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Do subcutaneously engineered stabilisation devices reduce PICC migration? A product evaluation report

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Abstract

Background Subcutaneous engineered stabilisation devices (SESD) are promoted as a strategy to reduce peripherally inserted central catheter (PICCs) migration and associated complications.

Method During a 4-month product evaluation period, a total of 51 PICCs were stabilised using a SESD from two clinical groups. These patients were evaluated weekly using multi-criteria, the Macklin and Blackburn framework.

Results Zero PICC migrations and two dislodgements – of the 51 insertions – were observed during the evaluation period. Ease of use and the ability to effectively clean the PICC exit site and safely remove the PICC site dressing were reported as additional benefits.

Conclusion The SESD used in this product evaluation proved a successful measure to reduce PICC migration. It was embedded into PICC care bundles for all adult patients in our service.

Introduction

Peripherally inserted central catheters (PICCs) have been used for over 4 decades to deliver intravenous (IV) infusions and medications and to allow blood sampling when frequent venepuncture may be problematic[1]. While there are advantages to using a PICC, this has to be weighed against potential risks such as catheter-related blood stream infection (CR-BSI), thrombus, occlusion and migration[2]. These complications are associated with significant social cost to the patient as well as having financial implications for the healthcare facility[3].

Frequently, complications arise due to catheter movement. Traditional methods for securing PICCs – such as transparent adhesive dressings, sutureless securement devices or sutures – do not completely eliminate movement of the PICC[4]. During PICC dressing changes, there is a potential risk of migration or dislodgement if the PICC is secured with adhesive dressings. PICC movement can result in skin irritation, exit site infection, migration or dislodgement, and can lead to more serious complications such as CR-BSI or thrombosis[4,5]. These complications can cause delays in treatment or be life threatening[5,6].

The use of a subcutaneous engineered stabilisation device (SESD) has been endorsed by two international groups that influence catheter management and best practice. The Infusion Therapy Standards of Practice recommends the use of an engineered stabilisation device to secure vascular access devices to prevent unintentional dislodgement and associated complications[7]. A review by the National Institute for Health and Care Excellence found that the adoption of the SESD to secure PICCs should be considered for any PICC whose dwell time will be 15 days or longer[8]. Hughes (2014)[6] reported only one PICC migration out of 31 patients, while Zerla et al. (2017)[9] described the SESD as a cost effective product and reduced catheter migration, particularly in 25 PICCs with a dwell time of greater than 30 days. In a paediatric setting, the use of the device significantly reduced the incidence

of complications, particularly dislodgement during the first 30 postoperative days[10]. SESD have the potential to reduce PICC migration.

Background

The product evaluation was undertaken in an acute tertiary teaching hospital in the South Island of New Zealand which provides services to a regional population of approximately 600,000. The Interventional Radiology Department at this hospital has the only New Zealand team of registered nurses (n=10) who are credentialled PICC inserters[11], placing between 1500–1711 PICCs annually, with an estimated annual cost of NZ$599,215).

In 2013, a concerning trend in PICC migration complications and re-insertions related to catheter movement was identified. This problem was initially addressed through the introduction of a trimmable PICC and a transparent adhesive dressing with an integrated reinforcement. Although this dressing provided a partial solution using additional reinforcement, it was reliant on good skin integrity for successful securement. Nevertheless, reasons for migration such as inadequate securement further challenged by skin integrity factors drove the product evaluation initiative. In 2014, 150 (11%) PICCs required reinsertion due to migration. This had both social costs in terms of patient suffering and delays in therapy, as well as financial implications in terms of associated additional costs, calculated to a value of NZ$54,750. Furthermore, in one of these cases of PICC migration, a fatality occurred that was linked to inadequate PICC securement which led to a quality review. This paper describes the implementation and outcomes of a product evaluation of an SESD. The aim was to evaluate the impact of a change of PICC securement on PICC migration events.

Methods

This product evaluation was underpinned by the Plan-Do-Check-Act (PDCA) tool[12]. This well-established tool has particular value in testing quality measures on a small scale in a continuous loop of planning (P), doing (D), checking (C) and acting (A) before updating procedures or working methods on a more widespread scale. This product evaluation was focused on impact of a change of PICC securement on PICC migration events. For the purposes of this product evaluation, catheter dislodgement was defined as an accidental removal that resulted in loss of function, whereas catheter migration was defined as movement greater than 2cm without loss of function even if the catheter tip was no longer at the cavo-atrial junction. Length of dwell time to removal was defined as successful completion of the intended course of therapy for which the PICC was inserted based on organisational policy.

Clinical product training

Before the product evaluation commenced, all staff who would be involved in the insertion, ongoing management and removal of the SESD received training by product experts. A transparent adhesive dressing in use at the time continued to be used as it was part of the 'PICC dressing bundle'.

PICC insertion procedure

Each PICC was inserted using ultrasound guidance with fluoroscopy tip placement verification. A small 'nick' was made in the skin to allow the folded SESD nitinol anchors to be placed into the subcutaneous layer. Once deployed, the securing anchors remained stable. The PICC site was dressed using a transparent adhesive dressing (Figure 1). Cyanoacrylate was not used to provide haemostasis at the insertion site by this organisation before or during this product evaluation.

Setting

Data collection took place during a 4-month period between June and October 2015. Two clinical areas were targeted for the product evaluation. Group A, a haematology unit, was selected as a speciality service. Group B, a general surgical ward, was selected due to the high rate of PICC migration incidents. Baseline data for Group A and Group B were obtained from a retrospective analysis of number of PICC reinsertions due to migration over two 4-month periods from January–May 2014 and June–October 2015.

Evaluation measures

The product evaluation framework was based on criteria proposed by Macklin and Blackburn[4] and further developed as the Health and Technology Synergy (HATS) framework by Chernecky et al.[13] was used to assess effectiveness of PICC securement. The evaluation framework included three criteria – patient, practice and product. For each SESD inserted, PICCs were monitored for 4 months or until removal, whichever occurred first.

Data collection

The PICC nurse inserters completed an initial evaluation form for each SESD placed at the time of PICC insertion. Nursing staff from Groups A and B completed evaluations of PICC management weekly during the product evaluation. This was documented on a specific form developed for this project. Data collected was based on the Numerical Rating Scale (NRS)[14] – similar to a Likert

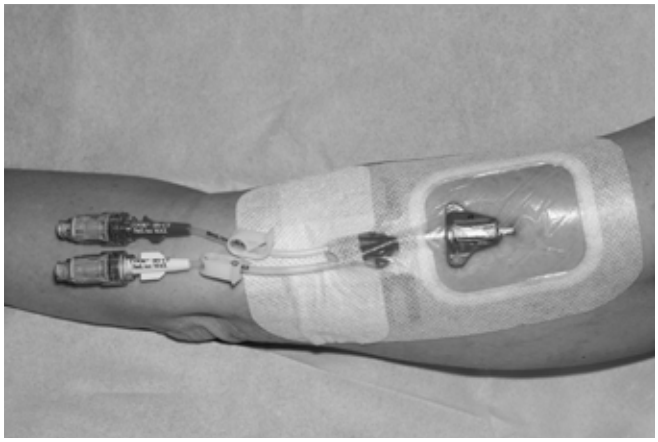

Figure 1. Dressed PICC site

scale – on the evaluation forms. Completed forms were stored securely in the unit by the charge nurse managers and collected daily by the project team leads.

Data analysis

At the end of the 4-month product evaluation period, 52 completed evaluation forms were available for analysis in hard copy. Data were collated and descriptive statistics analysis was undertaken by the project team leads.

Ethical considerations

The product evaluation of a change of securement for PICCs using an SESD was approved by the Central Venous Access Device Governance Group of the regional health authority as a quality improvement initiative and, in addition, its Research Office reviewed and approved this project (RO 19233). Institutional Review Board and Ethics Committee approval was waived. Informed patient consent was obtained prior to PICC insertion as per local hospital policy.

Results

A total of 51 PICCs were inserted between June and October 2015; 16 patients were in Group A and 35 were in Group B. A total of 23 female and 28 male patients had PICCs inserted that were stabilised with SESD. The median age for patients in Group A was 65 years and in Group B was 57 years.

Patient variables

The overall experience of patients was positive, with few complications in PICC management or the SESD.

Skin quality/integrity: Breaches in skin integrity were not observed. There were no reported skin-related issues such as skin tear associated with the nitinol anchors nor irritation from the body of the SESD against the skin surface either at the time of insertion or during the PICC dwell time. Skin irritation related to the dressing itself was not observed either.

Pain: The NRS[14] was used to measure pain levels on a scale of 1–10, with 10 being the worst. No patients reported pain during insertion probably due to the use of local anaesthetic. On PICC removal, 30 patients (58.8%) experienced no pain on removal of the device, 14 patients (27%) reported a score of 2, five patients (9.8%) reported a score of 4, and two patients (3.9%) reported a score of 5 on a scale of 1–10.

Bleeding: Bleeding post-PICC and SESD insertion was more evident than when inserting a PICC without an SESD. This was due in part to the method of inserting the SESD to allow placement of the nitinol anchors. PICC exit site bleeding at insertion and immediately post-insertion was observed in all 16 (100%) patients in Group A, likely related to thrombocytopenia and the myelosuppressive nature of patients. Bleeding gradually eased by day 2 post-insertion. There was slight bleeding during the insertion of the SESD but no reported ongoing bleeding in all 35 (86%) Group B patients. There was no report of bleeding on removal of the SESD in either group.

Practice variables

The overall experience of the staff using the SESD was positive, which also increased when patients reported fewer or no problems with the SESD.

*Table 1. Multi-criteria evaluation based on the Macklin and Blackburn framework**

	Criteria	Group A	Group B
Patient	Age	Median age 65	Median age 57
	Skin quality	No skin-related issues	No skin-related issues
	Pain during dwell**	None	None
	Pain score on removal**	A four out of ten	A four out of ten
	Bleeding	Slight to moderate	Slight
Practice	Dressing change	Staff confidence increased	Staff confidence increased
	PICC stability	Reduction in migration rates	Reduction in migration rates
	Device removal	Good acceptance following initial training	Good acceptance following initial training
Product	Migration	Nil	Nil
	Dislodgement	Nil	2 cases
	Pinching in device	Nil	2 cases
	Kinking PICC	Nil	4 cases
	Exit site infection	Nil	Nil
	Nickel allergy	Nil	Nil
	PICC dwell time	Elective removal (27.8 days)	Elective removal (23 days)

* The Macklin and Blackburn HealthCare and Technology Framework (2015)[4] represents synergy among conceptual variables of patient, practice and product components, with each affecting and being affected by the other.

** Pain score: The NRS from 0–10 (10 being worst) was used to assess pain levels whilst the Securacath® was in place and upon removal. Patients were verbally asked to score the level of pain experienced. This was recorded on the datasheet.

Device insertion: The PICC insertion team found the change of PICC securement to an SESD beneficial and reported that it was easy to place; during the initial 'learning curve' period, it took the expert PICC insertion team between 1–2 weeks to master the technique. They found that leaving the external length of the PICC at 4cms allowed both the device and the PICC to be positioned most effectively.

Dressing change: All staff reported that they felt more confident during dressing removal, site cleaning and dressing replacement with PICCs that had changed securement to an SESD. It also allowed for a 360° cleaning of the PICC exit site without dislodgement.

Device removal: Initially, removal of the SESD was identified as the main area of concern for staff. Removing a PICC required the additional step of removing the SESD nitinol anchors. Once staff gained confidence, they reported that removal became easier. By cutting the SESD into two parts, the nitinol anchors separated easily, aiding removal. It was noted that staff with more expert clinical practice skills found the SESD relatively easy to remove. Those with less clinical expertise found the removal process initially challenging.

A total of 31 staff commented on the ease or difficulty experienced when removing the device. Three staff (9.6%) found the device removal easy, 24 (77.4%) found removal manageable with practice, four (12.9%) found removal difficult. However, all agreed that once they gained confidence, removal became easier. If the device removal proved painful for the patient, administration of local anaesthetic provided a pain free removal.

Product variables

PICC migration/dislodgement: There were zero PICC migrations, two dislodgements, four events relating to PICC kinking, and two events relating to difficulty in flushing the PICC. The two dislodgements occurred in the first week of the product evaluation, whereby two patients in Group B inadvertently caught the external IV tubing attached to the PICC on the bedrail, dislodging the PICC back through the SESD by 2cms. Four PICCs in Group B became kinked external to the SESD. On investigation, the position of the PICC to SESD with incorrect dressing application was responsible; repositioning the dressing resolved the problem. Two PICCs in Group B were difficult to flush post-placement. On investigation, it was discovered that the coupling of the device was pinching the PICC; repositioning the PICC in the SESD channel resolved the problem. There were no further similar events in either Group A or Group B reported during the 4-month product evaluation.

Exit site infection: There were no PICC exit site infections identified in either group during the product evaluation.

Nickel allergy: Allergic reaction to the nitinol anchors was not observed during the product evaluation.

Length of dwell time: In Group A, 13 PICCs were electively removed at end of treatment, with the overall average dwell time being 27.8 days. Three PICCs were electively removed prior to end of planned IV therapy for clinical reasons. In Group B, all 35 PICCs were electively removed once IV therapy was completed, with the overall average dwell time being 23 days.

Impact of process change

Implementation of a change in securement resulted in reduced PICC migrations. Increased staff confidence was reported for dressing changes and general management of PICCs. Staff reported that, due to the stability of the SESD, they were able to lift the PICC to enable effective cleaning of the exit site and surrounding skin without the risk of the PICC migrating. In addition, a reduction of excess costs related to PICC reinsertion occurred. In a similar timeframe in the year previous to the SESD product evaluation, there were four PICC migrations in Group A (best estimate cost of NZ$395 per PICC reinsertion totalling NZ$1580). There were seven PICC migrations in Group B (best estimate cost of NZ$395 per PICC reinsertion totalling NZ$2765). This is in contrast to the absence of migration events – and therefore reinsertions – during the product evaluation. Therefore, the reduction in excess costs associated with PICC migration/dislodgement for 2015 was estimated at approximately NZ$4345. These results led to the organisational decision to embed the SESD as the preferred securement method in PICC care bundles for adult patients.

The findings described here are summarised in Table 1.

Discussion

Our findings showed that implementation of a SESD had benefits for both patients and staff. The aim to reduce PICC migration rates and associated complications was achieved. This is primarily attributed to the SESD; however, notable influences in improvements may also be attributed to patient education and staff training and education.

Patient variables form one core area of evaluation. Skin quality impacted by the ageing process slows epidermal cell regeneration in people over 50 years, negatively affecting skin elasticity and integrity. This has been implicated in the development of PICC-related contact dermatitis at the PICC exit site[15,16]. Although there was a potential for skin trauma, and given the median age of participants, there were no reported breaches in skin integrity during the product evaluation. However, research is limited in this area. Hughes[6] reported an exacerbation of eczema in one participant but it was not suggested that this was directly related to the SESD.

Pain associated with the device has been evaluated[5–7] at three stages – insertion, during the dwell time and at removal. Not all studies evaluated pain on insertion of the device, which is likely to reflect the use of local anaesthetic. The findings of this

product evaluation concur with Hughes[6], where no participants experienced pain during the PICC insertion procedure. Over 75% of participants in the study by Zerla et al.[9] experienced either no pain or a pain score of one (1) during the insertion procedure.

Pain during dwell time has been evaluated[5–7]. Egan et al.[5] reported (7.4%) participants experienced pain during the dwell time of the catheter. In this group, two PICCs were removed because of significant pain that resulted from the SESD being rotated or needing manipulation post-insertion. The three remaining participants reported intermittent pain only, which did not impact on dwell time. These results were also reflected in the paper by Hughes[6] who found that, while most people reported a pain score of 0, a small number of patients had the device removed because of ongoing pain above a pain score of 5. While Zerla et al.[9] reported similar results, they did not state if the SESD was removed prematurely due to unresolved pain. These results contrast with this product evaluation, in which none of the participants experienced pain during the dwell time.

Other papers[5–7] found that approximately half of the participants experienced very little pain (pain score 0–3) on removal of the device, while the remaining participants experienced significant amounts of pain (pain score 4–10) on removal of the device. The results of this product evaluation were more encouraging, with 59% of participants experiencing no pain on device removal, 27% participants reporting a score of 2, 9.8% participants reporting a score of 4 and 3.9% participants reporting a score of 5.

Bleeding post-SESD insertion has been reported as being more prolonged and extensive than when inserting a PICC alone.[6] Bleeding at the PICC exit site post-insertion was evident in all 16 (100%) in Group A during this product evaluation. This could be attributed to their haematological status, and the more invasive technique required to place the SESD. However, it was not a significant issue overall.

Practice variables form another core area of evaluation. Papers by Egan et al.[5], and Hughes[6] noted that the device placement could be problematic but all SESD in this project were placed successfully. During the product evaluation, the PICC nurse inserters reported that, with practice, insertion of the device got easier. This has been confirmed by Egan et al.[5] who reported that the more familiar the insertion team become with the device, the more proficient they became. Both Zerla et al.[9] and Goossen et al.[17] noted that using the SESD reduced the number of steps taken during a dressing change which resulted in time saving by the nurse. While this was not specifically addressed in the product evaluation, ease of performing the dressing procedure was. The SESD stabilised the PICC, which reduced the risk of catheter migration or dislodgement during a dressing change, therefore increasing the nurses' confidence during the procedure. This made dressings straightforward to complete.

The main concern expressed by the nurses was the challenge in removing an SESD compared to the uncomplicated removal of a PICC alone. With practice and familiarity, the nurses developed the removal technique with confidence. The SESD was easier to remove in two parts and, for those devices that were difficult to remove, the use of local anaesthetic was effective. Hughes[6] also found this an area of concern amongst staff, who reported difficulty with device removal; this happened quite frequently and was particularly stressful when the patient found it painful. Sometimes the anchors became stuck during the removal process or skin had granulated over the pins, making removal challenging. Local anaesthetic was used in these instances to ensure patient comfort. Therefore, training in device removal and supporting beginners was determined to be imperative for practice quality and patient comfort[6].

Product variables form a third core area of evaluation. The primary reason for introducing a SESD was to reduce PICC migration. During the product evaluation, this aim was successfully achieved, with only two PICCs dislodging by 2cm with no negative effect on overall dwell time. This has been identified in other papers[5–7] where minimal catheter migrations or dislodgements have been reported when using SESD. Previous reports have also found the device not coupling together correctly which resulted in catheter migration and dislodgement. The device has since been modified to improve the locking mechanism[5].

PICC kinking is a further factor that can be affected by the SESD. In both this product evaluation and another paper[6], kinking led to occlusion due to incorrect coupling of the SESD. To remedy this, the lid was removed to ensure that the catheter was not being pinched then replaced. Currently, recommendations indicate that the catheter should be flushed immediately post-insertion to ensure that the SESD has been coupled successfully.[6] Kinking of the PICC occurred four times during this product evaluation as a result of incorrect dressing placement. This was resolved by replacing the dressing. Both Egan et al.[5] and Zerla et al.[9] reported removal of a PICC due to kinking or occlusion.

While no participants in this product evaluation experienced PICC exit site infections, this finding contrasted with other papers. Skin was evaluated by Zerla et al.[9] using a visual exit site score. Using this score, over 97% of their participants scored either 0 or 1. However, Hughes[6] reported that 13% of participants developed an exit site infection and 6% patients developed tissue granulation around the nitinol pins[6]. Egan et al.[5] found that 1.5% of their subjects developed exit site cellulitis. There was little evidence on PICC exit site infections without the use of an SESD prior to this product evaluation and no concern emerged during this evaluation period.

Nickel allergy was not observed in either group of participants during the product evaluation. This is reflective of the literature where nickel allergy was not identified[6].

Dwell time is hard to evaluate as this data has been presented in different ways, over different timeframes. In two papers[5,6], approximately 30% of participants and 77.9% of participants respectively had a catheter dwell time of less than 30 days. This is in keeping with this product evaluation where overall catheter dwell days were less than 30 days in the evaluation period of 4 months. However, Zerla et al.[9] found over a 12-month period the average catheter dwell time was 45 days. This supports the longer-term use of this device.

Finally, another benefit of the SESD resulting from improved stabilisation over the 4 months of the product evaluation was a reduction in costs related to PICC migration or dislodgement. This is supported by Zerla et al.[9] where cost savings were identified as a critical point of evaluation.

Conclusion

The SESD used in this product evaluation proved a successful measure to reduce PICC migration events. An organisational decision was made to embed SESD as the preferred securement method in PICC care bundles for adult patients.

Disclosures

No grants or funding were received for this quality improvement initiative. The Regional Health Authority initiated contact with the supplier to source the SESD SecurAcath® (see Supplementary Material 2 and 3). The product was not available in Australasia at the time. A formal product evaluation was undertaken in 2015 and the SESD SecurAcath® was donated by the supplier for this purpose.

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Conflict of interest

The authors declare no conflicts of interest.

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