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Difficult intravenous access tool in patients receiving peripheral chemotherapy: A pilot-validation study

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ABSTRACT

Purpose: to develop a tool for measuring the difficulty of intravenous line insertion in cancer patients (DIVA-CP) receiving peripheral chemotherapy.

Methods: a pilot-validation study divided into two phases was performed in a north-eastern Italian outpatient chemotherapy centre. In the first phase, a review of the literature and brainstorming sessions/direct discussions among expert oncology nurses were used to develop items on the DIVA-CP tool, and a panel of expert oncology nurses assessed the tool face and content validity. In the second phase, 260 adult patients undergoing single chemotherapy cycles were consecutively enrolled. Data was analysed for construct validity (explorative factor analysis) and inter-rater reliability (Cohen's Kappa).

Results: a 10-item tool was developed with four factors that were identified through factor analysis, explaining a total variance of 61.578%: accessibility to first choice veins (23.057%), venous fragility (15.197%), probable difficulties during the procedure (12.642%), and repeated exposure (10.691%). The tool demonstrated excellent inter-rater reliability ($\kappa > 0.61$ for 7 out of 10 items).

Conclusions: the DIVA-CP tool is still a pilot instrument that needs to be improved through future studies. The tool has great potential and may perform an important role in oncological settings, allowing for easier venous assessment of patients receiving peripheral chemotherapy who are at risk of difficult intravenous access insertion. In addition, this instrument may help nurses to identify patients that may benefit from a central catheter promptly.

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1. Introduction

An increasing number of antineoplastic treatments are being shifted today from hospital administration to outpatient or home care setting administration (Polzien, 2006). Moreover, although the developments achieved in oral chemotherapy administration, both of traditional cytotoxics and of targeted agents, intravenous (IV) chemotherapy continues to be the most widespread treatment (O'Neill and Twelves, 2002). Thus, vascular access devices (VADs) have an important role throughout all the stages of oncological treatments, since they are employed in the initial phases for neo-adjuvant chemotherapy or post-surgery adjuvant therapy, in the

advanced stages for chronic treatment, and in the last stage for palliative measures (Gallieni et al., 2008). According to Gallieni et al. (2008) it is difficult to estimate the number of VADs that are currently used for oncology patients. However, given that almost all the protocols for the management of neoplastic disease require IV infusions, it is presumable that a high number of VADs are inserted in daily practice both by nurses (Gallieni et al., 2008).

The Registered Nurses' Association of Ontario Guidelines (2008), the Infusion Nurses Society Standards (2006) and the recommendations of the UK National Health System (2006), have documented that choosing the most appropriate VAD is the result of a collaborative process among patients, nurses, physicians and other members of the health-care team, taking into account the duration of the prescribed therapy, anticipated supportive therapy, physical assessments and patient health history. Patient-caregiver skills in handling the VAD, as well as device availability, and patient

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preferences are also important factors influencing the decision-making process regarding the most appropriate VAD to insert. However, despite the fact that central VADs are recommended for vesicant drugs, which are potentially dangerous due to the high risk of extravasation, infiltration, phlebitis, local tissue damage, and progressive loss of available peripheral veins (RNAO, 2008; EONS, 2007), several oncology units still deliver vesicant chemotherapy through peripheral veins (Gallieni et al., 2008). Therefore, in cancer patients, preserving peripheral venous access is a priority (Pérez Fidalgo et al., 2012; Wengstrom et al., 2008) and a proactive assessment of patient venous access needs, is also recommended (Wells, 2008a).

Clinical nurses have a primary role in choosing the optimal site for peripheral chemotherapy administration and the most appropriate device, as well as in preventing infusion-related complications and in identifying patients that may benefit from a central VAD (EONS, 2007; Gallieni et al., 2008; Schulmeister, 2011). Recognizing the risk of difficult IV access is essential and all patients should be evaluated for conditions that may increase the difficulty of catheter insertion (Schulmeister, 2011).

Difficult IV access is defined as multiple attempts and/or the anticipation of special interventions required to establish and maintain peripheral venous access (Kuensting et al., 2009). Moreover, clinical nurses are asked to also assess patients with optimal peripheral veins conditions carefully, exploring the potential factors that may lead to venous depletion such as the type of chemotherapy regimen and the duration of the treatment (EONS, 2007; Schulmeister, 2011; Wells, 2008a, 2008b).

Periodic assessment of the status of the peripheral venous asset is crucial to increase success rates in oncological patients, while reducing venous depletion and adverse events (Bauman et al., 2009). The assessment allows registered nurses (RNs) to identify patients at risk of venous depletion requiring greater attention in the management of IV access; it permits the critical evaluation of the need for alternative administration strategies; it suggests the use of ultrasound equipment when insertion may be complicated; also, it informs the decision-making process regarding the level of supervision required for novice nurses in their skills development of complex IV insertions, or the need to attribute the insertion to greater nursing expertise aimed at avoiding repeated insertions (Bauman et al., 2009; Wells, 2008a). However, while assessment tools for children are available (e.g., Difficult Intravenous Access [DIVA] scale; Yen et al., 2008), as well as for identifying or classifying veins according to their level of intravenous insertion difficulty (Vein Assessment Tool [VAT], Webster et al., 2007), the literature regarding factors associated with difficult IV access in adults is limited, but chemotherapy is among these factors (Lapostolle et al., 2007).

In the field on oncological care, Wells (2008a) has developed two venous access assessment tools that can be used by nurses: the adult Venous Assessment Tool (VAT) and the algorithm Deciding on IntraVenous Access (DIVA) on the basis of the literature review. The validity process was based on grounded theory study design and inter-rater reliability evaluated the percentage of agreement between the two tools as given by nurses (Wells, 2008b). More recently, the Oncology Nursing Society has developed a decision guide including a holistic assessment tool initiated before treatment and assessed at key points throughout the patient's treatment (UKONS Cancer Therapy Venous Access Device Decision Guide, 2014). However, there is a need to develop more research in the field of predicting IV access difficulty in peripherally administered chemotherapy patients. Therefore, the aim of this pilot study was to develop a tool for assessing the Difficulty of IV line insertion in Cancer Patients (DIVA-CP) receiving peripheral chemotherapy.

2. Methods

2.1. Study design and setting

A pilot-validation study articulated into two phases was performed in a north-eastern Italian outpatient chemotherapy centre with a >500,000 user base. The Internal Review Board of the hospital composed of university and hospital members has preliminarily approved the study protocol.

2.2. First phase: tool development, face and content validity

In the first study phase, developed between 2011 and 2012, the main aim was to identify the elements affecting the risk of IV access difficulties in the context of oncological care.

First, clinical expert RNs (see authors) working in the oncological centre for >5 years performed a review of the literature available (Ener et al., 2004; Gabriel et al., 2005; Lapostolle et al., 2007; National Health System, 2006; Ost, 1992; Pérez Fidalgo et al., 2012; Schulmeister, 2011; Uslusoy and Mete, 2008), and a critical analysis of tools developed in the field of difficult IV access (e.g., Goffredo et al., 1999; Yen et al., 2008; UKONS Cancer Therapy Venous Access Device Decision Guide, 2014; Webster et al., 2007; Wells, 2008a, 2008b). Those elements documented in the literature as well as those already included in previous tools, were considered as the basis for the emerging DIVA-CP tool.

Secondly, four brainstorming/direct discussion sessions were performed by the same group of experts under the supervision of a team leader. During each session, the team leader took notes on the agreed factors and then prepared the list for the next session. The final consensus was achieved in the fourth round. Those factors emerged from the literature and from the clinical experience of the nurses involved were collapsed in the same element when similar. At the end of the process, the experts also decided the number of elements (items) to be included in the tool as reported in Table 1.

A total of 16 items were selected. Some were dichotomous (e.g. small calibre veins [no = 0, yes = 1] while others were continuous, such as chemo-treatment type (vesicant = 0; vesicant = 1; irritant = 2). The higher the score, the greater the difficulty in IV peripheral catheter insertion.

The face and content validity (De Vellis, 2003) of the items were examined by a panel of five specialised oncology RNs with ≥ 10 years of experience in positioning peripheral catheters for chemotherapy treatment; easily understood and evaluated items were considered in the examination performed by the panel.

2.3. Second phase: pilot-validation study

In accordance to the items composing the tool ($n = 16$), at least 160 patients were expected to be included in the validation process (Di Iorio, 2007). A consecutive sampling method was adopted and a total of 260 adult patients aged ≥ 18 years undergoing single chemotherapy cycles were consecutively enrolled in 2013. Patients treated with oral chemotherapy or continuous IV therapies requiring a central catheter were excluded. All of the participants gave their informed consent after having received appropriate information with regard to the study aims by the researchers.

Clinical nurses were trained in the use of the tool with an educational session illustrating the items. In addition, those experts involved in the tool development were available during the data collection in case of doubts. Thereafter, each eligible patient was included. Demographic data was collected via interview and then data collection was started. Each forearm was analysed through accurate direct observation and touch; the tool was then filled out.

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