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PERIPHERAL VENOUS CATHETERS

Quality of Care Assessment

Margary Ahlqvist

Karolinska Institutet

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To do your best

“It is not enough to do your best,
You must know what to do,
And then do your best.”

W. Edwards Deming
(1900-1993)

ABSTRACT

About half of the patients admitted to hospitals receive intravenous therapy through peripheral venous catheters (PVCs). Unfortunately, the use of PVCs is associated with the risk of complications that may lead to increased morbidity and prolonged hospitalisation. Because of the frequent use of PVCs and the risk of PVC-related complications, there are good reasons to assess quality of care.

The overall aim of this study was to attain increased knowledge about PVC documentation in the patient's medical record and to develop methods for assessment of inserted PVCs.

Patients were recruited on medical and surgical wards at two emergency hospitals (Study I) and at one university hospital (Study I, II). A convenient sample of 933 adult in-patients with PVCs inserted into a vein on their upper extremity was included in study I. A study-specific data collection form was used for bedside registration of PVC insertion site, hand side, lumen size, patient's age and gender. The post-insertion documentation of the same PVCs was checked in patient medical record and recorded. The data were descriptively analysed via frequency distribution and factors associated with PVC documentation were examined using univariate and multivariate logistic regression analysis. Results showed that 10 descriptions could be used to explain PVC insertion site. Any kind of PVC documentation was found in 72% of the patients' medical records. Notes that included information on insertion site, hand side and lumen size were identified in 46%. Documentation, including the latter three variables, was significantly associated with medical wards at general hospitals and smaller lumen size.

A PVC assessment tool (PVC *ASSESS*) was developed through confirmation of content validity, evaluation of face validity, inter-rater and test-retest reliability (Study II). The tool consists of three sections: PVC management, signs and symptoms of PVC-related thrombophlebitis and PVC documentation. To test the reliability two groups of registered nurses (RNs) (Study II) and nursing students (NSs) (Thesis) used the tool to perform PVC assessments on 67 PVCs on actual patients at bedside (inter-rater reliability). Two other groups of RNs and NSs assessed 67 PVC photographs taken concurrently with the bedside assessments (test-retest reliability). The tool's reliability was evaluated by calculation of proportion of agreement and Cohen's unweighted kappa coefficient (κ) among the RNs and NSs. The inter-rater reliability (κ) ranged from moderate to almost perfect in 93% and 81% of the tested items among RNs and NSs, respectively. Test-retest reliability (κ) ranged between moderate and almost perfect in 95-100% of the items tested among RNs and in 90-95% among NSs.

In conclusion, the findings imply the need for education of RNs in PVC documentation and development of terms for documentation of PVC insertion site. The reliability of the PVC *ASSESS* instrument is considered satisfactory and of relevance for use in research and clinical audits.

Kappa
A mythical Japanese figure
Toriyama Sekien, *1712, †1788

http://sv.wikipedia.org/wiki/Fil:Kappa_jap_myth.jpg, Toriyama Sekien, public domain

LIST OF PUBLICATIONS

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Journal of Clinical Nursing 2009;18(13):1945-52.

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CONTENTS

1 BACKGROUND 1
1.1 Peripheral venous catheters 1
1.2 Complications related to peripheral venous catheter 2
1.2.1 Thrombophlebitis 2
1.2.2 Catheter-related infection 4
1.2.3 Other complications 5
1.3 Quality of care and patient safety 6
1.4 Documentation in patient medical record 8
1.4.1 Purpose of documentation 8
1.4.2 Documentation of peripheral venous catheter 8
2 AIMS OF THE STUDY 9
3 MATERIALS AND METHODS 10
3.1 Accuracy in PVC documentation (Study I) 10
3.2 Development of the assessment tool (Study II) 10
3.2.1 Selection of items 12
3.2.2 Content validity 12
3.2.3 Face validity 12
3.2.4 Description of the tool 12
3.2.5 Reliability tests 12
3.3 Data analyses 14
4 ETHICAL CONSIDERATIONS 17
5 RESULTS AND DISCUSSION 18
5.1 Accuracy in PVC documentation (Study I) 18
5.1.1 Descriptions used to explain PVC insertion site 18
5.1.2 Extent of PVC documentation 18
5.1.3 Variables associated with PVC documentation 19
5.2 Development of the assessment tool (Study II) 19
5.2.1 Inter-rater reliability 19
5.2.2 Test-retest reliability 22
5.2.3 Final version of PVC *ASSESS* 25
6 METHODOLOGICAL DISCUSSION 26
6.1 Accuracy in PVC documentation (Study I) 26
6.2 Development of the assessment tool (Study II) 26
7 CONCLUSIONS AND CLINICAL IMPLICATIONS 28
7.1 Conclusions 28
7.2 Clinical implications 28
8 FUTURE RESEARCH 29
9 ACKNOWLEDGEMENT 30
10 REFERENCES 32
Appendix I: PVC *ASSESS* instrument
Study I - II

LIST OF ABBREVIATIONS

BSI	Bloodstream infection
CI	Confidence interval
G	Gauge
ID	Inner dressing
IV	Intravenous
mm	Millimetre
NS(s)	Nursing student(s)
NS I, NS II, NS III	Three nursing students who performed test-retest assessments
OD	Outer dressing
OR	Odds ratio
P(A)	Proportion of agreement
PVC	Peripheral venous catheter
RN(s)	Registered nurse(s)
RN I, RN II, RN III	Three registered nurses who performed test-retest assessments
SC	Stop-cock
TH	Thrombophlebitis
κ	Cohen’s unweighted kappa coefficient

1 BACKGROUND

1.1 PERIPHERAL VENOUS CATHETERS

Attempts with administration of intravenous (IV) infusions to animals by using guts as tubes were performed already in the middle of the seventeenth century in Germany and England. These experiments started the evolution of silver plated and steel devices for placement in blood vessels. Steel reusable needles were used until the first plastic catheters of polyvinyl chloride material were introduced in the middle of the twentieth century (1). Today, polyvinyl chloride has been replaced with other materials, such as polytetrafluorethylene (Teflon) and different kinds of polyurethanes, which are inert and flexible substances well suited for IV use (2).

In modern health care about half of the patients admitted to hospitals receive IV therapy through a peripheral venous catheter (PVC) (3). Thus, the insertion and management of PVCs are daily tasks for health care professionals. In Sweden alone, approximately 5 million PVCs are inserted by registered nurses (RNs) each year (4) for administration of fluids, drugs, parenteral nutrition, contrast media or blood components. PVCs are usually inserted into peripheral veins on the patient's upper extremity, i.e. into veins on hands or forearms, and if needed, into veins on the lower extremities. The insertion procedure is a variant of Seldinger technique (5). Inside the catheter is a trocar or needle introducer to pierce the skin and the vein wall when the catheter is introduced into the vein. After removal of the trocar, the external part of the catheter is secured to the patient's skin to prevent accidental removal or micro movements against the vein wall and at the insertion site. A PVC and its components are shown in Figure 1.

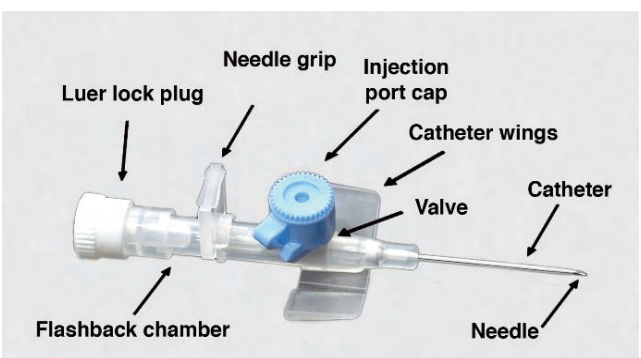


Figure 1. The components of PVC.
The photo is reproduced with kind permission from Karolinska University Hospital. Photographer: Staffan Larsson

PVCs are available in various designs, sizes/gauges and lengths. The sizes range from 0.6-2.2 millimetres (mm) or 26-14 Gauge (G) and lengths from 19-50 mm. Prescribed IV therapy, desired flow rate and condition of the patient's vein are aspects that influence the choice of PVC size. Larger sizes are usually inserted in surgery rooms and emergency situations when substantial fluid or blood requirement

is required. The size of a PVC can be identified from standardised colours of the injection port cap or the wings.

Unfortunately, the use of PVCs is associated with the risk of various complications that may lead to increased morbidity, delayed treatment and prolonged hospitalisation (6, 7).

1.2 COMPLICATIONS RELATED TO PERIPHERAL VENOUS CATHETER

Adult patients with inserted PVCs may be afflicted with catheter-related complications, including thrombophlebitis (TH), blood stream infection (BSI), haematoma, extravasation and infiltration (7-12).

1.2.1 Thrombophlebitis

TH is the most frequent PVC-related complication that may occur within a few hours post-insertion or even after the removal of the PVC. Although TH usually subsides within a few days signs and symptoms have been reported to last for several months (13).

Incidence and definition

TH incidence varies between 2.5% and 78% (9, 13-19). Tagalakis et al. (20) reported an average TH incidence of 30% in a review article based on studies published between 1966 and 2001. The wide TH incidence is in part influenced by different study designs, patient selection, follow-up time (20), different PVC materials (2), number of participating practitioners and because there is currently no standardised definition of TH (21). An early definition, including a grading system of PVC-related TH based on redness, tenderness and oedema of the vein, was proposed by the British Medical Research Council in 1957 (22). Variants of their recommended grading of PVC-related TH have evolved and have been used for reporting incidence and defining severity of TH during the past 30 years (Table 1). However, all signs may not develop in the same sequence that is indicated in the scales (23). As a result, some investigators have defined PVC-related TH based on two or more of TH signs and symptoms.

Pathogenesis

TH, a complex of inflammatory signs and symptoms, is a composed word of ‘thrombus’ (a blood clot formed within a blood vessel and remaining attached to its place of origin) and ‘phlebitis’ (inflammation of a vein). Phlebitis has been defined as an inflammatory process characterised by induration, erythema, warmth, oedema, pain and/or tenderness at or around a PVC insertion site (24). At the end of this inflammatory process, a manifest TH may develop and a cord is palpable along the vein (9, 25). Although the pathogenesis of TH remains unclear, the conventional explanatory model is an irritation of the endothelial cells that is caused by an inflammation, which is accompanied by thrombus formation. However, results from a small study suggest that thrombus formation may be a progenitor of phlebitis. This theory is supported by serially performed ultrasonographic examinations of long PVCs inserted into veins in antecubital fossa (23).

Table 1. The scales defining severity of PVC-related thrombophlebitis**.**

Grades	*Maddox (1977) (26)*	*Baxter (1988) (27)*	*Jackson (1998) (28)*	*Lundgren (1999) (29)*	*INS (2006) (30)*
0	No pain at i.v. site, no erythema, no swelling, no induration, no palpable venous cord	No pain at IV site, no erythema, [1] no induration, [2] no palpable venous cord [3]	IV site appears healthy	None or slight discomfort No redness or tenderness at/or round the insertion site/area	No symptoms
1	Painful i.v. site no erythema, no swelling, no induration, no palpable venous cord	Painful IV site or erythema, no swelling, no induration, no palpable venous cord	One of the following signs is evident: Slight pain near IV site Slight redness near IV site	Redness and tenderness at the insertion site/area < 15 mm	Erythema at the site with or without pain
2	Painful i.v. site with erythema, or some degree of swelling or both, no induration, no palpable venous cord	Painful IV site with erythema or some degree of swelling or both, no induration, no palpable venous cord	Two of the following signs are evident: Pain near IV site, erythema or swelling	Redness and tenderness at the insertion site/area >15 mm – < 25 mm Pain and slight swelling	Pain at access site with erythema and/or oedema
3	Painful i.v. site with erythema, and swelling and with induration, or a palpable venous cord less than three inches above i.v. site	Painful IV site with erythema and swelling and with induration or a palpable venous cord less than three inches above IV site	All of the following signs are evident: Pain along path of cannula Erythema Induration	Redness, tenderness, swelling and pain at the insertion site/area >25 mm - < 50 mm Increased temperature in the area Palpable cord/clot in the vein	Streak formation Palpable venous cord Pain at access site with erythema and/or oedema
4	Painful i.v. site, erythema, swelling, induration and a palpable venous cord greater than three inches above i.v. site	Painful IV site, erythema, swelling, induration and a palpable venous cord greater than three inches above IV site	All of the following signs are evident and extensive: Pain along path of cannula Erythema Induration Palpable venous cord	Redness, tenderness, swelling and pain at the insertion site/area > 50 mm. Increased temperature in the area. Pain spreading at the arm. Red string and/or possibly purulent area and fever. Palpable hard vein and/or hard cord/clot in the vein	Streak formation Palpable venous cord >1inch in length Purulent drainage
5	Frank vein thrombosis along with all signs of grade 4; + i.v. may have stopped running due to thrombosis	Frank vein thrombosis along with all the signs of grade 4 above. IV infusion may have stopped running owing to thrombosis	All of the following signs are evident and extensive: Pain along path of cannula Erythema Induration Palpable venous cord. Pyrexia		

INS, Infusion Nursing Society; i.v., intra venous; IV, intravenous. [1] Erythema = redness, [2] Induration = hardness, [3] Palpable venous cord = vein feels rope-like on palpation.

In this thesis TH will be used as a generic term for thrombophlebitis, phlebitis or thrombus.

Aetiology

It is well established that the aetiology of TH is multifactorial. Development of TH is mainly related to chemical, mechanical, bacterial factors or the patient's vulnerability. Patient characteristics (e.g., older ages, female gender, previously experienced PVC-related TH or underlying disease such as diabetes mellitus, burns and infectious diseases) may increase the risk of TH (6, 19). However, there are conflicting results reported concerning the patient's age (19) and gender (21, 31).

Chemical TH is a histological effect (32) of a cell toxic reaction that is caused by the composition of administered fluids (33) and drugs (10, 34). In experimental studies the incidence of TH signs are reported to correlate with the pH or osmolality that falls out of the tolerable range for endothelial cells and duration of hypertonic infusion (35, 36).

Mechanical TH is caused by trauma to the endothelial wall of the vein. Hence, the rate of mechanical TH is influenced by knowledge about prevention strategies and the insertion skills among clinicians cannulating the vein (9, 37). Risk factors associated with mechanical TH are: A large-gauge PVC preventing adequate blood flow around the catheter and dilution of the infusate (9, 13), insertion site on the upper arm, areas of flexion and lower extremities (9, 30, 38), duration of PVC placement (3, 9, 13, 17, 39-41) and deficient fixation and dressings (42, 43). A poorly secured catheter (44) causes small catheter movements that may increase irritation at the PVC insertion site and the vein wall. In an audit of 100 patients with inserted PVCs 67 had incorrectly secured PVCs. Two or more TH signs were developed in 71% of these 67 PVCs compared with 16% among those PVCs that were correctly attached to the skin (12). The thrombogenic effect of PVC compositions has also been studied. A new and more flexible type of polyurethane catheter is found to cause less mechanical trauma on the vein wall compared with polyurethane catheters coated with a silicon elastomer (Vialon) (2). Vialon catheters have been associated with lower TH incidence than Teflon catheters (9, 45).

1.2.2 Catheter-related infection

Selection of the PVC insertion site on the lower extremities or upper arm and dwell time are factors associated with an increased risk of catheter-related infection. However, catheter-related infection can be reduced by good hand hygiene, proper skin disinfection before cannulation and aseptic manipulation of the PVC (46). Severe TH signs, including pus and fever, are symptoms of local catheter infection that is confirmed by microbiological cultures from the insertion site (24). A local infection may turn into a serious suppurative TH and the resultant abscess can cause BSI, even after the removal of PVC (47).

A BSI that occurs in patients with an IV catheter in place when other sites of infection have been excluded is the minimal criterion used to define a catheter-related BSI (8). A stricter clinical definition requires that a culture of the catheter tip shows the same organism as identified in two blood samples separately drawn before starting therapy (24). Based on a systematic review of studies conducted between 1966 and 2005, the point incidence of PVC-related BSI was 0.5 per 1000 PVC days

or 0.1% (8). Thus, PVCs are rarely associated with development of BSI, although difficulties in clinical and laboratory diagnosis may influence the reported incidence of PVC-related BSI (24, 48).

1.2.3 Other complications

Other PVC-related complications are haematomas, extravasation and infiltration. These complications may lead to adverse events, such as skin necrosis, neuropathy and compartment syndrome (7). Extravasation and infiltration are accidental leakages of drugs or fluids into tissue surrounding the PVC. Extravasation refers to a leakage of fluids that have the potential to cause damage on the underlying tissue structures (e.g. acid, alkaline, vasoconstricting, cytotoxic or hypertonic fluids) while infiltration is a leakage of less tissue toxic fluids (49). Skin graft, surgical debridement, surgical evacuation, tendon transfers and carpal tunnel release are surgical procedures undertaken to repair tissue damage and to improve a patient's hand function. Pain, weak grip, skin depigmentation and scarring are reported sequelae as a result from these complications (7).

1.3 QUALITY OF CARE AND PATIENT SAFETY

Although health care professionals, authorities and politicians pay increased attention to the quality of care and patient safety (50), the concept of quality is not a new trend within health care. Defining quality started already in ancient Egypt and Greece when physicians were punished for care-related injuries indicating that good quality meant patient-safe care (51). Since the 1960s, quality in health care has an evaluating approach when Donabedian defined quality in evaluating terms of benefit and harm of provided care by comparing the outcome with predefined criteria of good care (52). This evaluating approach is in accord with the definition of quality care from the Institute of Medicine (53) and of safety practices by Shojania et al. (54).

In 1990, the Institute of Medicine defined quality of care as:

> "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".

Shojania et al. define patient safety practices as:

> "…practices that reduce the risk of adverse events related to exposure to medical care across a range of diagnoses or conditions".

Accordingly, health care professionals' require contemporary professional knowledge in PVC management to achieve quality in PVC care (52-54). Identification of PVC practices expected to provide quality care and subsequent patient safe outcome is facilitated by an evidence-based approach (54). Hence, evidence-based clinical guidelines are important components to recognise risk-reducing practices in PVC management (54) and to establish criteria for evaluation of adherence to PVC guidelines and patient outcome (52). Evidence-based strategies recommended for prevention of PVC-related complications are presented in Table 2.

Table 2. Evidence-based strategies recommended for prevention of PVC-related complications associated with PVC management (46).

Strategy	***Rationale***
Choose insertion of PVC in a peripheral vein, preferably on the back of the hand or on the forearm.	Poor anatomic location of catheter on the wrist or in the antecubital fossa increases mechanical irritation at the insertion site and in the vein.
Select smallest possible PVC gauge and insert in a straight vein of sufficient diameter.	Adequate blood flow around the catheter improves dilution of the infusate and decreases irritation on vein wall.
Apply gauze dressing or tube bandage.	Protects insertion site from any external harmful damage and unintentional dislodgement that may cause extravasation, infiltration or unplanned recannulation.
Apply self-adhesive sterile transparent polyurethane dressing.	Keeps insertion site dry. Protects insertion site from contamination. Ensures stability that protects from unintentional dislodgement, extravasation or infiltration. Allows easy visual monitoring to identify early signs of complications.
Secure catheter wings with sterile tape strips in lengthwise direction.	Ensures firm securement in order to maintain a small part of the catheter visible and to allow monitoring of the PVC insertion site. Avoids extension tubing from pulling PVC that may cause unintentional dislodgement, extravasation or infiltration.
Secure stop-cock firmly.	Prevents micro-movements of the catheter at insertion site and in vein.
Keep dressing and insertion site dry and clean.	Prevents bacterial colonisation.
Keep ports and hubs clean and closed.	Prevents bacterial colonisation of these entrances.
Replace PVC electively as recommended in guidelines.	Decreases frequency and severity of TH and BSI.
Document all aspects of care in timely manner in the patient's medical record.	Supports elective replacement and continuity in care.

1.4 DOCUMENTATION IN PATIENT MEDICAL RECORD

1.4.1 Purpose of documentation

Documentation in the patient's medical record serves multiple purposes. The primary reason is to disseminate structured information between caregivers to ensure patient safety and continuity of care (55), as well as to give the patient information about his or her treatment. Thus, the medical record is the main source to communicate the patient's health care and action plans. In addition to communicating the patient's health care, the documentation is also assumed to form a base of knowledge for evaluating the quality of care and research purposes (55). To obtain reliable clinical measures about interventions and patient outcome for quality assessments and research purposes the use of a uniform vocabulary is considered important (56, 57) and has been recommended (55). Additionally, the documentation is a reference for legal matters (58).

In Sweden, systems for record keeping have changed during the past 10-15 years from paper-based medical records to computerised records.

1.4.2 Documentation of peripheral venous catheter

PVC documentation is proposed to comprise information about PVC size, location, date and time of insertion and removal, including the signature of the clinician who executes the procedure (13, 59-61). The medical indication for the use of PVC, the results from daily inspections of potential signs of complication and specific nursing actions taken are also suggested to be recorded (62, 63). Accurate documentation of insertion date, time and location are needed to ensure elective PVC replacement that is recommended to reduce the risk of TH (64). Hence, PVC documentation supports the continuity of PVC management in accordance with guidelines and the action plans agreed upon between the medical staff and the patient.

The recorded notes are also expected to enable differentiation of inserted PVCs for evaluation of quality care, i.e. indwelling time, selected PVC size, insertion site and complication rate based on retrospective documentation review in the patient's medical record (52, 55). However, investigators have reported that PVC documentation is lacking regarding insertion and removal in 30-50% of inserted PVCs (13, 63, 65, 66) and fails to form a base for assessment of PVC complication rates per catheter days (67). In addition, nursing assessment and decision making regarding PVC management has been found to be poorly documented (68). Furthermore, PVC documentation may reflect the professionals' awareness of local PVC policies and guidelines and thus form a base for education in PVC management and documentation.

2 AIMS OF THE STUDY

About half of the patients admitted to hospitals receive necessary IV therapy through PVC during their stay. The use of PVC is associated with complications that may lead to increased morbidity and prolonged hospitalisation. PVC documentation in the patient's medical record and the use of evidence-based practice are expected to improve patient safety and treatment outcome. Accordingly, there is a major need to systematically assess PVC documentation and management in order to support prevention of future unsafe actions of care and, in the long term, their adverse effect.

OVERALL AIM

The overall aim of this thesis was to attain increased knowledge about PVC documentation in the patient's medical record and to develop methods for assessment of inserted PVCs.

SPECIFIC AIMS

I. The aim of study I was to explore the descriptions used to explain the PVC insertion sites and the extent of post-insertion PVC documentation in patients' medical records.

II. The aim of study II was to develop a tool to evaluate management, documentation and signs and symptoms of TH, as well as to determine the inter-rater and test-retest reliability of this new tool.

3 MATERIALS AND METHODS

3.1 ACCURACY IN PVC DOCUMENTATION (STUDY I)

Materials and methods are presented in Table 3.

Table 3. Description of material and methods used in study I.

Study	*Design*	*Material*	*Data collection*	*Statistics*
I	Descriptive, cross-sectional.	Convenient sample of 933 inpatients on 29 medical and 31 surgical wards at three hospitals in Stockholm.	A study-specific form was used by 103 NSs for collection of data during the autumn 2006.	Descriptive. Logistic regression.

NSs, nursing students

Material

Adult inpatients were recruited from 60 wards at one university hospital and two emergency hospitals. Eligible patients had one inserted PVC only into a vein on the upper extremity. Totally, 1004 PVCs were observed of which 7% were excluded because of protocol violation (n=19), observation or documentation error (n=50) and missing data (n=2), leaving a final sample of 933 PVCs. The distribution of patients at the university hospital and the two general hospitals was 52% and 48%, respectively. In this material PVC lumen size was 0.9 mm/22 gauge in 39% and 1.1 mm/20 gauge in 48% (Study I).

Data collection

A study-specific observation form was developed for collection of PVC size, insertion site, hand side and patient characteristics. Anatomic photographs of the dorsal and ventral side of the upper extremities were appended for marking of the observed insertion site. The data were collected by nursing students (NSs) from The Red Cross University College and Karolinska Institutet during their clinical education. Data collection started at bedside with notations of PVC variables, including notes of insertion site and patient characteristics. Thereafter, the post-insertion documentation in the patient's medical record was checked and recorded (Study I).

3.2 DEVELOPMENT OF THE ASSESSMENT TOOL (STUDY II)

The developmental process of the PVC *ASSESS* instrument is shown in Figure 2.

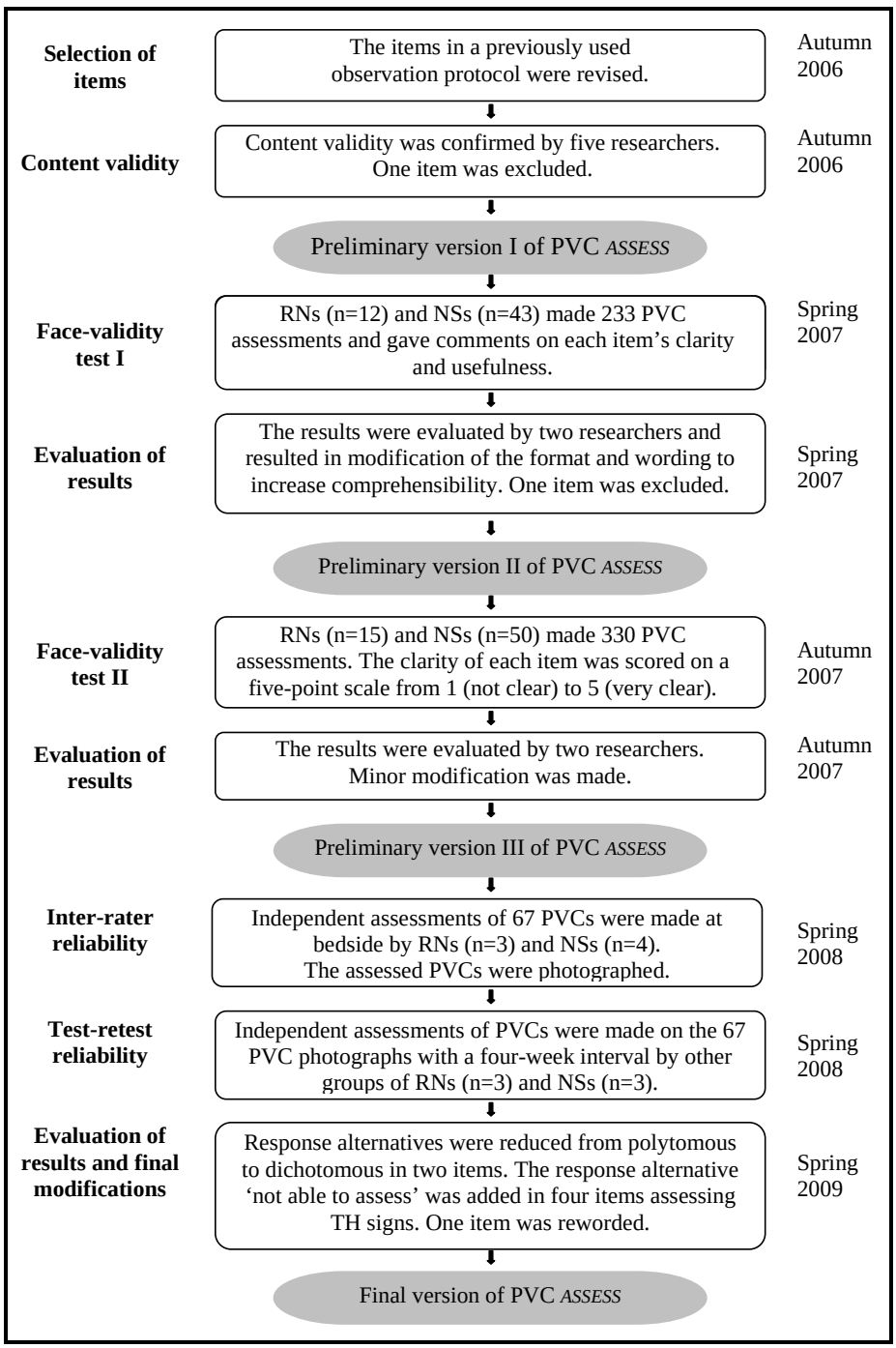


Figure 2. Development of the PVC *ASSESS* instrument (Study II).
PVC, peripheral venous catheter
RNs, registered nurses
NSs, nursing students

3.2.1 Selection of items

Selection of items for the assessment tool was based on a structured observation protocol (65) previously used at one department at a university hospital. Suggested items were modified into simple, straightforward wording in order to ensure comprehensibility. Long sentences as well as double-barrelled words were avoided (69).

3.2.2 Content validity

Content validity (69) was confirmed by the research group comparing the items in the tool with recommendations for PVC management and documentation in established guidelines (46, 60, 70) and scientific literature (44, 63, 65, 71). The items assessing signs and symptoms of TH were ascertained with published scales defining severity of TH (26-30) (Table 1). The TH sign 'pyrexia' (28) was excluded from the tool because interpretation of pyrexia may have different aetiology that demands extensive information about the patient's underlying condition.

3.2.3 Face validity

Comprehensibility was evaluated on two separate occasions by 27 RNs and 93 NSs who used the PVC *ASSESS* instrument to assess PVCs on actual patients at bedside (Figure 2). Together with written information about the purpose and assessment procedure, the RNs and NSs were asked to give comments on the clarity of the items and their usefulness in clinical practice. Two researchers (MA, EJ) evaluated the results and comments from the face validity tests. After the first test occasion, major layout changes were implemented. The TH item 'increased temperature in the area' (29) was excluded because palpation of increased skin temperature was perceived difficult and unsafe to evaluate by the testers. Face validity of the second test was evaluated using a study-specific form in which the clarity of each item was judged on a scale from 1 (not clear) to 5 (very clear). The testers judged the clarity high (mean score 4.6; range 4 - 4.8) at the second test occasion and only minor changes were made.

3.2.4 Description of the tool

The tested tool (PVC *ASSESS*) consists of 45 items grouped into three main sections: Section I consists of PVC management, including items for assessment of outer dressing (OD), inner dressing (ID), PVC and stop-cock (SC); Section II consists of items for assessment of signs and symptoms of TH; and Section III consists of items for review of PVC documentation in the patient's medical record. The response alternatives for the 45 items were mainly dichotomous (Yes/No, n=39); the response alternatives for the remaining six items were polytomous.

3.2.5 Reliability tests

Items in section I (PVC management) and section II (Signs of TH) were tested for inter-rater reliability (n=26) and test-retest reliability (n=21). Items assessing TH symptoms pain and tenderness were not included in the reliability tests because these items are self-reported by the patients. Assessment of PVC documentation in the patients' medical record (Section III) was not feasible for logistic reasons and thus these items were excluded.

PVC assessments were accomplished using the PVC *ASSESS* at bedside and on colour photographs to evaluate inter-rater and test-retest reliability, respectively. Four items were such that it was not possible to assess on photographs and therefore excluded from test-retest reliability: OD is dry (Item 2), Oedema at insertion site (Item 22), Induration at insertion site (Item 24) and Palpable cord along the vein (Item 26). PVC location (Item12) was excluded because there was a risk to misinterpret a patient's left- or right-hand side on some of the photographs.

Sample

PVCs were assessed and photographed on 10 wards (five medical and five surgical) at a university hospital in Stockholm. Sixty-four adult inpatients were asked to participate for research purposes of whom 60 gave written informed consent (26 women and 34 men, mean age 64 years, range 20-92 years). Seven patients had two or more PVCs, giving a final sample of 67 PVCs inserted on upper extremities. One patient was brought to surgery before all the raters had completed their assessments and thus excluded in the analysis for inter-rater reliability. Accordingly, calculation of inter-rater and test-retest reliability comprised 66 and 67 PVCs, respectively. The number of items assessed differed among the included PVCs as explained in the study II.

Raters and preparation

Raters were recruited among RNs with at least one year clinical experience in nursing care and NSs in their fifth semester. The participating RNs inserted or managed PVCs daily (n=5) or weekly (n=1) on wards providing medical or surgical care. The median age of the RNs was 32 years (range 26-44 years) and 28 years (range 22-42 years) for the NSs. The reliability tests were carried out by four groups of raters: two groups of RNs and two groups of NSs as shown in Figure 2.

Two weeks before administration of the reliability tests the raters were sent a letter with information about the study and instructions on the assessment procedure. A copy of the assessment tool was enclosed with the recommendation to make a few test assessments beforehand. At the time the PVC assessment started, information on the tool, test procedure, dressings and TH signs was repeated. Thereafter, potential questions regarding PVC assessments were considered only after completed assessments of the first PVC. If the raters judged any item not possible to assess, they were told to make a note indicating why the item could not be assessed.

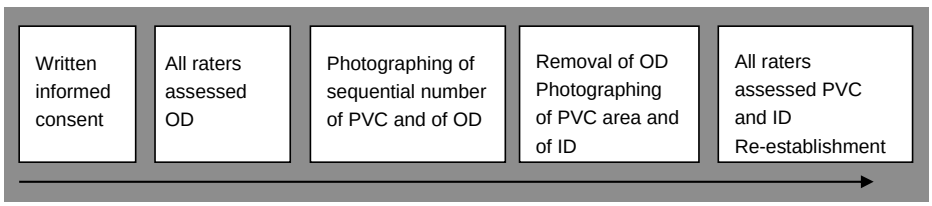
Inter-rater reliability

The raters (Figure 2) used the tool to make independent assessments of 67 PVCs at bedside. A flow chart of the bedside test procedure is depicted in Figure 3.

Test-retest reliability

By using the tool, three RNs (RN I, RN II, RN III) and three NSs (NS I, NS II, NS III) made independent assessments of the 67 PVC photographs taken concurrently with the bedside assessments. Retests of the same photographs were performed by the same raters four weeks later blindly to the results from the first test occasion (Figure 2).

Figure 3. The procedure of PVC assessments performed on actual patients at bedside.



OD, outer dressing
PVC, peripheral venous catheter
ID, inner dressing

3.3 DATA ANALYSES

Description of the statistical methods and their function are described in Table 4.

Table 4. Description of the statistical methods.

Method	*Function*
Descriptive statistics: mean, median, range, percentage (Study I) (72).	Descriptions of the distributions between hospitals, gender, PVC sizes and words used to explain PVC location in medical records.
Chi-square test (χ^2) (Study I) (72).	Investigation whether distributions of categorical variables differ from one another. For example, gender and hand side for PVC placement, PVC size and medical specialty, use of paper record and ward.
Univariate and stepwise multivariate logistic regression analysis (Study I) (72).	Determination of an association between potential independent variables and the following dependent variables: 'Any kind of PVC documentation' and 'documentation of insertion site, hand side and PVC size'. Estimates: Odds ratio (OR), chi-square (χ^2) and 95% confidence interval (CI).
Proportional agreement, P(A) (Study II) (72).	Determination of agreement between assessments among raters to demonstrate the tool's reliability.
Cohen's unweighted kappa coefficient (κ) (Study II) (72).	Determination of agreement between assessments among raters adjusted for expected chance agreement.
Box-whisker plot diagram (Study II) (72, StatView® statistical software).	Illustration of the distribution of inter-rater and test-retest agreement (P(A) and κ) among RNs and NSs who performed PVC assessments at bedside and on photographs. The ends of the whiskers in the diagram indicate the 10^{th} and the 90^{th} percentile. The box itself represents the inter-quartile range and the central horizontal line shows the median value.

PVC, peripheral venous catheter
RNs, registered nurses
NSs, nursing students

Statistical significance was set at $p<0.05$. The software StatView® 5.0.1 (© 1992-98 *SAS* Institute, Inc.) and SAS® System 9.1 (© 2003 *SAS* Institute, Inc., Cary, NC, USA) were used for the statistical analysis (Study I, II). In the analysis of test-retest reliability StatXact 4 (CYTEL Software Corporation, Cambridge, USA) was used for asymmetric contingency tables (Study II).

Accuracy of PVC documentation (Study I)

An overhead transparency with copies of the anatomic photographs in the data collection form was used to optimise precision in the comparison between the observed and the documented insertion sites. The areas of hand, wrist, forearm and bend of arm were defined and marked on the transparency, which was applied on each data sheet. If there was any ambiguity regarding the PVC data, the data form was re-assessed by two of the researchers (MA, EJ).

Gender, age, PVC size and location, hospitals and medical and surgical wards were used as independent variables in logistic regression analyses to examine their association with PVC documentation. Potential association between the independent variables and 'any kind of documentation' or documentation that included 'insertion site, hand side and PVC size' was first calculated in the univariate analysis. Next, the independent variables that were identified to be associated with PVC documentation ($p<0.05$) in the univariate analysis were entered into a stepwise multiple model to verify the probability of association. At the end, potential interaction between the variables hospital and care unit was controlled.

Attrition analysis was performed on gender, age, hospital, care unit and hand side of the PVCs excluded from the study because of documentation or observation error and missing data (n=52).

Development of the assessment tool (Study II)

The tool's inter-rater and test-retest reliability were determined by calculation of proportion of agreement [P(A)] and Cohen's unweighted kappa coefficient (κ) for each item (72). The chance agreement was expressed as the difference between P(A) and κ and the 95% CI was determined to confirm the interval of true κ (73). When any rater determined that an item could not be assessed, a third response category 'not able to assess' was applied in the statistical analysis for this item.

The clinical significance of P(A) was evaluated by using the following ranges defined by Cicchetti et al. (74): excellent = 0.90-1.0, good = 0.80-0.89, fair = 0.70-0.79 and poor = < 0.70. κ ranges suggested by Landis and Koch (75) were applied to interpret the strength of the obtained κ (Table 5).

Table 5. Magnitude of the obtained kappa according to Landis and Koch (1977).

Magnitude	*Kappa ranges*
Almost perfect	0.81-1.0
Substantial	0.61-0.80
Moderate	0.41-0.60
Fair	0.21-0.40
Slight	0.1-0.20
Poor	≤ 0

The advantage of κ statistics is that it adjusts the raters' agreement for expected chance agreement. However, a very low or high prevalence of the assessed item may convert a high P(A) into a low κ (76). To avoid this paradox the κ was calculated for items with agreed prevalence between 10 and 90% (i.e. proportion of yes responses) (77). Before the start of study II, a sample size calculation was performed based on a TH erythema frequency of 30% on average (20). A sample size of 48 PVCs was needed for determination of at least moderate inter-rater reliability, i.e. κ above 0.40 (H_0: $\kappa = \kappa_0 = 0.40$ vs. $\kappa > 0.40$) with alpha (α) 0.05 and beta (β) 80% using three raters.

4 ETHICAL CONSIDERATIONS

This study was reviewed by the Regional Ethical Committee in Stockholm (Registration number: 2006/902-31).

All the patients invited to take part in the studies participated voluntarily and were given verbal and written information about the aim of the studies. Patients who participated in the reliability tests of the PVC *ASSESS* instrument signed informed consent for assessment and photographing of their inserted PVCs. The signed informed consent (Study II) included permission for the potential use of the photographs in future education and presentations. Personal identifiers were not collected (Study I, II).

The researchers involved in this project have no conflicts of interests.

5 RESULTS AND DISCUSSION

5.1 ACCURACY IN PVC DOCUMENTATION (STUDY I)

5.1.1 Descriptions used to explain PVC insertion site

RNs used 10 descriptions in the patients' medical records to explain the PVC anatomic insertion site on the upper extremities. The following six descriptions were identified in the medical records at all three hospitals: 'Hand', 'dorsum of the hand', 'wrist', 'arm', 'forearm' and 'bend of arm'. The remaining four descriptions ('back of arm', 'back of wrist', 'arm joint' and 'upper arm') were more ambiguous and these were used at the university hospital alone (Study I). This mode of documentation may be based on the nurse's personal experiences (58) and knowledge (29). Personal modes of documentation run the risk of using different descriptions for the same PVC at insertion and removal. Consequently, when retrospectively reviewing a patient's medical record, the same PVC could be mistaken as being two PVCs rather than one.

Imprecise description of PVC location was found at all hospitals and wards. Three of the descriptions ('hand', 'forearm' and 'arm') were all used for PVCs placed between the hand and the bend of arm. Correspondence between the observed and documented PVC location varied from as low as 23% for PVCs placed in veins at the wrist to 91% for those inserted in veins on the hand (Study I). The wrist might be difficult to distinguish from the hand and forearm and could therefore explain the low correspondence (i.e. 23%). Lack of an appropriate documentation system (58, 78) and uniform terms (56) for PVC location on the upper extremities may explain the wide variation of descriptions and their anatomic inconsequent use. In addition to being a risk for the patient's well-being and safety (79), inaccurate descriptions of PVC insertion site prevent documentation-based research regarding PVC location, indwelling time and complications (67).

5.1.2 Extent of PVC documentation

Among the included 933 PVCs, any kind of documentation was identified in 72% (n=670) and notes that included insertion site, hand side and lumen size were found in 46% (n=431) of the medical records of the patients (Study I). These findings confirm a previously reported poor PVC documentation rate (29, 65). The identified inadequate content of PVC documentation may introduce a risk to forget elective PVC replacement within recommended intervals or removal at the time of the patient's discharge from the hospital. Poor nursing documentation is also reported to be a risk for deficient quality of care and patient safety in other areas (e.g., in nursing care of leg and pressure ulcers (80, 81) and in care of the elderly (79).

Paper-based PVC documentation (n=146) was found at all participating hospitals, although computerised patient records had been introduced. Paper-based PVC documentation was more often found on surgical wards (70%) at the university hospital (64%, p=0.05) (Study I), suggesting that these PVCs had been inserted in a surgery room or in an ambulance. Poor documentation of PVC insertion date (37%) and time (6%) was found in the paper-based records (Study I) that possibly may increase the risk of prolonged indwelling time and related complications (64). In the computerised patient record the date and time are automatically registered when the notes are recorded though there could be an unknown time interval between the time

of PVC insertion and documentation. Only a low frequency (3.9%) of the observed PVCs was documented in both paper and computerized patient record.

5.1.3 Variables associated with PVC documentation

'Any kind of documentation' was significantly associated with male gender and patient's age between 53 and 77 years when tested in univariate analysis. However, in multivariate analysis none of these variables was independently and significantly related with 'any kind of documentation' (Study I).

When a documentation including 'insertion site, hand side and PVC size' was used as the dependent variable in univariate analysis, an association with PVC size 0.9 mm ($p=0.002$) and general hospitals ($p<0.0001$) was found. This relationship remained in the multivariate analysis. When interaction was brought into this multivariate model, PVC size 0.9 mm (OR 1.81; CI 1.19-2.84; $P=0.006$) and medical wards at general hospitals (OR 4.59; CI 3.10-8.81; $P<0.0001$) proved to be the strongest independent predictors of PVC documentation containing 'insertion site, hand side and PVC size' (Study I). Larger PVC sizes were more frequently used on surgical wards as presented in study I. These PVCs are possibly more often inserted under stress in surgery rooms or in emergency situations that might distract RNs from proper attendance to PVC documentation guidelines. Routines, local cultural norms (29, 61, 65) lack of time (82), inappropriate documentation systems (58,78) and highly specialised care at university hospital (65) are factors previously suggested to interfere with proper nursing documentation.

5.2 DEVELOPMENT OF THE ASSESSMENT TOOL (STUDY II)

Inter-rater and test-retest reliability were determined among two groups of RNs (Study II) and two groups of NSs (Thesis). Results from PVC assessments made by NSs are presented for the first time in this thesis. Tables presenting corresponding results from assessments among RNs are found in study II.

5.2.1 Inter-rater reliability

Inter-rater reliability was evaluated by calculation of P(A) for 26 items and κ was determined for 15 items among RNs (n=3) and 16 items among NSs (n=4). P(A), κ, CI and the prevalence per response are presented for each item among RNs in Table 2 (Study II) and among NSs in Table 6 (Thesis). Distribution of inter-rater P(A) and κ are illustrated for RNs and NSs in Figures 4 and 5 (Thesis).

Inter-rater reliability of registered nurses

P(A) ranged from good to excellent in 96% of the items (Figure 4) while κ varied between moderate (n=2) substantial (n=5) or almost perfect (n=7) in 93% (Figure 5). Both P(A) and κ were fair in the item 'Erythema at insertion site' (Item 22; P(A) 0.77, κ 0.40).

The median chance agreement was 14% (range 0-37%). Assessments recorded as 'not able to assess' were, on average, 0.2% and 1.4% for items assessing PVC management and TH signs, respectively (Study II).

The PVC *ASSESS* instrument showed satisfactory inter-rater reliability among RNs. 'Erythema at insertion site' was the only item with κ below the predetermined

cut-off point (κ 0.41). In this group of RNs the agreed erythema prevalence was 21%, which was lower than the pre-study calculated rate of 30% that may explain the fair κ regarding this item (73). The low erythema frequency in this material could be a consequence of short time between the insertion and assessment of PVCs or good adherence to guidelines recommending removal of PVCs when TH signs develop. Inclusion of the third response category ('not able to assess') might also have resulted in the lower κ for this item (73).

Inter-rater reliability of nursing students

P(A) was good or excellent in 55% of the items assessed and fair in 27% (Figure 4). Two items had poor P(A): 'ID adheres well to skin' (Item 7) and 'PVC location' (Item 12). In 81% of items κ was between moderate and almost perfect (Figure 5): moderate (n=5), substantial (n=3) and almost perfect (n=5). Three items had fair κ: 'OD covers PVC site' (item 4), 'ID adheres well to skin' (Item 7) and 'Oedema at insertion site' (Item 22).

Median chance agreement was 24% (range 0-58%). The proportion of assessments recorded as 'not able to assess' was 0.6% and 0.3% for items assessing PVC management and TH signs, respectively.

For most of the items tested PVC *ASSESS* instrument demonstrated fair to excellent P(A) and at least moderate κ. However, the agreement for the assessments of the NSs demonstrated slightly wider P(A) and κ ranges compared with the RNs. This variation between RNs and NSs may be explained by differences in their clinical experience of nursing care and education. The importance of education and clinical experience has previously been reported in studies assessing nutritional status (83) and classification of pressure ulcers (84). The difference in κ agreement between RNs and NSs might also be influenced by the different numbers of raters in the two groups (73).

The NSs agreed upon an erythema prevalence of 38% compared with 21% among RNs. This difference may possibly be explained by that NSs paid more attention to small deviating details or they were uncertain about the assessment of erythema. By comparing the relation between P(A), κ and CI for items 4 and 7, the obtained κ seems probable for these items. For PVC location (Item 12) the fair P(A) [P(A) 0.66] supports the need of defined anatomic insertion sites as was suggested in study I.

Numerical comparison between inter-rater reliability results from assessments made at bedside and from photographs

Inter-rater reliability results [P(A), κ and CI] and prevalence per response from assessments of 21 photographed items are shown for RNs in Table 3 (Study II). Distribution of inter-rater P(A) and κ are illustrated for RNs and NSs in Figures 4 and 5 (Thesis).

The concordance between inter-rater reliability from assessments made by RNs at bedside and from photographs was considered satisfactory and thus assessments of the photographs were performed to calculate test-retest reliability (Study II).

Table 6. Inter-rater reliability of PVC assessments performed on actual patients at bedside by nursing students in group A (n=4).

Sections and subsections Items assessed bedside	P(A)	κ (95% CI)	Prevalence per response %[1]
I: PVC management			
Outer dressing (OD)			
1. OD is applied	.94	.91 (.82-1)	**20**/29/1/50
2. OD is dry [2]	.99	-	**99**/1
3. OD is clean [2]	.97	-	**94**/6
4. OD covers PVC site [2]	.70	.38 (.22-.54)	**60**/40
Inner dressing (ID)			
5. Transparent dressing is applied	.98	-	**99**/0.5/0.5
6. ID is visibly clean outside	.86	.63 (.47-.79)	**74**/26
7. ID adheres well to skin	.67	.36 (.26-.46)	**48**/51/1.5
8. ID covers insertion site	.92	-	**94**/5/1
9. Blood on skin under ID	.80	.54 (.40-.68)	**30**/69/1
10. PVC's both wings are taped	.75	.51 (.41-.61)	**47**/52/1
PVC			
11. PVC gauge	1	1 (.99-1)	**36**/15/41/8
12. PVC location	.66	.61 (-)	**20**/10/13/10/10/10/7/20
13. Injection port cap is closed	.98	-	**94**/6
14. Infusion being administered	.99	.96 (.78-1)	**24**/73.5/0.5
15. Blood/lipid visible in PVC [3]	.75	.43 (.27-.59)	**69**/29/2
Stop-cock (SC)			
16. SC is connected	.94	.85 (.69-1)	**74**/1/24/0.5/0,5
17. SC is taped close to PVC [4]	.88	-	**8**/91.5/0.5
18. SC is taped otherwise [4]	.84	.61 (.48-.74)	**27**/72.5/0.5
19. Infusion being administered [4]	.98	.95 (.79-1)	**30**/70
20. Blood/lipid visible in SC [5]	.74	.50 (.34-.66)	**39**/57.5/3
II. Thrombophlebitis (TH)			
Signs of TH			
21. Erythema at insertion site	.76	.50 (.40-.60)	**38**/61/1
22. Oedema at insertion site	.79	.21 (-.04-.46)	**14**/85/1
23. Purulent exudates	.97	-	**1**/98.5/0.5
24. Induration at insertion site	.77	-	**10**/86/4
25. Streak formation along vein	.89	-	**7**/92.5/0.5
26. Palpable cord along vein	.88	-	**6**/93.5/0.5

[1]Cohen's kappa (κ) is presented when the agreed prevalence of the assessed item was between 10 and 90% (Bolded response frequency = prevalence).
Polytomous response:
Item 1: Yes, tube sock; Yes, wrapper; Yes, some else; No.
Item 11: PVC gauges from 24 to 14.
Item 12: Right hand, right wrist, right forearm, right bend of arm, left hand, left wrist, left forearm, left bend of arm, other.
Item 16: Yes, three-way stop-cock, Yes, needleless connector, No, 'Not able to assess'.
Items 10, 18, 21-25: Yes, No, and the third category 'not able to assess'.
[2] n=33: Number of PVCs with applied outer dressing.
[3] n=49: PVCs with no infusion/transfusion being administered.
[4] n=50: PVCs with connected stop-cock.
[5] n=34: Stop-cocks with no infusion/transfusion being administered.

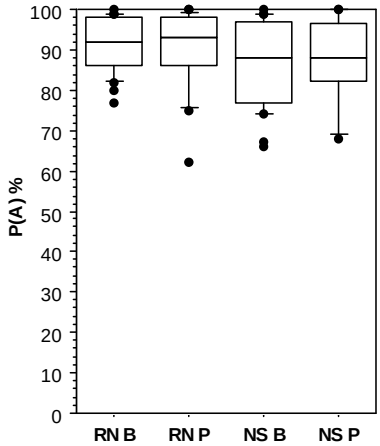


Figure 4. Distribution of inter-rater P(A) for 26 items assessed bedside (B) and 21 items assessed on PVC photographs (P) by RNs and NSs.

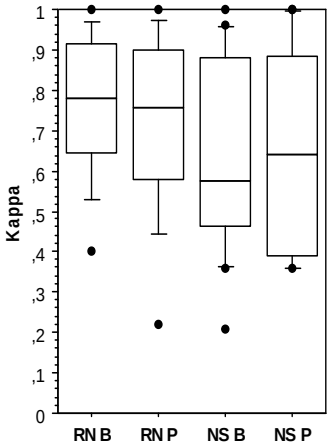


Figure 5. Distribution of inter-rater κ for 15 items assessed bedside (B) and 14 items assessed on PVC photographs (P) by RNs and NSs.

RN B and RN P, PVC assessments performed by registered nurses at bedside and on photographs, respectively
NS B and NS P, PVC assessments performed by nursing students at bedside and on photographs, respectively

5.2.2 Test-retest reliability

Test-retest reliability results [P(A), κ and CI] from assessments of 21 photographic items are shown for RNs in Table 4 (Study II) and for NSs in Table 7 (Thesis). Distribution of P(A) and κ are illustrated for each RN and NS in Figures 6 and 7 (Thesis).

Test-retest reliability of registered nurses

Of the items assessed the P(A) was good or excellent in 95% for two of the RNs (RN II and RN III) and in 100% for one (RN I) (Figure 6). κ varied between moderate or almost perfect in 95-100% (Figure 7). Only one item had fair κ ('Outer dressing is clean', RN III).

The median chance agreements were: RN I: 7% (range 0-38%), RN II: 9% (range 0-28%) and RN III: 9% (range 0-54%). The assessments classified as 'not able to assess' were, on average, 0.8% and 2.8% for items assessing PVC management and TH signs, respectively (Study II).

Test-retest assessments using the PVC *ASSESS* instrument demonstrated satisfactory agreement. Concerning TH signs, the P(A) among the RNs in the test-retest varied between fair and excellent, which corresponds well with the inter-rater agreement for these items from bedside and photographic assessments (Tables 2, 3, 4, study II). Clinical experience expressed as working years in nursing care was shorter among the RNs in the test-retest group than in the bedside group (Study II). However, the difference in clinical experience between these groups did not seem to influence the results as previously reported by other investigators (83, 84). The fair κ found for the OD item was a probable effect from low variation of responses in the 3x3

contingency table, which is supported by the excellent P(A) and the wide CI (RN III) (Item 2, Table 4, study II) (73).

Test-retest results of nursing students

Of the tested items the P(A) of the test-retest assessments was between good and excellent in 85-95% for NSs (Figure 6) and κ ranged between moderate and almost perfect in 90-95% (Figure 7). The fair κ concerned the 'ID covers insertion site', TH signs 'Erythema at insertion site' and 'Red string along the vein' (Items 8, 21, 25). One item on fixation of SC had poor P(A) and slight κ (Item 18).

Median chance agreements were: NS I: 17% (range 0-62%), NS II: 9% (range 0-43%) and NS III: 8% (range 0-57%). On average, the assessments classified as 'not able to assess' were 1.7% and 3.6% for items assessing PVC management and TH signs, respectively.

The results from the test-retest assessments of the NSs demonstrated good or excellent P(A) and moderate to almost perfect κ for the majority of items. The frequency of items 'not able to assess' was slightly higher among NSs than among RNs, which could possibly be due to their lower level of clinical experience in nursing care (83, 84). The fair κ and the large chance agreements for items 'Erythema at insertion site' and 'Red string along the vein' (NS I, items 21, 25) seemed to be a probable effect of the 3x3 contingency tables and skewed proportions of responses in the contingency table cells (73). One reason for the wide CI and fair κ found for item 8 (NS III) could be the asymmetric contingency table and high frequency of 'yes' responses. Thus, the evaluation of results for items 8, 21 and 25 are suggested to mainly be based on P(A). The test-retest agreement based on P(A), κ and CI for item 18 (NS II) indicated less stable assessments of SC fixation, which was not observed among the other raters in any of the performed tests.

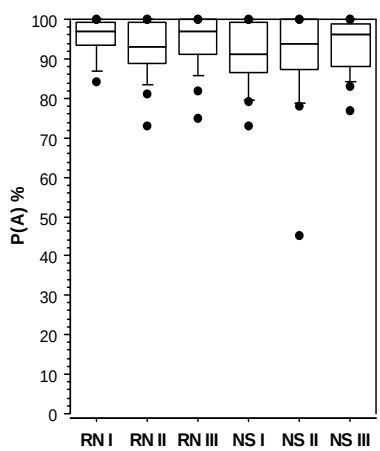


Figure 6. Distribution of P(A) in test-retest for 21 items assessed by three RNs (RN, RN II, RN III) and three NSs (NS I, NS II, NS III).

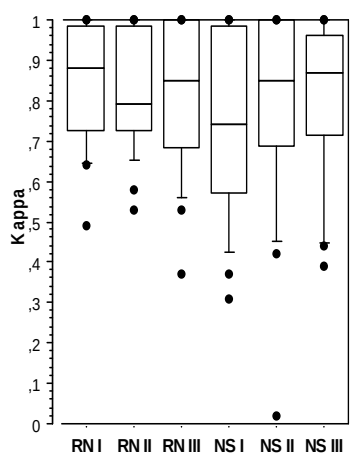


Figure 7. Distribution of κ in test-retest for 21 items assessed by three RNs (RN I, RN II, RN III) and three NSs (NS I, NS II, NS III).

Table 7. Test-retest reliability of the nursing students (n=3).

Sections and subsections Items assessed (photographs)	NS I		NS II		NS III	
	P(A)	**κ (95% CI)**	**P(A)**	**κ (95% CI)**	**P(A)**	**κ (95% CI)**
I: PVC management						
Outer dressing (OD)						
1. OD is applied	.99	.98 (.93-1)	1.0	1.0 (-)	.99	.98 (.93-1)
3. OD is clean [2]	1.0	1.0 (-)	.94	.64 (.18-1)	1.0	1.0 (-)
4. OD covers PVC site [2]	.82	.63 (.37-.90)	1.0	1.0 (-)	.91	.82 (.63-1)
Inner dressing (ID)						
5. Transparent ID is applied	1.0	1.0 (-)	1.0	1.0 (-)	1.0	1.0 (-)
6. ID is visibly clean outside	.91	.74 (.55-.94)	.91	.77 (.59-.94)	.96	.87 (.72-1)
7. ID adheres well to skin	.90	.66 (.42-.89)	.84	.68 (.51-.85)	.77	.45 (.27-.63)
8. ID covers insertion site	.91	.58 (.29-.88)	.97	.74 (.39-1)	.96	.39 (-.15-.92)
9. Blood is under the ID	.79	.55 (.34-.75)	.94	.85 (.72-.99)	.97	.92 (.81-1)
10. PVC's both wings are taped	.88	.75 (.60-.91)	.94	.88 (.77-.99)	.99	.97 (.91-1)
PVC						
11. PVC gauge	.99	.98 (.94-1)	1.0	1.0 (-)	1.0	1.0 (-)
13. Injection port cap is closed	.97	.65 (.21-1)	1.0	1.0 (-)	.99	.85 (.56-1)
14. Infusion being administered	1.0	1.0 (-)	1.0	1.0 (-)	.96	.88 (.71-1)
15. Blood/lipid visible in PVC [3]	.89	.74 (.54-.95)	.93	.84 (.68-1)	.89	.82 (.68-.95)
Stop-cock (SC)						
16. SC is applied [4]	1.0	1.0 (-)	.96	.91 (.80-1)	.98	.96 (.87-1)
17. SC is taped close to PVC [5]	.90	.55 (.16-.93)	.85	.42 (.05-.80)	.85	.44 (.10-.78)
18. SC is taped otherwise [5]	.80	.62 (.40-.83)	.45	.02 (-.22-.26)	.83	.67 (.46-.89)
19. Infusion being administered [5]	1.0	1.0 (-)	1.0	1.0 (-)	.95	.87 (.69-1)
20. Blood/lipid visible in SC [6]	.87	.75 (.54-.97)	.94	.86 (.68-1)	.95	.92 (.82-1)
II. Thrombophlebitis (TH)						
Signs of TH						
21. Erythema at insertion site	.73	.37 (.14-.58)	.79	.69 (.55-.83)	.85	.76 (.62-.89)
23. Purulent exudates	.85	.46 (.18-.74)	.88	.72 (.55-.90)	.88	.73 (.57-.90)
25. Streak formation along vein	.94	.32 (-.15-.79)	.78	.47 (.26-.68)	.88	.53 (.27-.80)

Items 2, 12, 22, 24, 26 were not assessable from the photographs.
[2] n=33: Number of PVCs with applied outer dressing.
[3] n=49: PVCs with no infusion/transfusion being administered.
[4] n=56: 11 photographs were excluded because connection of stop-cock was unclear.
[5] n=41: PVCs with connected stop-cock.
[6] n=32: Stop-cocks with no administration of infusion/transfusion.

5.2.3 Final version of PVC *ASSESS*

The final version of PVC *ASSESS* instrument is presented for the first time in this thesis (Appendix I).

Based on the results from the reliability tests minor modifications were made of the tested preliminary version III of the PVC *ASSESS* instrument (Figure 2). The polytomous responses for two items concerning applied OD and SC (Items 1 and 16) were transformed into dichotomous responses (Yes/No) to simplify evaluation and comparisons of the results from assessments of these items. For applied ID (Item 5) three response alternatives (Yes, transparent; Yes, other; No) are recommended but if preferred, the result can be analysed as dichotomous 'Yes/No) by merging the results from the two yes responses.

The response 'not able to assess' was not a predefined response alternative for any item in the preliminary versions of the tool, but instead the raters had possibility to record a note when they could not judge any item. The number of items recorded as 'not able to assess' was higher among assessments on TH signs because the insertion site could have been covered by a PVC dressing and fixation tape. Subsequently, the response alternative 'not able to assess' was added for items 21-24.

Comments from raters performing bedside assessments indicated ambiguity regarding items 14 and 19 (Infusion being administered) when the infusion was stopped but the infusion set was not disconnected. Because the administration of infusate is not the subject of interest in this context, the wording for items 14 and 19 has been changed from 'Infusion being administered' to 'Infusion set is connected'.

6 METHODOLOGICAL DISCUSSION

Strategies undertaken to ascertain validity and influence from potential factors on internal and external validity (85, 86, 87) regarding the obtained results are emphasised below.

6.1 ACCURACY IN PVC DOCUMENTATION (STUDY I)

The large sample size and the data collection performed in the short period of three months are strengths of this study. However, data collection performed by 103 NSs in different semesters of their education (83, 84, 88) may have influenced internal validity. Considering this possibility, special attention was paid to information or misclassification bias (89) when the study-specific data collection form was developed. The form included four anatomic photographs of the ventral and dorsal side of both left-and right-hand side to enhance validity of the recorded PVC insertion site. To facilitate locating PVC documentation in the electronic record a number of modules were predefined as where to look for potential PVC notes (88). If post-insertion documentation was not found on the observation day, the medical record should be re-checked the day after. Additionally, patients eligible for inclusion had only one PVC inserted by a RN and could participate only once to avoid potential PVC differentiation problems.

Data collection was judged to be carefully performed. This presumption is supported by the low frequency of re-assessed data collection forms and the low attrition rate because of protocol violation (Study I). Adherence to the protocol could also be estimated by checking the signatures of the NS collecting the data and the RN cannulating the vein, patient gender and age, the hospital and the ward. Systematic and selection bias were assumed low in this study because of the large group of reviewers and the large sample size from 60 wards at three hospitals.

The cross-sectional study design and the convenient sample of patients limit the external validity or generalisability of the results to other settings (85, 86, 87). However, previously reported PVC documentation rate (29, 63, 65, 66) supports the PVC documentation rate found in this study. Moreover, data collected on 60 wards at three hospitals may have enhanced external validity. Description of PVC insertion site has not been previously reported and thus further studies are suggested.

6.2 DEVELOPMENT OF THE ASSESSMENT TOOL (STUDY II)

For most items assessed, the PVC *ASSESS* instrument demonstrated good to excellent P(A) and substantial to almost perfect κ agreement among the RNs and fair to excellent P(A) and moderate to almost perfect κ agreement among the NSs. These results indicate slightly higher inter-rater and test-retest agreement among the RNs, a difference that could have been influenced by the purposive sampling of the RNs (85, 86). However, clinical experience from nursing care is a plausible explanation to account for the slightly lower agreement found among the NSs (83, 84).

If the PVC assessments had been performed at bedside for calculation of test-retest reliability, the results could have been influenced by unpredictable changes of PVC dressings and TH signs, in addition to the short time interval between the two

test occasions (85, 86). Therefore, to avoid these confounding variables PVC photographs were chosen for determination of test-retest reliability. Learning effects among raters may be another threat to the validity of the present test-retest results (85, 86). However, any discrepant rating patterns indicating learning effects could not be ascertained between the raters' assessments in the test and retest.

To adjust raters' agreement for expected chance agreement unweighted κ is the suitable statistical method for categorical data at the nominal level. Additional criteria for using κ are that all included PVCs are assessed only once and that the raters' assessments are made independently to avoid the possibility of influencing each other (73). All these criteria were met when the reliability of the PVC *ASSESS* instrument was tested.

In this study the dichotomous responses (Yes/No) were unequally distributed for many of the items, and subsequently, κ does not always reflect expected congruence with high P(A) (73, 77). Some items had three or more response alternatives and asymmetric contingency tables sometimes occurred in the test-retest data that could decrease the obtained κ value (73). Thus, P(A) is suggested to guide the interpretation of agreement when P(A) and κ seem to lack congruence (73, 77, 90).

The κ statistic is recommended to be used as a base for descriptive statistical comparisons, and as such, the size of κ is reported together with the width of CI that indicates the stability of κ (73). The sample size calculation made before the start of the study is not a strict power calculation used for statistical inference, i.e. acceptance or rejection of the null hypothesis. Instead, the power calculation was guided by a desire to determine least moderate reliability (κ=0.41) (76) and determination of sample size was based on an average TH erythema prevalence of 30% (20). The agreed erythema prevalence among the RNs was 21% from bedside assessments [P(A) 0.77] and 24% from photographic assessments [P(A) 0.76]. These results indicate lower TH prevalence than the calculated pre-study prevalence of 30%, which probably explains the obtained poor to moderate κ for this item (73). Severe TH signs were even rarer in this material, leading to non-calculated κ for most TH items. However, all items assessing signs of TH showed fair to excellent P(A) in all tests, suggesting satisfactory inter-rater and test-retest reliability.

7 CONCLUSIONS AND CLINICAL IMPLICATIONS

7.1 CONCLUSIONS

I Various descriptions of PVC insertion sites were imprecisely used and the extent of PVC documentation was unsatisfactory in the medical records of patients. The most satisfactory PVC documentation was found on the medical wards and in the emergency hospitals (Study I).

II The PVC *ASSESS* instrument demonstrated satisfactory inter-rater and test-retest agreement regarding evaluation of PVC management and signs of TH (Study II).

7.2 CLINICAL IMPLICATIONS

Post-insertion PVC documentation was found in less than half of the inserted PVCs and the insertion sites were often imprecisely described in the patients' medical records. This inadequate PVC documentation seems to communicate insufficient information to ensure patient continuity in PVC care and elective PVC replacement as recommended in guidelines for care and handling of PVCs. Furthermore, the poor frequency of adequate insertion notes fails when it comes to determining PVC indwelling time for a large number of PVCs. Development and implementation of uniform terms, guidelines and appropriate computerised record systems are needed to support accurate PVC documentation. Organised supervision, regular audits and education of RNs are also recommended to help improve PVC documentation.

The PVC *ASSESS* instrument is applicable in research as a means of gaining more knowledge about potential associations between PVC management, documentation and patient outcome. In clinical practice the PVC *ASSESS* instrument can be used in audits for quality of care assessment to support quality improvement and education of health care professionals. Additionally, the demonstrated agreement among the NSs suggests that they can assist in PVC audits using the PVC *ASSESS* instrument, which could be a part of their education in quality improvement of evidence-based nursing care.

8 FUTURE RESEARCH

Reliability test of section III in PVC *ASSESS* instrument remains to be performed and thus, evaluation of inter-rater reliability among raters reviewing PVC documentation in patients' medical record is highly recommended. Thereafter, there is a need to develop a classification system to evaluate the quality of PVC management and documentation based on the results obtained from PVC assessments made with the PVC *ASSESS* instrument.

The results from study I imply the need to develop uniform terms to describe PVC insertion site and a standardised PVC documentation in the medical records of patients. These terms are recommended to be developed and accepted for national use.

The extent of documentation of PVC removal and PVC-related complications, including predictors of PVC documentation, are other areas that require further study.

The reliability tests of the PVC *ASSESS* instrument explored the tool's stability when it was used by different raters and when one rater used the tool in repeated PVC assessments. Another important focus is to examine inter-rater reliability among RNs in diagnosing and classifying the severity of TH.

The patient's perspective in PVC management is an unexplored field and hence a number of questions need to be addressed, including the following: How do the patients perceive information given by RNs? Do patients desire to participate in the decision-making process of PVC management? What is their experience of pain in conjunction with skin analgesics at PVC insertion, their attitudes toward elective PVC replacement and experiences from PVC-related complications?

PVC material and drugs develop and change with time, facts that might influence the frequency PVC-related TH. In the future there are implications to perform a prospective randomised controlled multicentre study to investigate the possibility of differentiating PVC in-dwelling time because of patient's vulnerability, infused IV therapy and PVC management.

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PVC *ASSESS*

INSTRUMENT FÖR BEDÖMNING AV PERIFER VENKATETER AVSEENDE SKÖTSEL, TROMBOFLEBIT OCH DOKUMENTATION

Datum (år/månad/dag):_____ Tid:_____

Sjukhus: _____ Klinik:_____

Vårdavdelning: _____ Granskare:_____

Patientens personnummer: _____

Patientens kön ☐ Man ☐ Kvinna

Patienten är ☐ Högerhänt ☐ Vänsterhänt

Om patienten har flera PVK används ett formulär för varje PVK.

Välj endast ett svarsalternativ per fråga om inget annat anges.

I: Skötsel av PVK

PVK nummer: _____

Ytterförband - se bild 1 på formulärets sista sida

1. Ytterförband finns
   - ☐ Ja
   - ☐ Nej – ***Om nej, gå till punkt 5***
2. Ytterförbandet är torrt
   - ☐ Ja
   - ☐ Nej
3. Ytterförbandet är synligt rent
   - ☐ Ja
   - ☐ Nej
4. Ytterförbandet täcker hela PVK
   - ☐ Ja
   - ☐ Nej

Ev. kommentar _____

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Fixeringsförband - se bild 2 på formulärets sista sida

5. Fixeringsförband finns
   - ☐ Ja, transparent
   - ☐ Ja, annat
   - ☐ Nej – ***Om nej, gå till punkt 11***

6. Fixeringsförbandets utsida är synligt ren
   - ☐ Ja
   - ☐ Nej

7. Hela fixeringsförbandet fäster väl vid huden
   - ☐ Ja
   - ☐ Nej

8. Fixeringsförbandet täcker insticksstället
   - ☐ Ja
   - ☐ Nej

9. Blod finns under fixeringsförbandet
   - ☐ Ja
   - ☐ Nej

10. PVKs båda vingar är fixerade med tejpstrips
    - ☐ Ja
    - ☐ Nej

Ev. kommentar _____

PVK - se bild 2 på formulärets sista sida

11. PVK storlek
    - ☐ Gul 0.7mm/24gauge
    - ☐ Blå 0.9 mm/22 gauge
    - ☐ Rosa 1.1 mm/20 gauge
    - ☐ Grön 1.3 mm/18 gauge
    - ☐ Vit 1.5 mm/17 gauge
    - ☐ Grå 1.7 mm/16 gauge
    - ☐ Orange 2.2 mm/14 gauge

12. PVK lokalisation
    - ☐ Höger hand
    - ☐ Höger handled
    - ☐ Höger underarm
    - ☐ Höger armveck
    - ☐ Vänster hand
    - ☐ Vänster handled
    - ☐ Vänster underarm
    - ☐ Vänster armveck
    - ☐ Annan lokalisation, ange var _____

13. Locket på injektionsporten är stängt
    - ☐ Ja
    - ☐ Nej

14. Infusionsaggregat är anslutet
    - ☐ Ja – ***Om ja, gå till punkt 16***
    - ☐ Nej

15. Synliga rester av blod eller näringslösning finns i PVK
    - ☐ Ja
    - ☐ Nej

Ev. kommentar _____

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Trevägskran/injektionsventil - se bild 2, 3 och 4 på formulärets sista sida

16. Trevägskran eller injektionsventil finns
    - ☐ Ja (bild 3 och 4)
    - ☐ Nej – ***Om nej, gå till punkt 21***

17. Trevägskran eller injektionsventil är fixerad intill PVKs luerfattning (bild 2)
    - ☐ Ja
    - ☐ Nej

18. Trevägskran eller injektionsventil är fixerad på annat sätt
    - ☐ Ja
    - ☐ Nej

19. Infusionsaggregat är anslutet
    - ☐ Ja – ***Om ja, gå till punkt 21***
    - ☐ Nej

20. Synliga rester av blod eller näringslösning finns i trevägskran eller injektionsventil
    - ☐ Ja
    - ☐ Nej

Ev. kommentar _____

II a: Granskarens bedömning av symptom på tromboflebit

Symptom på tromboflebit vid PVK insticksområde

21. Rodnad finns vid insticksområdet
    - ☐ Ja - Om ja, ange uppmätt storlek: Längd _____ mm Bredd _____ mm
    - ☐ Nej
    - ☐ Kan ej bedöma, ange orsak: _____

22. Svullnad finns vid insticksområdet
    - ☐ Ja - Om ja, ange uppmätt storlek: Längd _____ mm Bredd _____ mm
    - ☐ Nej
    - ☐ Kan ej bedöma, ange orsak: _____

23. Pus (varig sekretion) finns vid instickssället
    - ☐ Ja
    - ☐ Nej
    - ☐ Kan ej bedöma, ange orsak: _____

24. Palpabel förhårdnad eller knöl finns vid insticksområdet
    - ☐ Ja
    - ☐ Nej
    - ☐ Kan ej bedöma, ange orsak: _____

25. Röd sträng/rodnad finns längs venen
    - ☐ Ja - Om ja, ange uppmätt storlek: Längd _____ mm Bredd _____ mm
    - ☐ Nej

26. Palpabel hård sträng finns längs venen
    - ☐ Ja - Om ja, ange uppmätt storlek: Längd _____ mm Bredd _____ mm
    - ☐ Nej

Ev. kommentar _____

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II b: Patientens bedömning av symptom på tromboflebit

Smärta relaterad till PVK

27. Kan patienten kommunicera

☐ Ja
☐ Nej - Om nej ange orsak_____och stanna här

Fråga patienten: Upplever du smärta av din PVK?

28. Smärta finns – flera svarsalternativ möjliga

☐ Ja, vid insticksområdet
☐ Ja, längs venen
☐ Ja, men patienten kan ej särskilja var det gör ont
☐ Nej

29. Upplevd smärtintensitet
(OBS! Denna fråga besvaras oavsett om svar Ja eller Nej på fråga 28)

Be patienten gradera smärta relaterad till PVK med en siffra från 0 till 10
Markera patientens svar med kryss i motsvarande ruta

☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
Ingen smärta										Värsta tänkbara smärta

Ev. kommentar _____

Palpationssmärta relaterad till PVK

Palpera varsamt med fingertoppen på ett område lika stort som fixeringsförbandet och uppåt längs venen

Fråga patienten: Upplever du smärta när jag trycker lätt med fingertoppen mot huden vid PVK?

30. Palpationssmärta finns - flera svarsalternativ möjliga

☐ Ja, vid insticksområdet
☐ Ja, längs venen
☐ Ja, men patienten kan ej särskilja var det gör ont
☐ Nej

31. Upplevd intensitet av palpationssmärta
(OBS! Denna fråga besvaras oavsett om svar Ja eller Nej på fråga 30)

Be patienten gradera palpationssmärta relaterad till PVK med en siffra från 0 till 10
Markera patientens svar med kryss i motsvarande ruta

☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
Ingen smärta										Värsta tänkbara smärta

Ev. kommentar _____

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III: Dokumentation av PVK i patientens journal

Insättande av PVK finns dokumenterad med följande uppgifter

32. Datum
☐ Ja Om ja, ange datum (år/månad/dag) _____
☐ Nej

33. Tidpunkt
☐ Ja Om ja, ange klockslag _____
☐ Nej

34. Signatur
☐ Ja
☐ Nej

35. Storlek på PVK (färg och/eller mm)
☐ Ja Om ja, ange storlek _____
☐ Nej

36. Sida (höger eller vänster)
☐ Ja Om ja, ange sida _____
☐ Nej

37. Lokalisation
☐ Ja Om ja, ange lokalisation _____
☐ Nej

38. Annan uppgift
☐ Ja Om ja, ange vad _____
☐ Nej

Ev. kommentar: _____

Borttagande av PVK finns dokumenterad med följande uppgifter

39. Datum
☐ Ja Om ja, ange datum (år/månad/dag) _____
☐ Nej

40. Tidpunkt
☐ Ja Om ja, ange klockslag _____
☐ Nej

41. Signatur
☐ Ja
☐ Nej

42. Storlek på PVK (färg och/eller mm)
☐ Ja Om ja, ange storlek _____
☐ Nej

43. Sida (höger eller vänster)
☐ Ja Om ja, ange vilken sida _____
☐ Nej

44. Lokalisation
☐ Ja Om ja, ange lokalisation _____
☐ Nej

45. Instickssställets utseende
☐ Ja Om ja, ange vad _____
☐ Nej

Ev. kommentar: _____

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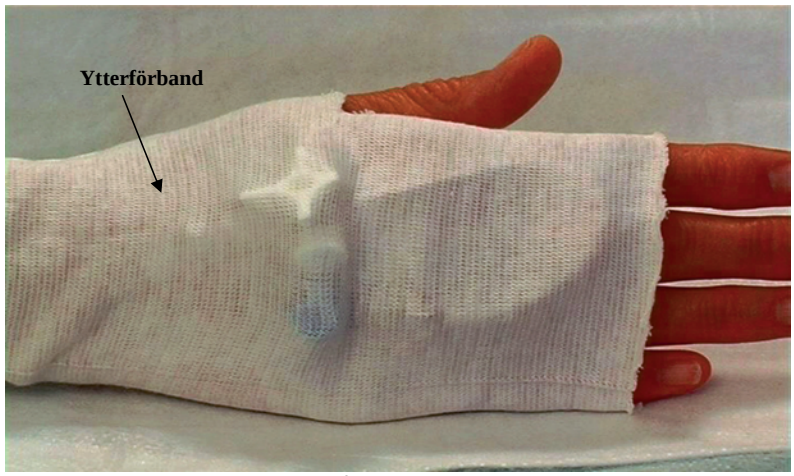

Bild 1. PVK med rent och torrt ytterförband.

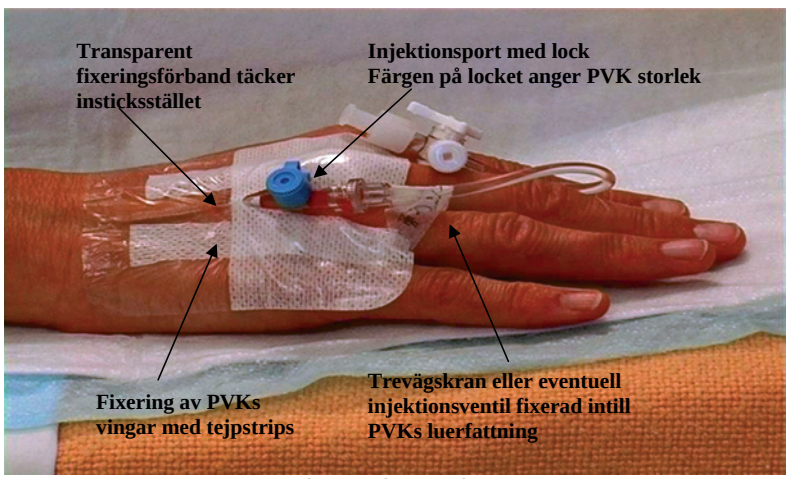

Bild 2. PVK med rent och torrt fixeringsförband, fixerade vingar, trevägskran är fixerad intill PVK's luerfattning. Locket på injektionsporten är stängt.

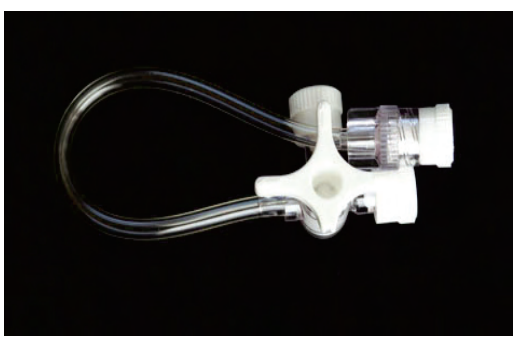

Bild 3. Trevägskran

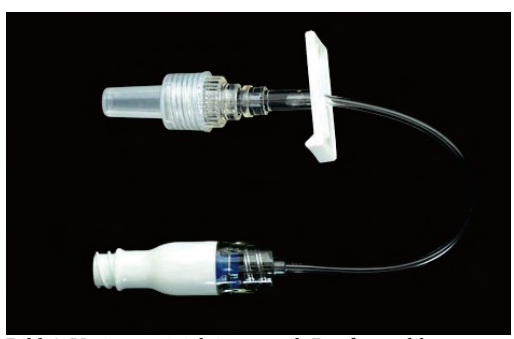

Bild 4. Variant av injektionsventil. Det finns olika fabrikat.

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