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A randomised, controlled trial comparing the long-term effects of peripherally inserted central catheter placement in chemotherapy patients using B-mode ultrasound with modified Seldinger technique versus blind puncture

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A B S T R A C T

Objective: To compare the effects of peripherally inserted central venous catheter (PICC) placement using B-mode ultrasound with the modified Seldinger technique (BUMST) versus the blind puncture.
Methods: One hundred chemotherapy patients were recruited to participate in a randomised, controlled trial in Guangzhou, China. Fifty were assigned to the experimental group (using BUMST), and 50 were assigned to the control group (blind puncture). Demographic and background data, data related to PICC placement, complications after PICC placement, the patients' degree of comfort (determined via a questionnaire), and patients' costs for PICC maintenance were collected to compare the effects of the two methods. *T*-tests and chi-square tests were used to analyse the data; $p < 0.05$ was accepted as statistically significant.
Results: Nighty-eight of the 100 PICCs were successfully inserted (50 in the experimental group and 48 in the control group). Compared with the control group, the experimental group had a lower rate of unplanned catheter removal (4.0% vs. 18.7%; $p = 0.02$), a lower incidence of mechanical phlebitis (0% vs. 22.9%; $p < 0.001$), a lower incidence of venous thrombosis (0% vs. 8.3%; $p = 0.037$), and a higher incidence of catheter migration (32% vs. 2.1%; $p < 0.001$). Compared with the control group, the experimental group experienced significantly less severe contact dermatitis ($p = 0.038$), had improved comfort at 1 week, 1 month, 2 months, and 3 months after PICC placement ($p < 0.001$), and had lower costs for PICC maintenance at 2 months, 3 months and when the catheter was removed ($p < 0.05$).
Conclusions: Using B-mode ultrasound with MST for PICC placement reduced complications and patients' costs for PICC maintenance and improved patients' degree of comfort; thus, this procedure should be more widely used.
The clinical trial registration number: ChiCTR-TRC-12002749.

Introduction

In recent years, the use of peripherally inserted central catheters (PICCs) has become increasingly popular in China, especially in chemotherapy cancer patients (Gong et al., 2012; Tian et al., 2010). PICC has the advantages of less reinsertion, less drug extravasation, a liquid flow rate that is not influenced by position, and a longer indwelling time than that associated with peripheral vascular access. Furthermore, its advantages over CVCs include a greatly reduced risk of complications from procedure-related trauma, such as pneumothorax, haemothorax and accidental arterial puncture; easy insertion by nurses rather than doctors, which reduces costs and improves care; and its availability to outpatients (Amerasekera et al., 2009; Moureau, 2006; Robinson et al., 2005). Thus, PICC has been proven quite suitable for cancer patients who require continuous or discontinuous long-term intravenous infusion with chemotherapeutics (Gong et al., 2012; Ng et al., 1997).

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However, PICCs can also cause a variety of complications, including local bleeding, haematoma, mechanical phlebitis, catheter infection, catheter obstruction, venous thrombosis, and catheter migration, any of which can increase patients' pain and expenses and can influence patients' treatment procedures (Moureau, 2008). Thus, nurses tried to find better ways to reduce complications. B-mode ultrasound and the modified Seldinger technique (MST) have been used since 1997 in Washington (Nichols and Humphrey, 2008); it has the advantages of making veins visible, allowing thinner needles to be used for vein puncture, and allowing placement above the elbow (Nichols and Humphrey, 2008), and it was reported to improve the success rate of catheter insertion, reduce complications and costs, and increase patient satisfaction (Doniger et al., 2009; Feller-Kopman, 2007; Robinson et al., 2005; Stokowski et al., 2009).

The working principle of B-mode ultrasound is converting the reflected sound waves into a real-time grey-scale image: blood is hypoechoic and appears dark on the screen, and tissue is more isoechoic and appears grey, allowing nurses to see the vein clearly through the image (Feller-Kopman, 2007). MST is a technique known as the modified Seldinger technique. It involves establishing initial venous access with a small needle with the help of an introducer and the insertion of a guide-wire followed by progressive dilation to the point of PICC insertion (Goodwin, 1989; Sansivero, 2000). Using B-mode ultrasound with MST in PICC placement is a combination of the two techniques, with B-mode ultrasound helping to achieve easy puncture of the vein through the visible image and MST helping to send the catheter to the right position.

In the United States, this technology was endorsed by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Disease Control and Prevention (CDC) (Yildizeli et al., 2004). The procedure has also been recommended by the National Institute of Clinical Excellence (NICE) in the United Kingdom (O'Grady et al., 2011). In China, nurses began to use B-mode ultrasound and MST in PICC in recent years; it had been used only in a few large hospitals, and there were more catheter dwell days than in the USA or the United Kingdom. However, there has been no randomised study to compare the effects of PICC placement with blind puncture with those of MST under the guidance of B-mode ultrasound. Thus, we designed a randomised, controlled trial (RCT) and a long-term flow-up survey to evaluate the comprehensive value of B-mode ultrasound with MST.

The primary outcome was the incidence of complications after PICC placement, including mechanical phlebitis, venous thrombosis, contact dermatitis, infection, catheter migration and catheter occlusion; and patients' degree of comfort. The secondary outcomes were the success rate of PICC placement; the rate of tip malposition during PICC placement; the amount of bleeding during PICC placement; the rate of unplanned catheter removal; and the patients' costs for PICC placement maintenance.

Materials and methods

Trial design

This study was a randomly controlled trail (1:1 randomisation) with long-term follow-up conducted at Sun Yat-sen University Cancer Center (SYSUCC) in Guangzhou, China from July 2011 to February 2012. SYSUCC had three thousand chemotherapy patients with newly placed PICCs in 2011.

Patient recruitment and inclusion

Patients who were intended to insert PICC for chemotherapy were recruited. The inclusion criteria were as follows: 1) age between 18 and 75 years; 2) had completed at least a primary school education; 3) would receive chemotherapy; 4) was undergoing PICC insertion for the first time; and 5) would receive catheter maintenance at our hospital. The exclusion criterion was the contraindication of PICC placement. One hundred eligible patients were 1:1 randomly assigned to an experimental group and a control group. When PICCs were inserted, B-mode ultrasound guidance with modified Seldinger technique was used for the experimental group, and the blind puncture was used for the control group. The study was approved by the institutional ethical review board and passed the clinical trial registration (ChiCTR-TRC-12002749).

Sample size and randomisation

We referred to the incidence of mechanical phlebitis (one of the complications after PICC placement) before and after the use of B-mode ultrasound guidance with MST for PICC placement (before: 17%, after; 0) (LaRue, 2000; McMahon, 2002). According to 2-sided power calculations and the formula for comparing a 2-sample rate (Eng, 2003), a sample size of 86 participants would assure a power of 0.90 given a significance level of 0.05. Taking a dropout rate of 15% into consideration, we needed a sample of 100 subjects (50 in each group). The patients were randomly assigned in a 1:1 manner to the experimental group and the control group using a computer-generated, permuted-block randomisation scheme. Meanwhile, we used envelopes to hide the randomisation scheme.

Inserting and maintenance

All 100 PICCs were inserted by one PICC specialist, and all of the maintenance was conducted by an IV team at this hospital. Both groups used closed-tip, three-way-valve PICCs manufactured by Bard (Bard Access Systems, Salt Lake City, UT, USA). The PICCs were made of silicone and single-lumen, 18-gauge catheters (4F). For the experimental group, first, we used a uniform B-mode ultrasound device (Bard, USA) equipped with a 5–10 MHz linear array transducer to view the peripheral vein for catheter entry in the upper arm; second, we used a 21 G 'micropuncture needle' to puncture the vein through an introducer; third, we sent a guidewire into the vein through the needle; fourth, the needle was withdrawn over the wire and a 'peel-away sheath' was is advanced over the guidewire into the vein; and fifth, after removal of the dilator component of the peel-away sheath, the PICC was introduced through the sheath and advanced into position. For the control group, we used blind puncture to establish venous access near the elbow using a 14-G puncture needle and then sent the catheter through the needle into position. The first-choice vein was the right basilica. The tip of the PICC was positioned in the superior vena cava.

The maintenance of the PICC consisted of disinfecting around the PICC insertion site, the insertion site and the catheter (75% alcohol for 3 times to clean the skin around and 2% chlorhexidine in 70% alcohol for 2 times to disinfect the whole site and the catheter), changing the dressing and the connector, flushing and locking the catheter heparin saline (20 ml saline mixed with 200U heparin) (before and after injecting medicines, at the end of therapy, every 7 days when the catheter were not in use), and addressing complications. In our hospital, patients need maintenance on the 2nd and 5th days after placement and then once a week, and we record the patient's condition at each maintenance visit. Our treatment for mechanical phlebitis involved using mucopolysaccharide polysulfide cream to wipe the skin along the vein 5–6 times a day plus hot compresses. Venous thrombosis was treated with low molecular weight heparin for hypodermic injection and oral warfarin. We treated catheter migration according to the distance of the