guidance is regarded as the gold standard. In addition, less intervention can result in less fatigue for the trainer.

Number of instrument movements per time significantly decreased resulting in improvement in the economy of movement during the application of the checklist. Participants performed the task more accurately and with less number of movements when they tended to slow down, as in general the accuracy of a movement tends to decrease when its speed increases above a threshold. Our interpretation is that slowing down could give the participants more time for visual feedback.

The participants' satisfaction survey indicated the general acceptance of the checklist by the trainees. The median satisfaction score was 4 on a scale of 1-5 for finding it easy to apply and for finding the checklist useful. However, we noted that the score was lower in the two most senior trainees comparing to the other participants. All trainees scored 5 for considering using the checklist routinely in future practice.

Time	Movements	Errors	Errors/time	Errors/movements
Increase/decrease	Constant	Constant	Decrease/increase	Constant
Constant	Increase/decrease	Constant	Constant	Decrease/increase
Constant	Constant	Increase/decrease	Increase/decrease	Increase/decrease
Increase/decrease	Increase/decrease	Constant	Decrease/increase	Decrease/increase
Increase/decrease	Constant	Increase/decrease	Constant	Increase/Decrease

Table 14 Examples of combination and permutation for time, movements and errors

5.6 Conclusion

The performance based self-administered intra-procedural checklist improved the performance of senior surgical trainees and decreased the number of interventions by the trainer during laparoscopic cholecystectomy. The trainees were generally satisfied using the checklist during the procedures.

Chapter 6

6 Conclusions, strengths, limitations and future directions

Chapter 6

6.1 Conclusions of the thesis

We have developed standardised checklists to be applied during elective and emergency laparoscopic tasks. The performance based self-administered intra-procedural checklist had a significant accelerating effect on the acquisition of technical skills when applied by novices during a standardised laparoscopic lab-based routine task and improved the task performance during a simulated laparoscopic emergency scenario.

The checklist enhanced the performance of surgical trainees and decreased the number of interventions of the trainer during elective laparoscopic cholecystectomy.

6.2 Strengths

The design of the studies was helped and the conduct was facilitated by experts in the fields of laparoscopic surgery and ergonomics. The lab-based studies were conducted in a well-equipped unit.

All the studies in this research were controlled. The lab-based studies in chapter 2, 3 and 4 were randomised. The end product of this research is a simple checklist that is effective, practical and easy to apply.

6.3 Limitations

The study design in chapter 4 did not take into account stresses often encountered during live surgery in clinical environment, which could be added factors depreciating surgical performance.

The sample size of the study in chapter 5 was affected by the bed shortage during the winter months resulting in the cancellation of elective procedures at Ninewells

Hospital. The relative small number of trainees included in this study is a reflection of the small number of general surgery trainees at NHS Tayside. Furthermore, some trainees could not be included in this study due to their rotation in the colorectal or vascular departments.

6.4 Future directions

The simulated emergency task in chapter 4 needs to be adopted and studied during more complex scenarios in the lab, as well as introducing the concept of the checklist during emergency clinical settings are potentially areas for future research.

Because of the non-obtrusive and simple format of the checklist, we envisage that trainees will be able to apply it on their own or simply prompted by the trainer. After completing the initial standardized training, the checklist can be applied subconsciously from memory without the need of displaying it for viewing during every procedure. These could be the subject of future studies. One further direction of future research is the introduction of the checklist in surgical training e.g. core skills and intermediate postgraduate surgical courses.

We are looking forward to study the effect of the checklist in a bigger sample size for laparoscopic cholecystectomy. As the checklist is based on generic items not specific to any laparoscopic procedure, we can test the application of the checklist during different operations e.g laparoscopic colectomy.

Chapter 7

7 References

Chapter 7

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Chapter 8

8 Appendices

Chapter 8

8.1 Participant information sheet of the lab-based study

Dear Sir/Madam,

As a clinical research fellow at the Cuschieri Skills Centre, I would like to invite you to take part in a research which studies the effect of a checklist on the laparoscopic task performance. This research study is supervised by Mr. Afshin Alijani.

We aim to study the effect of standardised intra-procedural checklist during defined surgical tasks on the technical performance of novices as a way of error reduction mechanism.

Participants in this research will be taught basic Laparoscopic skills like "Laparoscopic Square Knot Tying" at the Cuschieri Skills Centre.

Participants will be asked to attend for a maximum of one hour per session.

Your participation in this study is voluntary and with no known risks. You may decide to stop being a part of the research study at any time without explanation and without penalty. The data collected do not contain any personal information about you and will stay anonymous.

Mr. Michael El Boghdady will be glad to answer your questions about this study at any time. You may contact him at m.elboghdady@dundee.ac.uk

The University Research Ethics Committee of the University of Dundee has reviewed and approved this research study.

8.2 Consent form of the lab-based study

In this study, you will be asked to perform intra-corporeal laparoscopic double knots or to perform a clipping task on LapSim virtual reality simulator.

We aim to study the effect of standardised checklist (trainer or trainee administered) on the technical performance of novices as a way of error reduction mechanism, in both routine (knot tying) and emergency (clipping bleeding vessel) surgical tasks.

By signing below, you are indicating that you have read and understood the Participant Information Sheet and that you agree to take part in this research study.

Participant's signature

Date

Participant's name

Signature of person obtaining consent

Date

Name of person obtaining consent

"I agree to the use of anonymous extracts from my interview

Yes
☐

No
☐

in conference papers and academic publications”

Yes

☐

No

☐

“I agree to the audio recording of the interview”

8.3 Participant information sheet of the clinical-based study

Dear Sir/Madam,

I am a clinical research fellow at the Cuschieri Skills Centre, Ninewells Hospital and Medical School. I would like to invite you to take part in a research which studies the effect of an intra-procedural checklist on the laparoscopic task performance of surgical trainees. This research study is supervised by Mr. Afshin Alijani.

We aim to study the effect of standardised intra-procedural checklist during elective operations on the technical performance of senior surgical trainees as a way of error reduction mechanism. You will have to attend a quick introduction about the checklist and its application before you participate.

In this study, we require the attendance of a trainer during the procedure as per routine practice. A number of 2 elective operations for each trainee will be video-recorded without the use of the checklist, directly followed by 2 further operations after the introduction of the checklist.

Your participation in this study is voluntary and there are no known risks for you in this study. You may decide to stop being a part of the research study at any time without explanation and without penalty. The data collected do not contain any personal information about you and will stay anonymous.

Mr. Michael El Boghdady will be glad to answer your questions about this study at any time. You may contact him at m.elboghdady@dundee.ac.uk

The University Research Ethics Committee of the University of Dundee has reviewed and approved this research study.

8.4 Consent form of the clinical-based study

We aim to study the effect of a performance based trainee self-administered intra-procedural checklist in clinical environment during elective procedures as a way of error reduction mechanism.

General surgical trainees at Tayside will be included in this study and require the attendance of a trainer during the procedure as per routine practise. Record year of trainees and previous experience on laparoscopic cholecystectomy will be noted. A number of 2 elective operations for each trainee will be video-recorded without the use of the checklist, directly followed by 2 further operations after the introduction of the checklist.

By signing below, you are indicating that you have read and understood the Participant Information Sheet and that you agree to take part in this research study.

Participant's signature

Date

Participant's name

Signature of person obtaining consent

Date

Name of person obtaining consent

"I agree to the use of anonymous extracts from my interview
in conference papers and academic publications"

Yes

☐

No

☐

Yes

☐

No

☐

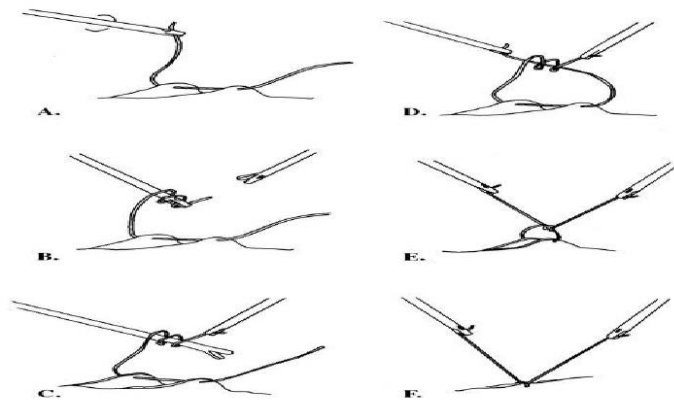
"I agree to the audio recording of the interview"

8.5 Invitation leaflets for the laparoscopic knot tying study

Medical Students, FY1- FY2, CT1 & CT2 doctors.

We require your participation in a research study.

You will be taught basic laparoscopic skills as
“Laparoscopic Knot Tying” at the Cuschieri Skills
Centre.



Supervised by Mr. Afshin Alijani, consultant surgeon
and honorary senior lecturer.

If interested, please contact Mr. Michael EL Boghdady
(m.elboghdady@dundee.ac.uk)

