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# Prepackaged Central Line Kits Reduce Procedural Mistakes During Central Line Insertion – a Randomized Controlled Prospective Trial

## Vorgepackte Sets verringern Verfahrensfehler bei der Anlage von Zentralvenenkathetern - eine randomisierte kontrollierte prospektive Studie

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# Table of Contents

## List of Abbreviations

| | |
|---|---|
| CDC | Centers for Disease Control and Prevention |
| CLAB | Central line-associated bacteremia |
| CLC | Central line catheter |
| CVC | Central venous catheter |
| ICU | Intensive care unit |
| IOM | Institute of Medicine |
| MTS | MPEG transport stream |
| NaCl | Sodium chloride |
| OR | Odds Ratio |
| OSATS | Objective Structured Assessment of Technical Skills |
| OSCE | Objective Structured Clinical Examination |
| PGY | Post-graduate year |
| SD | Secure Digital |
| SUSI | Single use surgical instrument |
| TLC | Triple lumen catheter |
| UKT | Universitätsklinikum Tübingen (University Clinic Tuebingen) |

# 1. Introduction

Central line catheters (CLCs) are used in critically ill patients [1] for both diagnostic and therapeutic purposes. From the diagnostic point of view, CLCs allow to procure venous blood samples, directly measure the central venous pressure and facilitate hemodynamic monitoring in intensive care units (ICUs) as a central component of various systems based on the thermodilution principle. In regard to the therapeutic perspective, CLCs allow the application of a broad range of intravenous medications via a safe vascular access that is able to tolerate even non-isotonic solutions for longer time periods.

Despite often being a necessity for clinical care, CLCs can cause serious complications, such as infection and mechanical problems including arterial puncture, catheter misplacement, pneumothorax, hemothorax, cardiac arrhythmias, air emboli, or even death [1-4]. The prevalence of these complications is estimated to be about 5.3 per 1000 catheter days [1, 5]. The rate of complications fluctuates between 5% and 19% based on the site of insertion [6, 7]. Yet, some studies have shown most CLC complications are preventable and a very low complications rate can be accomplished [8, 9]. There is strong evidence suggesting that almost all infections can be averted by multifaceted measures like educational interventions, maximum barrier precautions, insertion site disinfection, hand hygiene, antiseptic coating of the catheter, early removal of unneeded or potentially infected catheters and use of all-inclusive catheter carts during the insertion procedure [9-14]. Failed puncture can often be avoided using ultrasound guidance [15, 16].

Studies have shown that inexperienced and moderately experienced physicians are more likely to fail or induce mechanical complications while placing a central line than their experienced colleagues [6, 17]. The complexity of the segmented catheter insertion technique is the main reason for this finding, as this procedure represents a mentally demanding task for inexperienced healthcare professionals. According to the cognitive load theory, the human working memory can only hold between five and nine pieces of information and actively handle between two and four of those at the same time [18]. Tasks with high element interactivity are difficult to understand and result in

a high cognitive load because learners must deal with several elements simultaneously [18]. However, there are several methods that can be used to reduce the cognitive load in novices. The split attention principle focuses on replacement of multiple sources of information, distributed either in space (spatial split attention) or time (temporal split attention), with one integrated source of information [18]. This principle is utilized when using a prepackaged kit containing all materials necessary for a certain procedure.

One may assume that prepackaged central line kits may facilitate the rather complex insertion procedure for novices. To our knowledge, there are only two studies that have investigated the introduction of an all-inclusive central line cart and an all-inclusive central line catheter insertion kit respectively [9, 19]. The limitation of both studies is that several changes were introduced at once (checklists, staff education, and daily central line assessments). Neither study assessed the effect of the prepackaged all-inclusive central line catheter kit or cart in reducing mechanical complications or time resources nor the central line catheter insertion procedure itself. In addition, there was no differentiation between novices and experts for analysis of patient safety during and after CLC insertion.

Modern process engineering allows prepackaging of most, if not all, necessary components into handy kits while maintaining sterility of all individual articles. Most manufactures of prepackaged all-inclusive central line kits propagate that this tool may help new physicians in performing this difficult procedure, and these kits are already in use in most hospitals in North America and Europe [20]. However, there is little to no evidence that such kits per se, without additional measures as used in the study outlined above, are really helpful for the CLC insertion procedure nor that they improve patient safety.

We thus designed a randomized, controlled study to assess whether use of a prepackaged all-inclusive central line catheter insertion kit by novice physicians and advanced medical students is effective in reducing the number of procedural mistakes,

time needed to perform the procedure, potential breaches of asepsis, and completeness of procedure.

## 1.1. Patient Safety

The subject of patient safety has gained a lot of attention in the recent years. A report published in 2000 by the Institute of Medicine (IOM), "To Err is Human: Building a Safer Health System", estimated that 48,000 to 96,000 people died per year as a result of medical errors [21]. This publication had a big impact on the current scientific debate about new ways to improve occupational safety, communication, diagnostic procedures, safety of new and already established therapeutic methods, better guidelines and – last but not least – the implementation of new IT technologies designed to reduce human errors [19, 22, 23].

In response to mounting evidence, many hospitals both in Europe and the US have been introducing concrete measures that help prevent and reduce medical errors [24, 25]. These measures are varied and encompass different aspects of medical errors: checklists, legal limits on work hours for trainee physicians, and staff education [26-29]. Furthermore, training programs in the US have restructured their training to achieve better results in teaching potentially dangerous procedures without comprising the safety of patients. In this aspect, training manikins and simulators have been successfully introduced to teach difficult clinical techniques to novice residents and medical students [30].

Newly minted physicians present an independent risk factor in terms of patient safety. The study by Dean et al. found that house officers (i.e. doctors still in training) were responsible for 89% of prescribing errors in the UK teaching hospitals [31]. In regard to the subject of our study, it was shown that inexperienced physicians were more likely to fail or induce mechanical complications while placing a central line than their experienced colleagues (19.4% vs. 10.1% failure rate and 11% vs. 5.4% complications rate) [6].

## 1.2. Central Line Catheter

A central line catheter (CLC), sometimes referred to as a central venous catheter (CVC), is a relatively large venous catheter typically used in critical care [1]. The procedure was first described in 1929 when Dr. Werner Fossman inserted a catheter into his own heart through the cephalic vein [32]. Dr. Fossman received the Nobel Prize in Physiology and Medicine for successful catheterization of the heart in 1956 [33]. A more sophisticated technique that allowed relatively easy catheter placement into vessels was later developed by the Swedish radiologist Dr. Sven Ivar Seldinger (1921 – 1998) in 1953 [34]. The method was named after Seldinger and was established as the gold standard for insertion of a broad range of intravascular devices into both venous and arterial vessels [35]. Seldinger's technique is performed as follows: the desired vessel is punctured with a sharp hollow needle called a trocar. A round-tipped guidewire is then advanced through the lumen of the trocar, and the trocar is withdrawn. A blunt cannula is passed over the guidewire into the vessel. Once the blunt cannula is secured inside the vessel, the guidewire is withdrawn [34]. The major advantage of the Seldinger technique is that the puncture is first performed with a relatively small needle, then the access is secured via the wire and only then is the much thicker catheter introduced into the vein [34]. The preferred locations for CLC are the chest (subclavian vein), neck (internal or external jugular vein), or in certain circumstances, the groin (femoral vein). The internal jugular and the subclavian veins are the most frequently used sites because of their better accessibility and reduced risk of infection [7, 36].

Common indications for placement of CLCs include:

- Administration of medication: vasopressors, chemotherapy, certain antibiotics (e.g. macrolides) and parenteral nutrition by hyperosmotic fluids (amino acids, glucose ≥10%, lipids ≥20%) are usually administered through a CLC because they frequently cause (thrombo-)phlebitis when administered through a peripheral catheter due to their locally irritating effects on the venous wall.
- Hemodynamic monitoring: a CLC allows measurement of the central venous pressure and venous oxyhemoglobin saturation. It also allows

introduction of a pulmonary artery catheter or other devices as e.g. the PiCCO system [37] for monitoring of important cardiac parameters.

- Transvenous cardiac pacing and defibrillation.
- Poor peripheral venous access [1, 38].
- Although a standard CLC is not suitable for extracorporeal treatment such as plasmapheresis, lipid apheresis, chronic intermittent hemodialysis and continuous renal replacement therapy because of its relatively small lumen, it has to be mentioned that a so-called Shaldon catheter, which facilitates flow rates of up to 300 ml/min, can be introduced via the same anatomic access as a standard CLC.

Use of CLCs is very common in critically ill patients. In the United States alone, more than five million central lines are inserted each year. About 8% of hospitalized patients require a CLC at some point during their hospital stay [1, 39]. Noncuffed percutaneously inserted catheters placed in the femoral, internal jugular, or subclavian vein are the most common centrally placed devices for short-term use, with more than 7 million devices sold in the United States each year [40].

### 1.2.1. Central-Line Associated Complications

Although often vital in a clinical setting, CLCs are associated with a number of serious complications [1]. In the United States alone, patients at the intensive care units (ICUs) experience 15 million central line catheter days (i.e., the total number of days of exposure to CLCs by all patients in the selected population during the selected time period) per year [41]. The rates of complications are estimated to be about 5.3 per 1,000 catheter days [5]. This works out to be 79,500 catheter-related complications per year just in the United States. Other studies have estimated the number of central-line associated bacteremias (CLABs), a blood infection that resulted directly from inserted CLCs, at approximately 80,000 per year in the United States ICUs [42] and the prevalence of bloodstream infections at ICUs across 75 countries at about 15% [43]. Although peripheral catheters also account for some of the catheter-related infections, the majority of serious catheter-related infections are attributed to CLCs, especially when placed in an ICU setting [44, 45]. Central venous catheters of all types are the

most frequent cause of nosocomial bloodstream infection [46, 47], and an estimated 250,000 to 500,000 episodes of IVD-related bloodstream infection occur in the United States annually [41, 47]. These episodes are associated with a prolongation of hospitalization by 10 to 40 days [48, 49]. Furthermore, in the United States, the number of annual deaths attributed to the complications of CLCs is estimated at about 28,000 [50]. As described above, CLC-related infections and other complications present a serious and common problem in hospitals worldwide.

#### *1.2.1.1. Mechanical complications*

Mechanical complications of CLCs include arterial puncture, catheter misplacement, pneumothorax, hemothorax, cardiac complications, air emboli, and even death. Most frequent mechanical complication in femoral catheters is major femoral or retroperitoneal hematoma [51, 52], while for catheters inserted through the subclavian vein, the most frequent mechanical complication is pneumothorax [35, 53]. One study showed the rate of mechanical complications for the femoral catheters to be about 17% and for the subclavian catheters at almost 19% [7]. The risk factors for mechanical complications included the duration of CLC insertion (odds ratio (OR) for each additional minute: 1.05) and catheter insertion at night (OR: 2.06) [7].

#### *1.2.1.2. Infections*

There are two main categories of catheter-related infections: local and systemic. The local infections take many forms, ranging from the insertion site infection to phlebitis (inflammation of the vein). Systemic catheter-related infections also include several types, such as bloodstream infection, suppurative thrombophlebitis, and distant infections such as endocarditis [5]. Catheter-related bloodstream infections are defined as bacteremia/ fungemia in a patient with an intravascular catheter with at least one positive blood culture obtained from a peripheral vein, clinical manifestations of infection (i.e., fever, chills, and/or hypotension), and no other apparent site of the infection. Bloodstream infections are considered to be associated with a central line if the line was in use during the 48-hour period before the development of the bloodstream infection [44]. Central line-associated bacteremias (CLABs) are associated with high rates of morbidity and mortality, as well as high health care costs. Each catheter related infection costs approximately $45,000 (£28,000, €35,000) [54].

Rates of infection related to CLCs differ for the various anatomical sites, thus the choice of location for the catheter is very important. The subclavian vein has been reported to have the lowest rate of associated infections, while the femoral vein has the greatest one [7]. However, it has been shown that the differences in infection risk between the different anatomical sites can be minimized when physicians placing the catheters are more experienced [45].

### 1.2.2. Prevention of Central Line-Associated Bacteremias

Previous studies have identified the following steps in CLC-placement as effective in prevention of CLABs: proper hand hygiene [10, 11]; use of all-inclusive catheter carts [9]; use of sterile barriers (mask, cap, sterile gloves, gown, and drapes) during the procedure [12]; use of subclavian approach for CLC [2, 55]. Hand hygiene and strict adherence to asepsis during insertion and dressing changes remain the most important measures in prevention of catheter-associated infections [54].

Several studies have focused on implementation and success of checklists in prevention of medical errors, including prevention of central-line associated bloodstream infections [29]. However, checklists have an obvious limitation in that they only work if people use them. Education of the staff and timely removal of unnecessary catheters has also received a lot of attention [56, 57]. One study in an urban US teaching hospital demonstrated a considerable reduction in catheter-related bloodstream infections following an educational program highlighting the risk factors for developing infections and correct practice for central venous catheter insertion and maintenance. The number of CLC-related bloodstream infections dropped from 10.8 per 1,000 catheter days to 3.7 per 1,000 catheter days. Furthermore, the authors estimated the cost savings secondary to the intervention to be between $185,000 and $2,808,000 over the course of 18 months [58]. However, few studies are available on improvement of patient safety using pre-packaged all-inclusive central-line placement kits.

So far, we found two studies detailing the introduction of a central line cart and a central line kit at two different ICUs. A central-line cart was introduced at Johns Hopkins Hospital in 1999 as part of an intervention aimed at eliminating catheter-

related bloodstream infections. The cart included all the materials necessary for a CLC insertion and helped increase doctor compliance with the Centers for Disease Control and Prevention (CDC) guidelines [44] by reducing the number of steps required for CLC placement preparation from eight to just one. Although the number of CLABs has decreased, it is not clear whether the introduction of such a central-line cart alone could be attributed to the result, since the study simultaneously implemented a number of other interventions. These included educational awareness, procedure checklist, authorizing nurses to stop CLC insertion if the guidelines were not followed, and timely removal of unnecessary catheters [9]. A more recent study performed at the Montefiore Medical Center in Bronx, USA in 2005 demonstrated significant (about 50%) reduction of CLABs at an ICU using a specially designed central-line kit, which included the catheter, drapes, barriers and skin antiseptic [19]. Just like in the study done at Hopkins, several changes were introduced at once (checklists, staff education, and daily central line assessments). The relevant co-variables present in these 2 studies render the assessment of the extent to which an all-inclusive central line cart or kit per se contributed to the reduction of CLABs or improved the insertion procedure, impossible.

## 1.3. Novice Physicians

As mentioned in Section 1.1, beginners are especially prone to committing errors that may endanger patient safety [31, 45]. However, in order to learn the proper technique of CLC placement, the beginners have to actually practice doing it, thus, inexperienced physicians and medical students often perform complicated procedures such as central line placement, especially at teaching hospitals [59].

CLC placement is a complex multi-step task with a high cognitive load. Cognitive load theory assumes that the human cognitive system has a limited working memory that can hold no more than five to nine information elements [18] and actively process no more than two to four elements simultaneously. Tasks with high element interactivity are difficult to understand and yield a high cognitive load because learners must deal with several elements simultaneously [18].

There are several methods aiming to reduce cognitive load in novices. The split attention principle focuses on replacement of multiple sources of information, distributed either in space (spatial split attention) or time (temporal split attention), with one integrated source of information [18]. Placing all the necessary materials required for a certain procedure into one kit represents this principle. The report "To Err is Human: Building a Safer Health System" concluded that "*mistakes can best be prevented by designing the health system at all levels to make it safer – to make it harder for people to do something wrong and easier for them to do it right*" [21]. Reducing the cognitive load of the physician through a careful design of a prepackaged kit could potentially help him or her to perform the procedure correctly and avoid or at least minimize mistakes.

Considering the high complication rates of CLCs, the costs associated with these complications and the fact that novice physicians are more likely to induce the complications, there is a clear need for better training and other measures, which would help reduce medical errors and thus improve patient safety. Evidence shows that inexperienced physicians are more likely to fail or induce mechanical complications while placing a central line than their experienced colleagues [6]. In the report "To Err is Human", the Institute of Medicine emphasized that most medical errors are systems-related and not attributable to individual negligence or misconduct [21]. A 2004 study by Vincent et al. showed that "systems improvements" during surgical procedures, which included such factors as equipment design and use, could reduce error rates and improve the quality of healthcare [60]. This concept can be easily transferred to most other medical procedures, including CLC placement. Mechanical complications related to CLC placement usually arise from the complex multistep insertion procedure. In order to achieve the goal of reducing the number of CLC-related complications, it is necessary to identify practices that contribute to a technically correct central line catheter insertion and are easy to implement.

Studies have shown that differences in infection risk among sites of catheterization (femoral site is associated with the highest risk) may be reduced when strict asepsis is maintained and more experienced physicians insert the catheter [45]. As it is not

feasible to require all CLCs to be placed by experienced physicians (not enough experts available; becoming an expert requires performing multiple procedures as a novice first), ensuring that a sterile technique is used during catheter placement should be a priority. An all-inclusive central line kit may be effective in helping maintain asepsis as they are designed to contain most materials needed for central line insertion, thus reducing the number of instances in which a new item has to be introduced to the sterile field.

## 1.4. Prepackaged Kits

In recent years the market for prepackaged medical kits and trays has been flooded with customized packages for almost every type of invasive procedure, with some manufacturers designing new kits almost as soon as a new technique is developed [20]. These kits have become quite popular among clinicians due to several distinct features:

- The kits package all of the typical tools and supplies needed to perform a particular procedure.
- The kits can be stored, and thus pulled, from a single location for a procedure. Locating and gathering supplies and equipment from multiple locations is eliminated. This save time and reduces the chance of human error during the collection process.
- Fewer touch points may improve infection prevention.
- Some kits come with the components packaged in order of use, so that the clinician can progress efficiently through the workflow of the corresponding procedure [20]. (See section 1.3 on cognitive load theory).

The United States and Europe are two largest markets for the prepackaged kits, while Asia-Pacific is the fastest-growing market as of March 2012 [20].

B.Braun Melsungen AG (Melsungen, Germany) designed its first prepackaged kit (ProSet®) in 1979. The ProSet® line offers customer-defined personalized solutions for clinical procedures such as central line insertion, infusion therapy, and local anesthesia. In 2010, the kits were sold to some 800 medical providers in Germany.

B.Braun estimates six million interventions a year performed using ProSet® kits in Europe and the demand for prepackaged kits is continually growing. In 2010, B.Braun sold 2.5 million prepackaged kits in Germany alone; 170,000 of those were CLC kits (Johannes Knigge, Junior Product Manager, B. Braun Melsungen AG, personal communication in 2012).

As mentioned in section 1.2.2, few studies exist as to the effectiveness of such prepackaged products in reducing complications, improving asepsis, etc. The major limitation of most studies that implemented prepackaged kits as part of the intervention is that other relevant variables were not effectively excluded or at least controlled for. Thus it would be interesting to create an environment that allows for clear assessment of the kits themselves, without any influence of outside factors, such as interruptions by colleagues, size and morbidity of the patient, lighting, etc. Therefore, a simulated setting seemed a viable option (see Section 1.5).

## 1.5. Skills Lab Training

Simulation is a technique to "*replace or amplify real-patient experiences with guided experiences, artificially contrived, that evoke or replicate substantial aspects of the real world in a fully interactive manner*" [61]. Numerous studies have shown that simulation training is effective in teaching clinical skills [62]. Some studies focused specifically on the effect simulation-based training has on CLC placement and demonstrated that such training significantly reduced the number of mechanical complication rates [63] as well as infections associated with CLCs [64, 65]. Furthermore, studies have shown that simulation techniques can be used not just for practice and learning, but also for assessment of technical procedures [66, 67].

The Objective Structured Clinical Examination (OSCE) was developed in 1979 as a new assessment method for practical clinical sills [68]. Over the past 30 years, it has been proven to be a valid and reliable assessment tool [69] as it provides a standardized setting (every student sees the same patient with the same set of symptoms and complaints) and tests what the student would actually do in a certain situation as opposed what they might do inferred from essays/ multiple choice questions. The

OSCE became so widely used that other tests were developed based on its structure. One such test is the Objective Structured Assessment of Technical Skills (OSATS), developed in Toronto in 1997. In this test, students perform elements of a technical procedure while being scored by experts using a standardized checklist and global rating forms [70].

## 1.6. Hypothesis

The main question of this randomized, controlled study is whether young physicians with limited clinical experience who used a prepackaged central-line kit (ProSet®) would make fewer procedurals mistakes while placing a central line than their novice colleagues who used a standard central line catheter ("stand alone catheter"). In order to minimize statistical bias owing to other potentially influencing variables, the study was be performed in a simulated and controlled environment. We assessed the differences between both study groups in regard to the number and quality of procedural mistakes using a standardized checklist. Furthermore, we assessed how the use of a prepackaged kit influences the time needed to perform the insertion of a central line catheter. The last question we want to address by this study is the maintenance of aseptic conditions during the central line insertion.

# 2. Materials and Methods

## 2.1. Study Design

We designed a randomized, controlled, prospective, single-blind study to assess whether the use of a prepackaged all-inclusive central line catheter insertion kit (prepackaged kit) vs. a central line catheter kit with separately packaged items (standard kit) resulted in fewer procedural mistakes when the central line placement was performed by a doctor-nurse team, who were both beginners.

Teams consisting of one physician and one nursing student were assigned either to the interventional group (provided with the ProSet® CLC insertion kit; see Section 2.2.1.) or to the control group (provided with a material cart which included the same items provided in the ProSet®, but packaged individually). Both groups then inserted a central line into a manikin (see Section 2.2.3.) using the provided material. The standard for the CLC insertion procedure was set based on the clinical experience at the intensive care unit and the hemodialysis center at the University Hospital of Tübingen (UKT) and on the CLC placement guidelines outlined in the 4$^{th}$ edition of the German standard textbook of clinical procedures (*Medical Skills*; Thieme, 2009) [71]. The complete CLC insertion procedure was recorded on videotape and subsequently evaluated using a standardized checklist by two video assessors blinded to the study question. The assessors could record the number of correctly performed steps using a binary checklist and whether the mistakes themselves were considered “minor” or “major” in regard to the patient’s safety. Furthermore the tapes were evaluated for the maintenance of asepsis, the time required to perform the procedure, and for global patient safety. The collected data was then statistically analyzed (see Section 2.7.3.). The complete study design is presented in Figure 1.

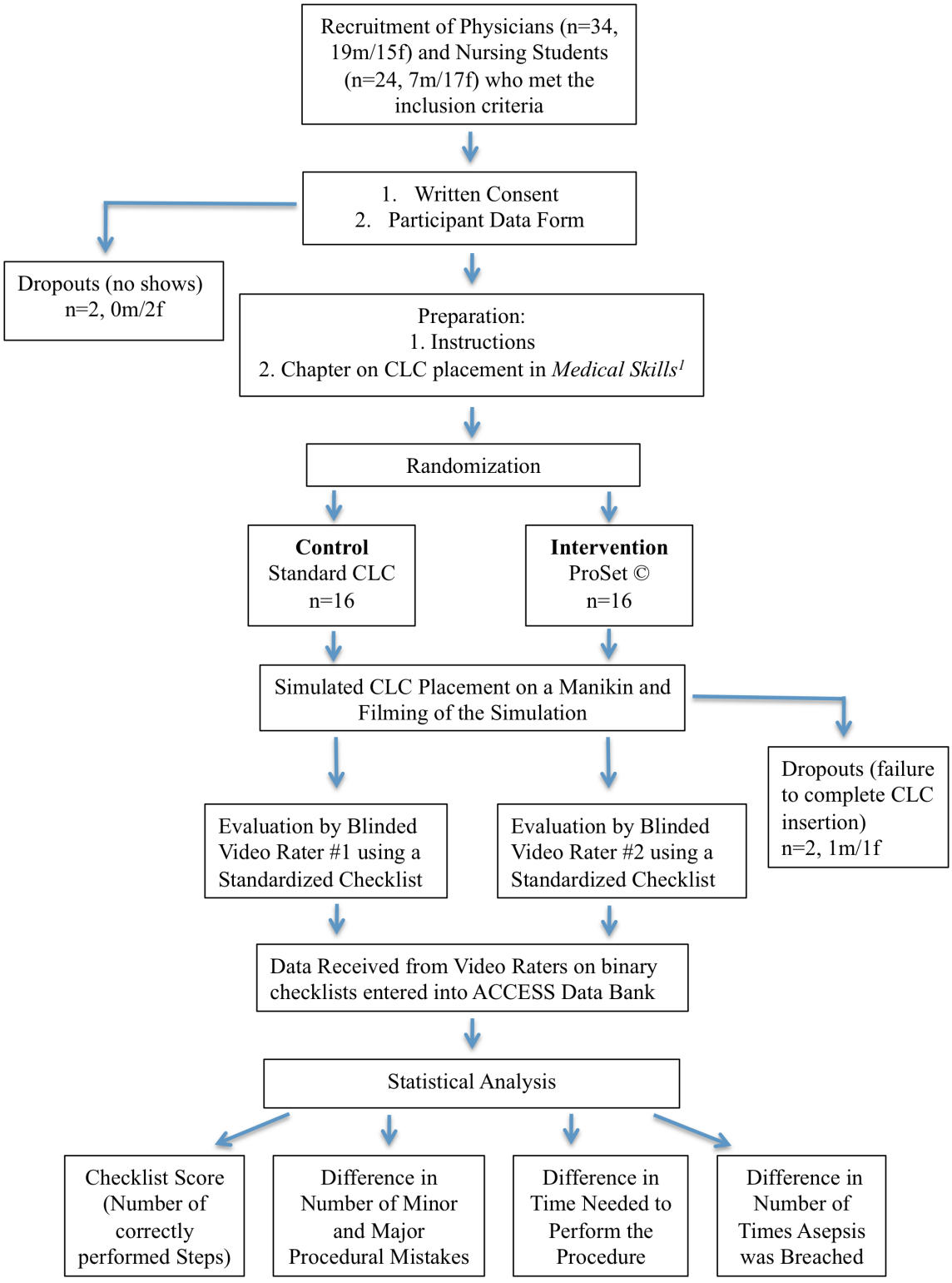


**Figure 1. Flow Chart of the Study Design**

[1] Vieten, M.H., C. , *Medical Skills für Famulatur und PJ*2009, Stuttgart: Georg Thieme Verlag.

## 2.2. Equipment

### 2.2.1. ProSet® CLC insertion kit

In cooperation with B.Braun Melsungen AG (Melsungen, Hesse, Germany), we designed a CLC insertion kit (ProSet®) in accordance with the local ICU and hemodialysis centre standards logged in the databank of standard operating procedures of the UKT. The ProSet® included virtually all materials necessary for a CLC insertion (Table 1). B.Braun Melsungen AG manufactured and supplied these kits according to our specifications. The kit included the contents outlined in Table 1.

| | |
|---|---|
| **Sterile covering** | Drape 75x90cm<br>Gown XL<br>Fenestrated drape 75x110 cm<br>Ultrasound cover |
| **Patient preparation** | 3 sponges<br>5 gauze<br>ECG cable |
| **Central line catheter insertion** | Ultrasound gel<br>3-way infusion ports<br>Syringe 10mL<br>Scalpel<br>Cannula 0.9x40mm<br>Cannula 0,7x30<br>5 compresses<br>Syringe 3mL<br>Triple lumen catheter (TLC)<br>Nitinol guide wire<br>Seldinger needle<br>Plastic dilator |
| **Central line fixation** | TLC holder/ clip<br>Suture thread with attached curved needle size 2-0, 75cm<br>Needle driver<br>Adhesive bandage |

**Table 1. Contents of the ProSet® CLC insertion kit**

Some items could not be included into the package owing to sterilization concerns (NaCl, lidocaine, mask, cap, and syringe for blood gas analysis) or size-dependency (sterile gloves). This was clearly labeled on the outside of the ProSet® kit (Figure 2).


**Figure 2. ProSet® Kit. Upper left corner: Label specifying items not included in the kit.**

### 2.2.2. Materials Cart

The materials cart (Figure 3) used in the study was stocked and labeled according to the internal standards of the UKT. Aside from the ProSet® kit, the cart included all materials (individually packaged) needed for the CLC insertion and some random articles not required for the CLC insertion such as butterfly needles, blood collection tubes, and peripheral lines that served as typical distracters. These items are routinely included in the injections carts of the UKT as the same injection carts are used for routine blood draws, injections, and placement of both peripheral and central lines. In general, all individual components used by the control group were identical to those provided in the ProSet® kit and also provided by B. Braun Melsungen AG.


**Figure 3. Materials Cart used in the Study**

### 2.2.3. Central Line Manikin

A central-line manikin (CentralLineMan) manufactured by SimuLab Corporation (Seattle, Washington, USA) was used in our study (Figure 4). This model was chosen because of its superior design, which allowed a complete CLC placement, including ultrasound-guided identification of the jugular vein, adhesion of the fenestrated drape, use of the dilatator, and suturing of the CLC into place. Furthermore, it has higher face validity than older CLC simulators and allows over 150 punctures [72].

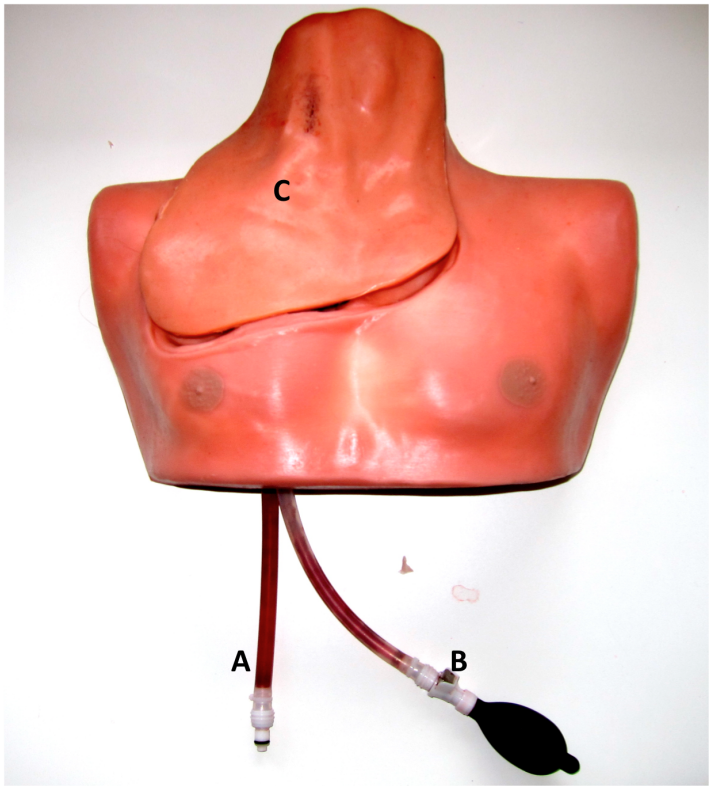


**Figure 4. Central Line Manikin. A: Filling nozzle, venous system B: Filling nozzle, arterial system C: Silicone block, suitable for ultrasound-guided CLC insertion procedure**

The manikin consisted of a silicone block, equipped with plastic tubes simulating the central veins (internal jugular and subclavian) and the carotid artery. These vessel tubes were filled with colored fluid (dark red in the veins, light red in the artery) with a specific density equaling human blood and could be visualized on ultrasound (Figure 5). A small hand pump attached to the line designated as “artery” allowed simulation of the arterial pulse by an assistant not involved in the CLC insertion procedure. The neck of the manikin was positioned at a 30° angle (to the left) and all the classic landmarks

such as the sternocleidomastoid muscle, jugular notch, the clavicle, and the nipples were easily identifiable both visually and haptically.

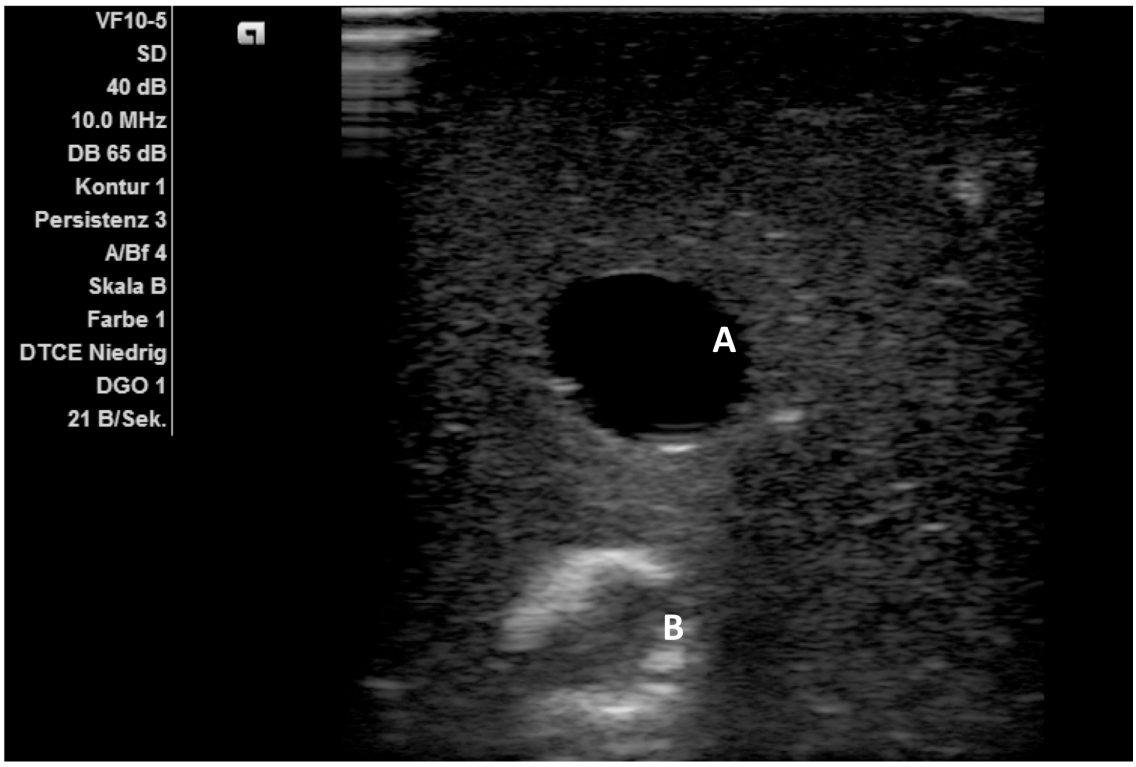


**Figure 5. Ultrasound Image of the Neck Vessels. A: Jugular Vein, B: Carotid Artery**

Due to the structural design of the manikin, two steps of the CLC insertion procedure had to be modified. The injection of the local anesthetic would damage the model because it is not designed to accept fluids injected outside of the vessel tube system. Therefore, holding a filled syringe to the injection site and indicating the puncture, aspiration prior to injection, and the injection itself only implied injection of the local anesthetic. The second modification consisted in omitting the skin incision before dilator insertion, as repeat incisions would create a cavity at the incision site rendering further CLC placement unrealistic. Hence, holding a scalpel to the incision site only indicated the incision. The participants received precise instructions as to correct execution of both the injection and the incision steps (Appendix 5).

An ultrasound machine (Acuson X 300 Premium Edition, Software Version 7.0, Siemens Medizintechnik, Erlangen, Germany) was provided for use in case the physician failed to locate the jugular vein on the first attempt. Since a sterile cover was

required for the procedure, we showed a short video provided by the manufacturer on the proper use of this recently developed equipment [73].

### 2.2.4. Video Equipment

A Panasonic HDC-SD100 video camera (Panasonic Corporation, Osaka, Japan) was used to record the simulation central line placement at a screen resolution of 1920x1080 pixels. The videos were first saved on a standard secure digital (SD) memory card (SanDisk Corporation, Milpitas, California, USA) and then transferred onto a hard drive in MPEG transport stream (MTS) format. The videos were than compressed using Blaze Media Pro 9.0 software (Hampstead, North Carolina, USA), transferred to a DVD-ROM and sent to the video raters.

## 2.3. Participants

Internal medicine residents, final year medical students, and 1st and 2nd year nursing students participated in our study. We purposefully recruited only novices, as to exclude any impact of prior experience with CLC placement on the outcome of the study. The inclusion criteria for physicians and medical students were either graduation from medical school within the last 2 years or current enrollment in the final year of medical school. The exclusion criteria were clinical rotations in the ICU or anesthesiology and completion of residency. An invitation email was sent to those medicine residents who have met the inclusion criteria. Medical students were contacted personally during the afternoon teaching conferences. All those who expressed interest in the study were scheduled for a one-hour appointment during which they performed the CLC placement.

The nursing students were recruited in cooperation with the University Hospital of Tuebingen Nursing School (UKT Krankenpflegeschule). The headmaster of the nursing school addressed all 1st and 2nd year nursing students during lectures. The inclusion criteria for nursing students were enrollment in 1st or 2nd year at the nursing school, the exclusion criteria were prior experience in assisting with CLC placement on more than three separate occasions. The headmaster forwarded a list of all nursing students who expressed interest to the ProSet® study team. Nursing students were randomly assigned to a physician in no particular order based on their availability on a given date.

We recorded the following data for all participants (physicians as well as nursing students) in order to identify possible confounders: educational status (Student vs. Resident), prior central line catheter insertion experience, age, and sex (Appendix 1-2).

### 2.3.1. Consent

Prior to participating in the study, the participants were informed as to the purpose of the study verbally and in writing, , though the research question was not disclosed to avoid any systematic bias that could result from this knowledge. All participants signed consent forms stating voluntary participation and agreeing to be filmed (Appendix 3).

### 2.3.2. Compensation

All study subjects (physicians as well as nurses) received 25 Euro each for their participation.

## 2.4. Location

All the recordings were made at the Emergency Department, Medical Hospital of the University of Tuebingen (Zentralbereich Notaufnahme, Medizinische Klinik, Universitätsklinikum Tübingen) in a room reserved specifically for the purpose of the study. The location remained unchanged throughout the study, so that all participants performed under identical conditions.

## 2.5. Procedure

The placement of the central line was simulated on a plastic manikin (see 2.2.2). The participants were allowed one attempt to successfully place a central line in the right internal jugular vein on the manikin. Multiple attempts to locate the jugular vein were allowed, including the use of ultrasound guidance if palpation alone did not suffice. However, once the participant began inserting the wire, he or she had to complete the procedure or was disqualified.

All participants (physicians as well as nursing students) received written instructions concerning their immediate task (Appendix 4-5) specifying their roles in the study and additional information on using the manikin directly prior to insertion of the central

line. Additionally, all physicians were allocated 15 minutes to read through pages 97 through 103 in the 4th Edition of the textbook *Medical Skills (*Thieme, 2009) detailing the central line placement [71]. This step was meant to simulate a real-life situation in which any novice would look up relevant information before performing an unfamiliar complicated clinical procedure. Additionally, this step ensured that all physicians used the same technique during the CLC placement, so that the intervention (ProSet® CLC insertion kit vs. standard CLC set) remained the only variable throughout the whole procedure.

## 2.6. Randomization

The physicians were assigned to two equally large groups (n=17). We used randomization software provided at http://www.random.org/ by the School of Computer Science and Statistics at Trinity College (Dublin, Ireland) to generate 32 random 5-digit numbers. The 4th digit was used to determine the assignment to a group: the numbers with an odd 4th digit were assigned to the control group, the numbers with an even 4th digit to the intervention group.

Every physician participating in the study personally drew a number from the aforementioned number pool before starting the simulation. The drawer marked „CLC“ in the materials cart used in the study was then equipped with either a ProSet® CLC insertion kit or a standard central line catheter based on the number chosen by the participant.

## 2.7. Evaluation

The videos taken during the study were sent to two independent and clinically experienced physicians acting as video assessors at the University of Heidelberg, Germany. Both assessors had previous experience in evaluation of similar studies, and thus did not require any additional training in regard to either the procedure itself and or its evaluation. The hypothesis of the study was not disclosed to the assessors in order to ensure non-biased assessment. Both assessors received monetary compensation for their work.

Both raters evaluated the performance of all subjects following a standardized checklist (Section 2.7.1). We used the arithmetic mean of these two sets of data for the statistical analysis. The use of both a binary checklist and a global assessment tool allowed for a complete evaluation of the participant's performance [74].

### 2.7.1. Binary Checklist

The binary checklist was designed to accurately reflect all the steps required in a CLC placement. It was subdivided into 4 categories: preparation of materials, patient preparation, central line catheter insertion, and clean up, resulting in a total of 55 different and independent steps (Appendix 6) [75]. The approach via binary checklists was chosen as they represent an appropriate and very well established assessment tool especially in regard to procedural skills [76-78].

### 2.7.2. Global assessment

Global assessment tools allow better acquisition of procedural errors that were not foreseen in the design of the binary checklist. They also facilitate the assessment of non-procedural skills as e.g. communication between novice and nurse, which also represent an important factor for patient safety. It is also well established that global assessment tools are more suitable in measuring higher levels of clinical competence, expertise, and professionalism [75, 79]. Therefore, our checklist included three additional columns in which the raters could indicate the severity of the mistake (minor vs. major) in regard to patient safety in case a certain step was performed incorrectly or forgotten entirely, and whether or not asepsis potentially has been broken during the performance of a certain step. Since both raters were experienced clinicians, the decision to designate a mistake as minor vs. major was left to their personal appraisal, and no exact definitions of minor or major mistake have been provided deliberately.
Using the global assessment form, four independent quality indicators were recorded:

1. Number of major technical mistakes (every deviation from the correct central line catheter insertion procedure that might have resulted in patient harm according to the rater's judgment).

2. Number of minor technical mistakes (every deviation from the correct central line catheter insertion procedure that might not have necessarily resulted in patient harm according to the rater's judgment).
3. Number of correctly performed steps (each step of the central line catheter insertion procedure that was performed in the right order with the correct technique) according to the binary checklist provided.
4. Every contact between sterile and non-sterile material as a surrogate marker for maintenance of asepsis.

Finally, the time needed to perform the procedure (from the start of the preparations to the end of the cleaning up process) has been recorded in two separate intervals:

A: time needed to gather the necessary materials and to set up
B: time needed to place the CLC

### 2.7.3. Statistical Analysis

All data provided by the video raters were entered into a Microsoft ACCESS 2008 (Microsoft Corporation, Redmond, Washington, USA) database and subsequently analyzed using the JMP 8.0 software package (SAS Institute; Cary, North Carolina, USA). We used Student's t-test on normally distributed numerical data, the Wilcoxon-test for non-normally distributed parametric data and the $Chi^2$-test on nominal data. The power analysis was done using G*Power software (Erdfelder, Faul, & Buchner, 1996, Düsseldorf, Germany). We aimed for a power $\geq 0.80$ based on an assumed effect size of Cohen's d=1.2. A $p$-value of $\leq 0.05$ was considered statistically significant. Inter-rater reliability was calculated with IBM SPSS Statistics Version 20 as intraclass correlation coefficient with a 2-way mixed-effects/ absolute agreements model (ICC (3,k)) according to the definition of Shrout and Fleiss [80].

## 2.8. Ethics

The study protocol was reviewed and accepted by the local ethics committee; decision number 059/2011BO1. The experiments were then conducted from 28.03.2011 to 08.04.2011 in the Emergency Department of the Medical Clinic of the University of Tuebingen, Tuebingen, Germany. Study participation was voluntary, as outlined above.

The results remained anonymous and were not used in any academic evaluations or assessments of the participants. All participants gave written informed consent (Appendix 3) prior to participation in the study. The study was performed in accordance with the declaration of Helsinki, revised form, Seoul 2008 [81].

### 2.8.1. Data and Information Privacy

Personal information (name, age, education, etc) provided by the subjects was encrypted with numbers. All information gathered during the study was handled confidentially. Where necessary, the information was distributed strictly in encrypted form, so that no inferences could be made in relation to a single person. Correlation of the encrypted data to a single participant is only possible by using a subject list, which was stored separately from all other data. All personal data and information gathered in the study will be stored in a secure location for the duration of 3 years. After that, all these data will be destroyed.

### 2.8.2. Declaration of Potential Conflict of Interest

The project was supported by B.Braun Melsungen AG (Melsungen, Hesse, Germany), which designed and manufactured the ProSet® CLC insertion kit used in the study, provided all the materials needed for the control group and funded the monetary reimbursements of the subjects. B.Braun Melsungen AG never had access to the collected raw data and was informed of the final results only after the completion of the study and its statistical analysis. Neither the author nor her mentor received any monetary – or otherwise – compensation from B. Braun Melsungen AG or its employees. No other potential conflict of interest relevant to this dissertation exists.

# 3. Results

## 3.1. Power and Sample Size

The calculated power [82, 83] of our study in regard to achieved binary checklist points equaled to 69% owing to a higher standard deviation in the control group (5.87 instead of the assumed 5.0) and a lower effect size (0.94 instead of 1.2) than estimated in the planning phase of the study design, despite the fact that we recruited N=15 participants for each group.

## 3.2. Inter-rater Reliability

The inter-rater reliability for the two blinded video raters calculated by interclass coefficient was .841.

## 3.3. Subjects

A total of 34 physicians and 24 nursing students signed up for the study. Two physicians had to be excluded from the final analysis due to inability to complete the procedure successfully; another one was excluded due to misinterpretation of instructions and subsequent failure to complete the task correctly. Additionally, one physician failed to show up for the study, resulting in a final study cohort of 30 different central line insertion teams (physician/nurse). Randomization revealed two equal group sizes (n=15).

As mentioned above, we were not able to recruit as many nursing students as physicians. Additionally, not all nursing students were able to participate due to scheduling conflicts. Thus, only 19 nursing students assisted in CLC placement and some nursing students were allowed to participate twice. These were chosen on the basis of availability and not their prior experience. The nursing students who participated twice were equally distributed between the control and intervention group ($p=1$ according to the Chi-Square test, degrees of freedom: 1) in order to minimize any potential bias that could result from a potential learning effect in the cohort of assisting nurses.

Study participants' characteristics are summarized in Table 2 (physicians) and Table 3 (nurses). There were no significant differences between the prepackaged kit group and standard kit group in regard to sex, age, prior experience in central line catheter insertions and educational status (all $p > .12$).

| | **Control** | **Intervention** | **P** $\chi^2$, **TT, Wilcoxon** |
|---|---|---|---|
| Gender (m/f) | 11m<br>4f | 7m<br>8f | **0.13** |
| Age | 27.3 ± 2.2 | 27.3 ± 2.5 | **0.93** |
| Prior CLC experience (Manikin) | 1.5 ± 3.2 | 0.2 ± 0.4 | **0.12** |
| Prior CLC experience (Patient) | 1.8 ± 2.8 | 2.2 ± 3.9 | **0.75** |
| Education status (Physician/ Student) | 8 Students<br>7 Physicians | 6 Students<br>9 Physicians | **0.46** |

**Table 2. Physicians' Characteristics**

| | **Control** | **Intervention** | **P** $\chi^2$, **TT, Wilcoxon** |
|---|---|---|---|
| Gender (m/f) | 4m<br>11f | 5m<br>10f | **0.69** |
| Age | 23.1 ± 3.7 | 21.6 ± 3.4 | **0.19** |
| Prior experience in assisting with CLC | 2 | 2 | **1** |
| Year in Training | $1^{st}$ – 6<br>$2^{nd}$ – 6 | $1^{st}$ – 8<br>$2^{nd}$ - 5 | **0.56** |

**Table 3. Nursing Students' Characteristics**

## 3.4. Procedure

All physicians attempted a CLC placement once. The EKG monitoring, that is normally used in order to control the wire position and to immediately detect arrhythmias, was not utilized because the manikin was not equipped with EKG simulation possibilities. In addition, the ultrasound equipment, although principally applicable, was not employed as positioning of the needle and puncture of the internal jugular vein was always possible without ultrasound support. Thus, both steps were

removed from the evaluation checklist and the participants were instructed to ignore this equipment during the procedure.

## 3.5. Results

### 3.5.1. Time needed to perform the procedure

The prepackaged kit group required less time to perform the procedure than the standard kit group (26:26±3:50 min vs. 31:27 ± 5:57 min, p = .01) (Figure 1). We timed preparation and execution of the CLC placement separately and the results were as follows: preparation time was 3:52±0:45 min in the control group and 2:08±0:59 min in the intervention group (p=0.001), execution time in the control group was 27:35±6:35 min and in the intervention group 24:16±3:33 min (p=0.06).

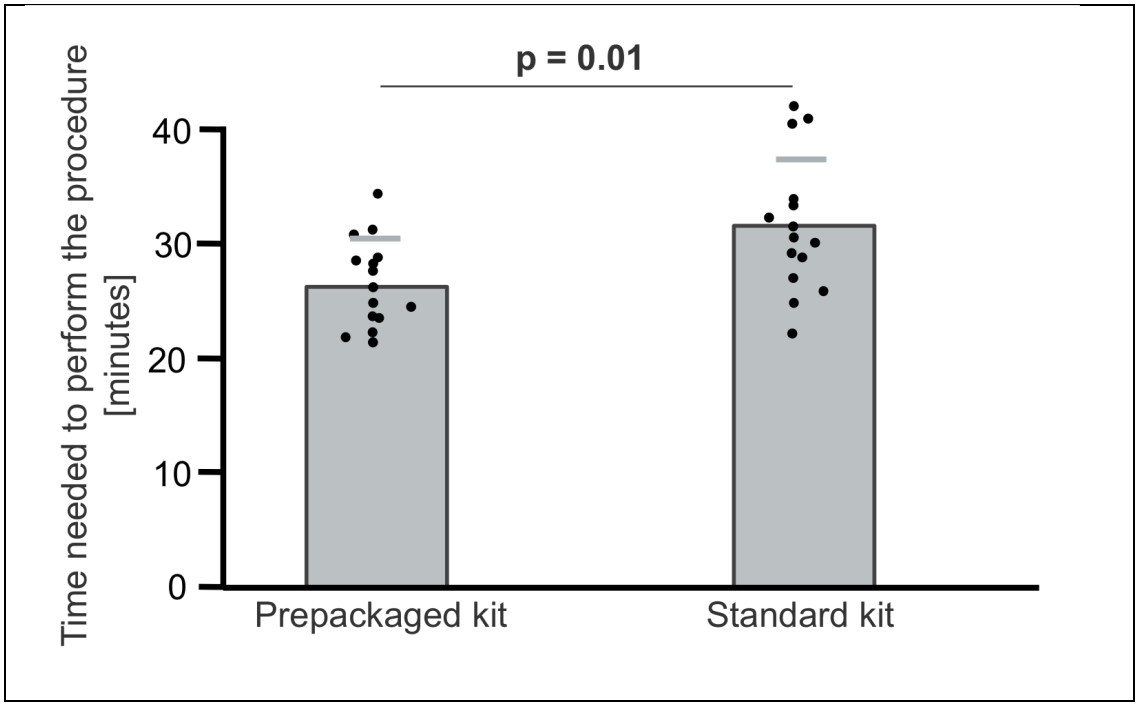


**Figure 6. Total time (preparation + execution) needed to complete the CLC placement**

### 3.5.2. Number of Correctly Performed Steps

The binary checklist with number of participant (in percent) performing each step correctly is provided in Table 4.

| Procedural Step | Control % Rater 1 | Control % Rater 2 | Intervention % Rater 1 | Intervention % Rater 2 |
|---|---|---|---|---|
| Sterile gloves | 93 | 93 | 100 | 100 |
| Sterile gown | 80 | 93 | 100 | 100 |
| Cap | 87 | 87 | 93 | 93 |
| Mask | 100 | 100 | 93 | 93 |
| Disinfecting agent | 93 | 73 | 100 | 100 |
| Sterile gauze | 53 | 33 | 80 | 100 |
| Sterile compresses | 53 | 67 | 93 | 100 |
| Local anesthetic | 100 | 100 | 100 | 100 |
| 3ml Syringe (for the anesthetic) | 100 | 100 | 100 | 100 |
| Needle (for the anesthetic) | 100 | 100 | 100 | 100 |
| Sterile drape | 53 | 53 | 80 | 100 |
| Sterile fenestrated drape | 93 | 93 | 100 | 100 |
| 10 ml Syringe | 100 | 100 | 100 | 100 |
| Distilled water (to simulate NaCl 0.9%) | 100 | 93 | 100 | 100 |
| TLC | 100 | 100 | 100 | 100 |
| Seldinger needle | 100 | 100 | 100 | 100 |
| Guide wire | 100 | 100 | 100 | 100 |
| Dilator | 100 | 100 | 93 | 100 |
| Scalpel | 93 | 100 | 93 | 100 |
| 3-way ports | 47 | 60 | 67 | 100 |
| Blood gas syringe | 20 | 20 | 60 | 40 |
| TLC holder/ clip | 60 | 87 | 67 | 100 |
| Suture thread | 93 | 87 | 93 | 100 |
| Needle driver | 93 | 87 | 93 | 100 |
| Adhesive bandage | 80 | 60 | 80 | 100 |
| Sharps container | 60 | 20 | 53 | 27 |
| Sterile use of ultrasound equipment, if used to find the vein | ** | ** | ** | ** |
| Hand washing/ sanitizing | 33 | NA | 40 | NA |
| All of the following are worn correctly: sterile gloves and gown, mask, cap | 60 | 93 | 93 | 93 |
| Disinfection of the injection site | 100 | 100 | 100 | 100 |

| | | | | |
|---|---|---|---|---|
| Fenestrated drape is applied to injection site | 67 | 80 | 80 | 87 |
| Injection of the local anesthetic (must aspirate before injection!) | 87 | 93 | 93 | 93 |
| Both 10mL syringes are filled with NaCl 0.9% | 60 | 80 | 60 | 100 |
| All 3 lumina of the catheter are flushed with NaCl | 73 | 67 | 100 | 93 |
| All ports are blocked after the flush | 73 | 40 | 100 | 87 |
| Disinfection of the injection site (assistant) | 60 | 27 | 53 | 33 |
| Insertion of seldinger needle (30° angle) | 80 | 93 | 100 | 87 |
| Patient is asked if he can still feel the needle | 20 | 13 | 0 | 7 |
| The needle is inserted until the vein is punctured and blood can be drawn | 100 | 100 | 93 | 100 |
| A sample for blood gas analysis is drawn | 20 | 13 | 60 | 53 |
| Blood gas syringe is transferred to assistant | 20 | NA | 47 | NA |
| Insertion of the guide wire | 87 | 93 | 93 | 100 |
| Removal of the needle (the guide wire is secured in place) | 93 | 93 | 100 | 93 |
| Skin incision along the guide wire | 80 | 80 | 80 | 93 |
| Insertion of the dilator over the guide wire | 87 | 93 | 87 | 93 |
| Insertion of the catheter over the guide wire | 100 | 87 | 100 | 93 |
| The catheter is inserted through the skin only after the guide wire is secured | 80 | 93 | 80 | 80 |
| Removal of the guide wire (the catheter is secured in place) | 100 | 93 | 100 | 100 |
| Safe disposal of the guide wire (double knot/ sharps container) | 27 | 33 | 20 | 27 |
| Blood is drawn from all 3 lumina | 60 | 47 | 47 | 33 |
| All 3 lumina are flushed with NaCl | 47 | 53 | 27 | 40 |
| TCL clip is attached to the catheter | 47 | 87 | 60 | 100 |
| TLC clip is sutured in place | 60 | 93 | 87 | 100 |
| The site of insertion is covered with an adhesive bandage | 80 | 73 | 80 | 80 |
| All needles and the scalpel are safely disposed of (sharps container) and the work station is left clean | 40 | 40 | 47 | 47 |

**Table 4. Binary checklist representing all the steps used to evaluate performance.**

***** The step was excluded from the statistical analysis because none of the participants utilized the step. NA: The rater was not able to assess the correctness of the step.**

In summary, the prepackaged kit group performed more steps correctly (45 ± 2.6 % vs. 40.7 ± 5.9, p = .016). Figure 6 shows the number of correctly performed steps in percent. Since step number 27 (sterile use of ultrasound equipment) was removed from the final assessment, a total of 54 steps were set as 100%.

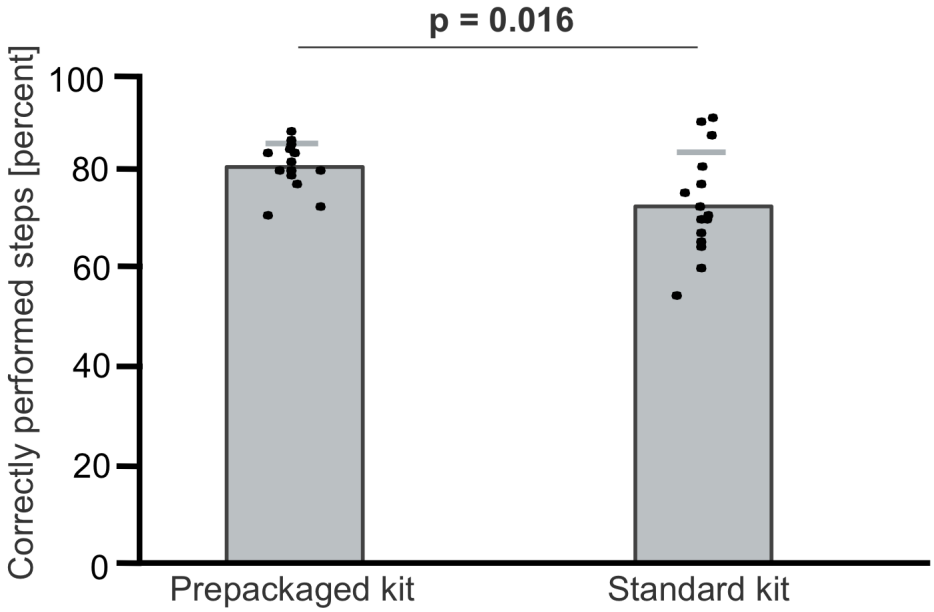


**Figure 7. Number of correctly performed steps in percent.**

### 3.5.3. Minor and Major Procedural Mistakes

The prepackaged kit group committed 35 % fewer major mistakes (3.1±1.4 vs. 4.8±2.6, p = .033; Figure 2), and 35 % fewer minor mistakes (5.2±1.7 vs. 8.0±3.2, p = .007; Figure 3) during the procedure.

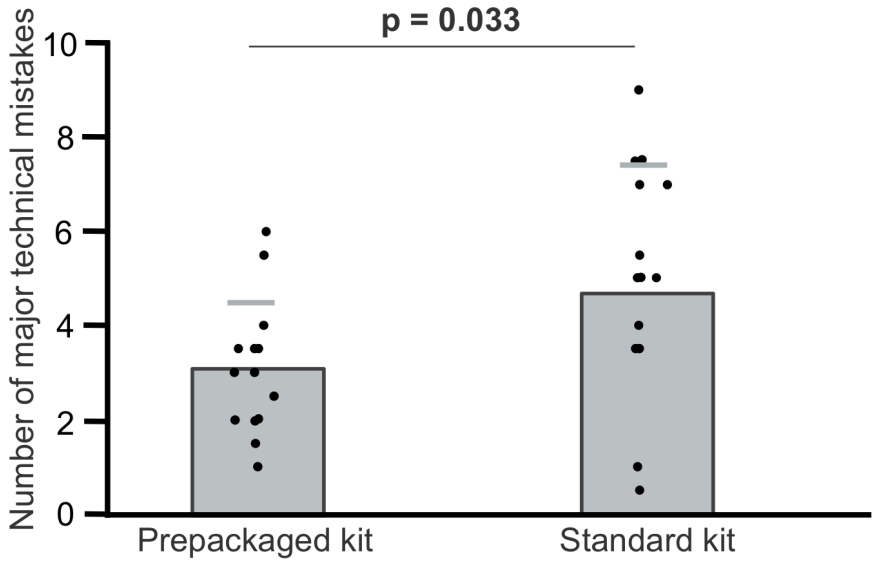


**Figure 8. Number of Major Technical Mistakes**

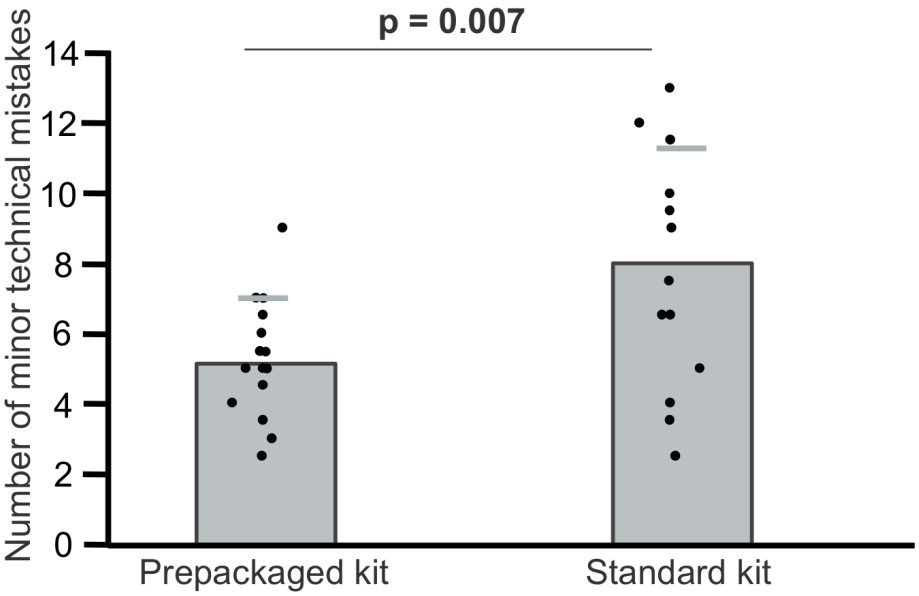


**Figure 9. Number of Minor Technical Mistakes**

### 3.5.4. Potential Breaches of Asepsis

There was a trend toward a reduced number of events with potential breaches of asepsis (every contact between sterile and non-sterile material was treated as a surrogate marker for maintenance of asepsis) in the prepackaged kit group (1.2±0.8 vs. 3.0±3.6, p = .06) although it was not statistically significant (see figure 5).

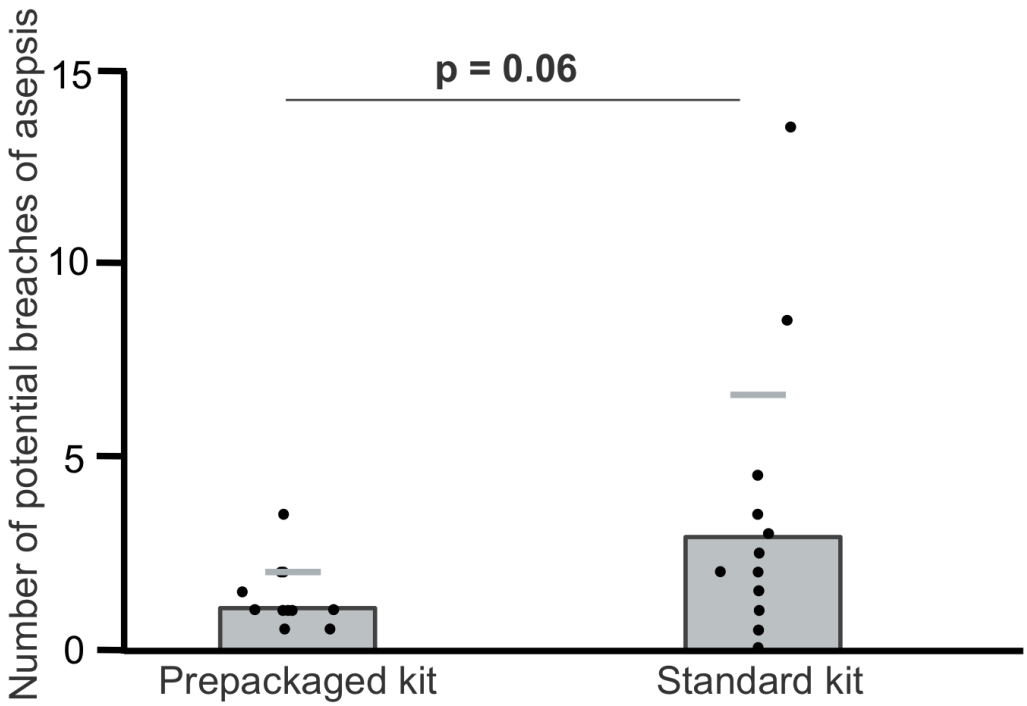


**Figure 10. Number of Potential Breaches of Asepsis**

### 3.5.5. Distribution of Correctly Performed Steps by Category

Table 4 summarizes the distribution the steps preformed correctly during the CLC placement grouped by categories.

| | Control | Intervention | P ($x^2$) |
|---|---|---|---|
| Preparation of Materials | 21.2±2.3 | 23.9±1.2 | 0.0003 |
| Patient Preparation | 3.75±0.8 | 4.27±0.8 | 0.1094 |
| Central Line Insertion | 12.6±2.9 | 13.7±1.3 | 0.1332 |
| Securing the Catheter and Clean-Up | 2.6±0.9 | 3.0±0.8 | 0.2056 |

**Table 5. Distribution of Correctly Performed Steps by Category**

# 4. Discussion

Since the publication of the report "To Err is Human" by the IOM in 2000, more and more attention has been paid to patient safety both by the hospitals and practicing physicians [21, 24, 25]. Many procedures that are medically necessary may present a certain risk for the patient. For example, although central line catheters are associated with a significant number of complications, they are widely used in hospital settings [1-4, 39].

There is clear evidence that inexperienced physicians are more likely to commit errors, which may negatively affect patient safety [31]. During central line placement they are more likely to fail or induce mechanical complications than their more experienced colleagues [6]. We thus designed a study to investigate a possible way to reduce complications associated with a common procedure (CLC placement) performed by the group most prone to mistakes (inexperienced physicians).

In our study we compared the effect of a prepackaged all-inclusive central line catheter insertion kit (prepackaged kit) with a standard kit that had some of the items packaged separately for five quality indicators:

1. Time needed for central line catheter insertion
2. Number of correctly performed steps
3. Number of major technical mistakes
4. Number of minor technical mistakes
5. Number of potential breaches of asepsis

In four out of five categories the novice residents and final year medical students who used the prepackaged kit performed significantly better than the standard kit group. And the fifth category has shown at least a trend ($p=.06$) in the same direction, although the level of significance was narrowly missed.

Central line catheter insertion is a frequently used, complex, multistep procedure that renders a high cognitive load, especially for inexperienced physicians such as interns

and residents. According to the cognitive load theory, the usage of prepackaged kits should reduce the complexity of the insertion procedure for novices by streamlining the process and ensuring an uninterrupted workflow [18]. This, in turn, would have a positive effect on reduction of mechanical complications associated with the procedure. As prepackaged kits are designed to include most if not all items required for a certain procedure, the frequency with which a new item has to be introduced to the sterile field is significantly lower. As a result, potential breaches of asepsis during the insertion would be reduced as well.

There are some studies that have used prepackaged CLC kits or carts and have demonstrated a significant reduction in CLC-related complications [9, 19]. However, in these studies, the prepackaged CLC kit was part of a multistep intervention (checklists, staff education, daily assessment of the necessity of the catheter were all part of these studies), so no conclusions can be made about the actual effect a CLC kit had on the outcome per se. In our study we carefully controlled the conditions for central line catheter insertion as to assess the pure effect of using prepackaged versus standard kits in order to exclude a sampling error or unequal working conditions as the cause for the difference. A simulated setting was chosen in order to avoid any relevant variables that may interfere with the study question. Furthermore, our study was designed as a "worst case" scenario: an inexperienced physician trying to insert a central line catheter with assistance from an equally inexperienced nurse.

There are three reasons why we wanted to single out the potential beneficial effect of prepackaged kits:

1. Novices, who have been shown to have a higher complication rate than experts, need all the help they can get in order to minimize potential complications.
2. This rather simple measure can be easily transferred to other invasive procedures with a high cognitive load for novices, i.e. insertion of a chest tube or bone marrow aspiration.

3. The use of a prepackaged kit facilitates materials manipulation and allows homogenous sterilization.

The advantages gained through the use of prepackaged kits for complex procedures may outweigh the additional costs of prepackaging and other possible drawbacks such as material surplus as not all the components provided in the kit will always be used. On the other hand, the cost associated with such kits is probably negligible compared to the cost of CLC complications that may be averted through the use of these kits. The usage of prepackaged kits should be rather easy to implement, since it does not require a change of routine or infrastructure.

However, our study had some limitations: we used a manikin in order to standardize the conditions for the central line catheter insertion procedure and control for such parameters as different patient anatomy, morbidity and size. Thus, our results cannot be directly transferred nor generalized for central line catheter insertions on real patients. Furthermore, the standard deviation in our control group, which used the standard CLC kit, was somewhat larger and the effect size smaller than assumed in the power analysis that was used to determine the number of participants. This resulted in lower than aspired power ($p=.69$), but nevertheless did not interfere with the claimed level of significance in 4 out of 5 indicators. The study failed to demonstrate a significant difference in one quality indicator, namely the number of potential breaches of asepsis. However, it has to be mentioned that the trend towards an advantage of a prepackaged kit was shown to be almost significant ($p=.06$) for this indicator as well. We therefore assume that this indicator also does benefit from a prepackaged CLC kit, and that a larger study cohort would render this indicator significant. Since our study concentrated on procedural performance, we could not measure patient outcomes. The category “potential breaches of asepsis” is only a surrogate parameter for a central line catheter bloodstream infection, as is the non-adherence to the procedural algorithm for mechanical complications. Thus, a potential breach of asepsis and non-adherence to the procedural algorithm may or may not result in real patient harm.

Our study augments current research on improvement of patient safety. We have demonstrated a clear benefit of using prepackaged kits for central line placement, especially when an inexperienced physician performs the procedure. One could further speculate that similar advantages would be seen when using prepackaged kits for other procedures, such as urinary catheter insertion or lumbar puncture, as well. We thus think that such kits should be implemented in the hospital setting whenever possible as it is a very simple and rather cost-effective way of improving patient safety.

# 5. Summary

Introduction: Central line catheter insertion is a complex procedure with a high cognitive load for novices. Placing all required materials into one prepackaged all-inclusive kit is a simple and cheap measure that reduces the cognitive load. We therefore assessed whether the use of prepackaged all-inclusive central line insertion kits reduces procedural mistakes during central line catheter insertion by novices.

Methods: A total of 34 final year medical students and recently qualified physicians were randomized into two equally large groups. Both groups performed central line catheter insertion on a mannequin, assisted by nursing students. One group used a prepackaged all-inclusive kit, the other a standard kit with separately packaged items. The procedure was videotaped and analyzed by two blinded raters using a checklist.

Results: The prepackaged kit group outperformed the standard kit group in four of the five quality indicators: time needed to perform the procedure (26:26±3:50 min vs. 31:27 ± 5:57 min., p = .01), major technical mistakes (3.1 ± 1.4 vs. 4.8 ± 2.6, p = .033), minor technical mistakes (5.2 ± 1.7 vs. 8.0 ± 3.2, p = .007), and correct steps (83 ± 5 % vs. 75 ± 11 % p = .016). The difference in potential breaches of asepsis (1.2 ± 0.8 vs. 3 ± 3.6, p = .06) was not statistically significant.

Conclusions: Prepackaged all-inclusive kits improve the procedure quality and save staff time when used by novices in a controlled simulation environment. Future studies are needed to evaluate possible effect these kits might have on patient safety.

# 6. Appendix

## Appendix 1



### Stammdatenblatt ZVK-Studie

**Nummer/ Pseudonym:** _____

**Geschlecht:** ☐ **M** ☐**W**

**Alter:** _____

**Ausbildungsstand:**

**Student** ☐ ja ☐ nein **Semester**: _____

**Assistent** ☐ ja ☐ nein **Ausbildungsjahr**: _____

**Frühere (medizinisch relevante) Ausbildungen (Pflege, RA, etc.):**

_____

**Haben Sie schon einmal einen ZVK am Phantom gelegt?** ☐ ja

☐ nein

Wenn ja,

Wie oft? _____ Wann zuletzt? _____

**Haben Sie schon einmal einen ZVK am Patienten gelegt?** ☐ ja

☐ nein

Wenn ja,

Wie oft? _____ Wann zuletzt? _____

**Appendix 2**

# Stammdatenblatt ZVK-Studie

**Name, Vorname:** _____

**Geschlecht:** ☐ **M** ☐**W**

**Alter:** _____

**Ausbildungsstand:**

**Ausbildungsjahr**: _____

**bisherige Berufserfahrung:**_____

**Frühere Ausbildungen:**

_____

**Haben Sie schon einmal bei einem ZVK am Phantom assistiert?**

☐ ja ☐ nein

Wenn ja,

Wie oft? _____ Wann zuletzt? _____

**Haben Sie schon einmal bei einen ZVK am Patienten assistiert?**

☐ ja ☐ nein

Wenn ja,

Wie oft? _____ Wann zuletzt? _____

## Appendix 3

**Einverständniserklärung**

Die Studie untersucht die Patientensicherheit bei der Anlage von zentralen Venenkatheter durch Berufsanfänger.

Hiermit gebe ich, _____ (Name, Vorname), mein Einverständnis zur Teilnahme an der Studie "Patientensicherheit".

Ich bin einverstanden, dass die Versuche gefilmt werden und die Aufnahme zu Auswertungszwecken innerhalb der Studie einmalig kopiert wird. Es werden keine personenbezogenen Daten mit den Aufnahmen gespeichert. Die Aufnahmen werden nach Auswertung durch Videorater umgehend vernichtet. Die Aufnahmen werden nicht, auch nicht in Auszügen, veröffentlicht.

Die Aufnahmen selbst sind nicht Gegenstand der Studienfrage. Es werden aus den Aufnahmen lediglich Informationen extrahiert, die daraus gewonnenen Erkenntnisse/Zahlen werden möglicherweise publiziert, werden aber von den Aufnahmen strikt getrennt. Somit kann aus den gewonnenen Daten nicht auf einzelne Personen zurückgeschlossen werden.

_____
(Datum, Ort)

_____
(Unterschrift)

## Appendix 4

Ihre Aufgabe ist die Anlage eines zentralen Venenkatheters (ZVK) an einem Modell. Dabei erhalten sie Hilfe von einer Pflegekraft, der Sie Anweisungen erteilen können. Sie sollen offen sagen, was Sie benötigen.

Bitte beachten Sie folgende Besonderheiten, die sich aus den Eigenschaften des Modells ergeben:

- Das Modell verträgt keine nicht-intravasale Flüssigkeit. Falls Sie die Anwendung von Flüssigkeiten beabsichtigen, deuten Sie dies nur an.
- Falls Sie das Gefäß beim ersten Versuch nicht treffen, benutzen Sie bitte das Sono-Gerät. Beachten Sie dabei bitte, dass der Abominalschallkopf verwendet werden soll. Dazu benötigen Sie einen sterilen Überzug, dessen Verwendung Ihnen in einem Video bereits vorgestellt wurde.
- Die Durchführung eines Schnitts mit einem Skalpell wie in der Wirklichkeit würde das Modell unwiederbringlich zerstören. Bitte deuten Sie auch diesen Schritt daher nur an.
- Zur Desinfektion benutzen Sie bitte die bereitgestellte Flasche. Falls Sie noch mehr Desinfektionsmittel benötigen, können Sie die Pflegekraft darum bitten.

## Appendix 5

Sie assistieren einem Arzt bei der Anlage eines zentralen Venenkatheters (ZVK) an einem Modell. Dabei helfen Sie dem Arzt beim sterilen Ankleiden, dem Anreichen von Materialien und der Aufrecherhaltung der sterilen Arbeitsumgebung. Bitte greifen Sie nicht eigenmächtig in das Prozedere ein, sondern folgen Sie den Anweisungen, die Sie vom Arzt erhalten.

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# 8. Deutsche Zusammenfassung

Einführung: Die Anlage von zentralen Venenkathetern (ZVK) ist ein komplexer Vorgang und stellt für Anfänger eine kognitiv anspruchsvolle Aufgabe dar. Diese kann leicht und preiswert durch die Verwendung von vorab gepackten Instrumentensets vereinfacht werden. Daher haben wir die Auswirkungen der Verwendungen vollständig vorbereiteter Instrumentensets auf Verfahrensfehler während der Anlage eines ZVK durch Berufsanfänger untersucht.

Methoden: Insgesamt 34 Berufsanfänger und Medizinstudenten im letzten Studienjahr wurden zufällig auf zwei gleich große Gruppen aufgeteilt. Assistiert von Krankenpflegeschülern führten beide Gruppen die Anlage eines ZVK an einer Puppe durch. Eine Gruppe verwendete ein vorab gepacktes Instrumentenset, die andere ein Standardset mit zum Teil getrennt verpackten Gegenständen. Die Anlage des ZVK wurde gefilmt und die Aufnahmen von zwei verblindeten Sachverständigen mittels einer Checkliste bewertet.

Ergebnisse: Die Gruppe, die das vorab gepackte Instrumentenset verwandte, übertraf die Gruppe des Standardsets in vier von fünf qualitätsrelevanten Kategorien: Zeitaufwand (26:26±3:50 min vs. 31:27 ± 5:57 min., $p = .01$), grobe technische Fehler (3.1 ± 1.4 vs. 4.8 ± 2.6, $p = .033$), kleine technische Fehler (5.2 ± 1.7 vs. 8.0 ± 3.2, $p = .007$) und richtig ausgeführte Schritte (83 ± 5 % vs. 75 ± 11 % $p = .016$). Der Unterschied (1.2 ± 0.8 vs. 3 ± 3.6, $p = .06$) im Verhalten, welches das sterile Millieu gefährdet, war nicht statistisch signifikant.

Schlussfolgerungen: Die Verwendung vorab gepackter Instrumentensets durch Berufsanfänger verbessert die Verfahrensqualität und spart Arbeitszeit unter kontrollierten Versuchsbedingungen. Zukünfige Studien sind nötig, um die Auswirkungen von vorab gepackten Instrumentensets auf die Patientensicherheit zu bewerten.

# 9. Publications

Parts of this dissertation have been used in the following publication:

Fenik Y, Celebi N, Wagner R, Nikendei C, Lund F, Zipfel S, Riessen R, Weyrich P. *Prepackaged central line kits reduce procedural mistakes during central line insertion: a randomized controlled prospective trial.* BMC Med Educ. 2013 Apr 30;13(1):60.

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# Curriculum Vitae

## Personal Data

| | |
|---|---|
| Name: | Yelena Fenik |
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## Education

| | |
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| 2000 – 2005 | BA Geography, BA German (Honors in both) |
| | ***University of California Berkeley, Berkeley, CA, USA*** |
| 2007 – 2013 | MD Candidate 2013 |
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## Work Experience

| | |
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## Publications

**Fenik Y**, Celebi N, Wagner R, Nikendei C, Lund F, Zipfel S, Riessen R, Weyrich P. *Prepackaged central line kits reduce procedural mistakes during central line insertion: a randomized controlled prospective trial.* BMC Med Educ. 2013 Apr 30;13(1):60.

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Gregoric I, Radovancevic R, Patel M, **Fenik L**, Cohn W, Frazier OH. *Use of Sealed Grafts in the HeartMate II Inflow and Outflow Conduits*. The Journal of heart and lung transplantation 2012 Apr; 31(4):2