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ORIGINAL RESEARCH ARTICLE

Evaluating safety, efficacy, and cost-effectiveness of PICC securement by subcutaneously anchored stabilization device

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ABSTRACT

Purpose: In recent years, a large variety of medical devices has become available. Every device must be efficient, safe and cost effective, but it is not enough to use it properly without considering the environment in which it will be employed. We applied this kind of analysis to subcutaneously anchored sutureless devices (SAS).
Methods: This is a one-center prospective observational study on safety, effectiveness and cost effectiveness of an SAS device (SecurAcath, Interrad) for securement of peripherally inserted central catheter (PICC) in 30 adult cancer patients with treatment expected to be >60 days.
Results: During 4963 catheter days and after 709 dressing changes (documented by 373 pictures), the use of SAS was associated with no episode of PICC dislodgement and a lower incidence of complications if compared to traditional securement devices. Insertion, management and removal of SAS were not associated with an increased pain perception by the patients. Cost effectiveness was particularly evident for long dwelling PICCs.
Conclusions: Our study suggests that SAS is a highly effective and cost-effective method for securement of medium- to long-term PICCs with expected duration longer than 30 days. The introduction of SAS had a positive impact on our healthcare organization.

Keywords: Complication, Cost-effectiveness, Oncology, SAS, Securacath

Introduction

A continuous and fast development of medical technologies, introducing new discoveries and techniques, generates continuous improvements. These innovations require a redefinition of professional roles.

Peripherally inserted central catheter (PICC) use for administration of several therapies is an important aspect of current hospital practice, particularly to ensure minimal hospitalization and increase the patient care in the home environment.

To improve the standard of practice related to PICC placement and maintenance, the proper use of a subcutaneously anchored sutureless devices (SAS) can be the key to avoid early and late complications, improving safety and effectiveness of care. It can probably lead to economic advantages.

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Materials and method

In our hospital, ASST Melegnano Martesana (Lombardy, Italy), a PICC team has been active since 2010, with an average of 1000 insertions/year, mainly on oncology patients who are treated in 70% of cases at the same vascular access center.

The population of patients included in our observation consists of patients with increasing complexity, specifically those with the existence of several co-morbidities and other conditions for which the request for complex therapies, including multiple intravenous pharmaceuticals and medium- to long-term infusions are necessary.

This is a one-center prospective observational study on the use of SAS (SecurAcath, Interrad Medical, Minneapolis, MN) to secure PICCs, started in September 2014 up to January 2016, involving 30 adult cancer patients with therapy expectation >60 days.

Two kinds of PICCs were used: 28 PICC 4 Fr single-lumen silicone Groshong (Bard Access Systems, Inc.) and 2 PICC 4 Fr single-lumen Polyurethane Power (MedComp).

Groshong PICCs were positioned in oncology patients already diagnosed undergoing chemotherapy, Power PICCs

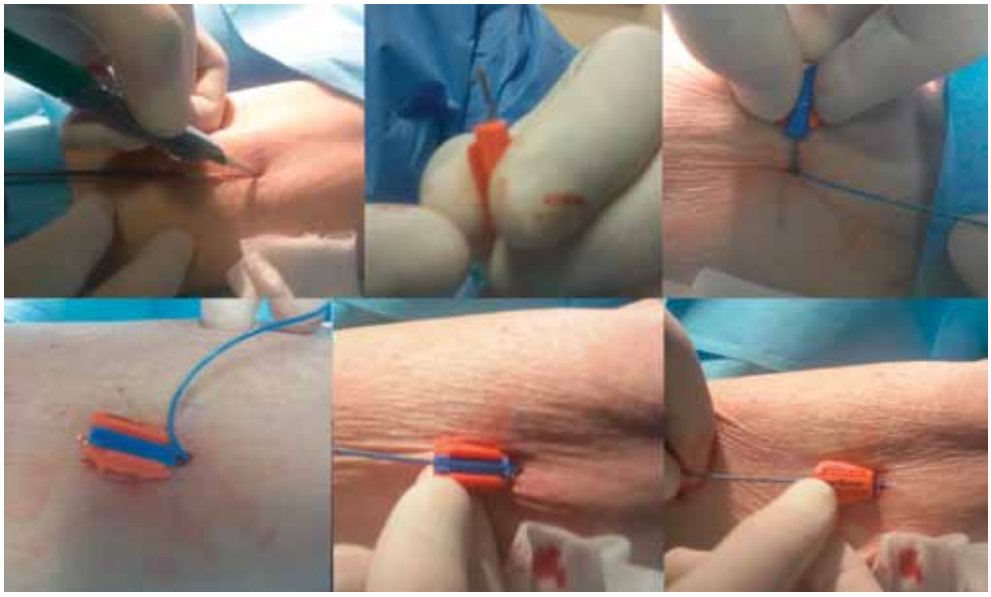


Fig. 1 - Sequence for subcutaneously anchored sutureless device (SAS) insertion.

were positioned in patients with suspected cancer waiting for diagnosis that needed CT, CVP measurement and surgery.

The SAS was placed at the end of PICC insertion, following the manufacturer's instructions.

Data were collected with forms and inserted in a database containing the following records:

1. Mechanical thrombotic and infective complications
2. Pain during insertion, maintenance and removal
3. Skin integrity status during maintenance of SAS
4. Arm photographic documentation:
   a) before insertion
   b) after insertion
   c) weekly for initial 4 months
   d) monthly for >5 months until removed
5. Cost-effectiveness analysis

Data collection was performed using Microsoft Excel software, while SAS System V.8.2 software for Windows was used for data management procedures and statistical analysis.

Indication

The PICC was inserted under clinical prescription and then removed when the PICC was no longer indicated. These indications were:

- The need to preserve patient's venous system while using infusions with vesicant or irritant effect on the endothelium and with pH <5 and >9 or osmolality >600 mOsM/L.
- Patients requiring continuous or intermittent access for infusion therapy for more than 6 days until infusion therapy is no longer indicated at hospital or home (1, 2).
- Patients with high risk of mechanical complications in case of conventional central venous catheter (CVC) insertion (obese patients with anatomical or pathological alterations, patients with severe coagulopathy).
- Patients with high risk of infection if traditional CVC is used (tracheotomy patients, immunosuppressed patients or those at high risk of bacteremia) (3, 4).

PICC insertion and nursing protocol

All catheters were inserted employing sterile technique, maximal barrier precautions and skin antisepsis with the use of 2% chlorhexidine. All PICCs were inserted by ultrasound guidance, using a micro-introducer and tip location was verified by chest x-ray.

Before insertion, the nurse completes the informed consent. After the procedure, the nurse enters the data in the nursing chart as well as into the database; this will include all the information related both to the insertion and to dressing changes.

The physician updates the patient's medical record and provides the indication for use for the PICC after evaluation of the radiological reports, having previously obtained the patient informed consent and handed the information to facility.

Vein choice and evaluation was based on ultrasonography under the following criteria:

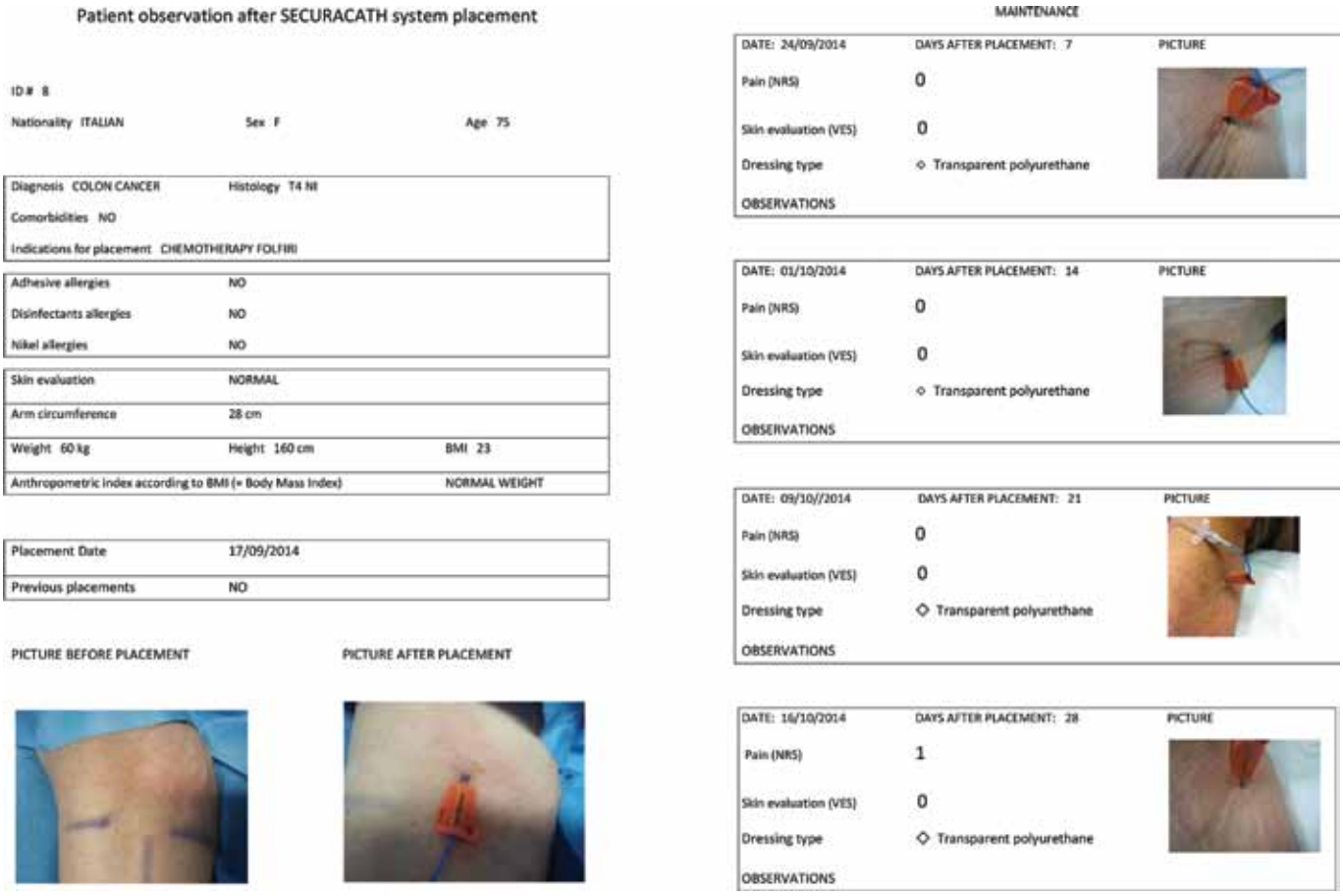
1) Vein depth >5 mm
2) Vein diameter >4 mm
3) Vein route without bifurcation from insertion site >30 mm

Placement of the SAS device was performed following manufacturer indications and following the hospital procedure (5). SAS insertion technique also included:

1. Appropriate sterile technique
2. Max barrier precautions
3. Skin antisepsis with the use of 2% chlorhexidine (6-9).

For PICC and SAS insertion (Fig. 1), the following procedure was used:

After venipuncture and introduction of guide wire, >1 mL of anesthetic was injected on insertion site and scalpel was intro-



Patient observation after SECURACATH system placement

ID# 8

Nationality ITALIAN Sex F Age 75

Diagnosis COLON CANCER	Histology T4 N0	
Comorbidities NO		
Indications for placement CHEMOTHERAPY FOLFIRI		
Adhesive allergies	NO	
Disinfectants allergies	NO	
Nikel allergies	NO	
Skin evaluation	NORMAL	
Arm circumference	28 cm	
Weight 60 kg	Height 160 cm	BMI 23
Anthropometric index according to BMI (= Body Mass Index)		NORMAL WEIGHT
Placement Date	17/09/2014	
Previous placements	NO	

PICTURE BEFORE PLACEMENT

PICTURE AFTER PLACEMENT

MAINTENANCE

DATE: 24/09/2014	DAYS AFTER PLACEMENT: 7	PICTURE
Pain (NRS)	0	
Skin evaluation (VES)	0	
Dressing type	◇ Transparent polyurethane	
OBSERVATIONS		

DATE: 01/10/2014	DAYS AFTER PLACEMENT: 14	PICTURE
Pain (NRS)	0	
Skin evaluation (VES)	0	
Dressing type	◇ Transparent polyurethane	
OBSERVATIONS		

DATE: 09/10//2014	DAYS AFTER PLACEMENT: 21	PICTURE
Pain (NRS)	0	
Skin evaluation (VES)	0	
Dressing type	◇ Transparent polyurethane	
OBSERVATIONS		

DATE: 16/10/2014	DAYS AFTER PLACEMENT: 28	PICTURE
Pain (NRS)	1	
Skin evaluation (VES)	0	
Dressing type	◇ Transparent polyurethane	
OBSERVATIONS		

Fig. 2 - Maintenance form.

duced tilted 45 degrees downward. Once catheter was inserted, we bent the base of the SAS and inserted the nitinol feet and legs to follow the path created with needle and scalpel. Then we aligned and released the base to open the feet just beneath the dermal layer. We finally snapped the SAS cover on to the base and locked the clean and dry catheter into final position.

A picture of arm was taken before and after SAS insertion and included in the insertion form.

Following the nursing hospital protocol, the first dressing was replaced after 24 hours from the insertion and switched to transparent dressing in absence of complications. In presence of significant amount of blood, a compressive dressing was maintained for the next 24-48 hours.

In the first 24 hours, the dressing was checked periodically and replaced if wet, lose or visibly dirty. After this initial 24-hour period the transparent dressing was replaced every 7 days, or if needed.

All dressing changes were performed with sterile or no-touch technique and preferably in a dedicated environment. The dressing change included dressing inspection, disinfection, and a transparent semi-permeable dressing application (10).

For the first four months, a picture of the arm was taken every week during dressing maintenance. After 4 months, in cases of no complications, picture was taken once a month until device was removed.

For SAS removal, the following procedure was performed:

Sterile or no-touch technique was adopted. SAS cover and catheter were removed. With pain-sensitive patients we considered the administration of <2 mL of anesthetic.

After placement of sterile gauze under SAS, we used a scalpel or scissors to cut in a half SAS base.

Once in two halves, we removed them with a rotation towards the outside of 45 degrees while maintaining a slight pressure on the exit site. Finally, a gauze dressing was applied.

Data management and analysis

Data collection was done by completing a form on the insertion procedure.

Insertion form included 24 items: Surname, Name, Nationality, age, sex, diagnosis, histology, comorbidity, insertion indications, bandage allergies, disinfectants allergies, nickel allergies, skin assessment, arm circumference, weight, height to determine body mass index (BMI).

Dressing change form included 7 items: date, skin picture after dressing removal, pain assessment on dressing change and during rest, exit site evaluation, type of medication in case of complication, notes. All dressing changes reported in the form included a photo of SKIN, as shown in Figure 2.

Both forms were loaded into the database.

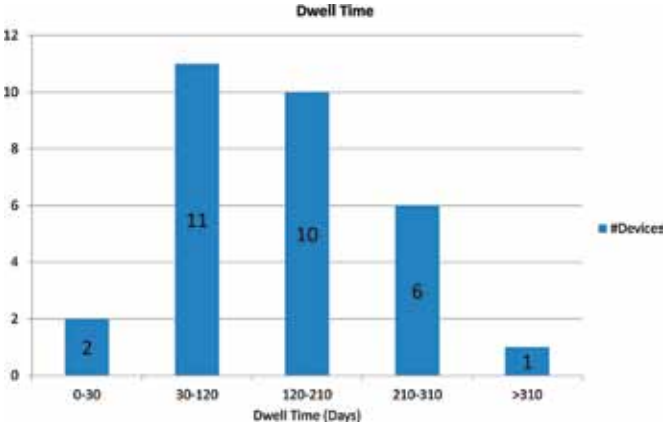


Fig. 3 - Histogram.

Results

Clinical analysis

We placed SAS in 30 PICCs from September 2014 until September 2015 in 30 patients of both sexes (12 males - 1904 days/SAS and 18 females - 3059 days/SAS) for a total of 4963 days until the end of observation time January 15, 2016. At the end of the follow-up, 7 devices were still in use.

In 4963 days with SAS, 709 observations were performed and 373 pictures were taken. The average dwell time for SAS was 4.8 months (145 days), with a maximum duration greater than 13 months (410 days) and a minimum duration of 9 days.

In Figure 3, the third column (120-210) includes the 7 devices still in use.

BMI was also considered. Patients with BMI <18.5, n = 2 (7%); normal weight BMI 18.5-24.9, n = 15 (50%); overweight BMI 25-29.9, n = 12 (40%); obese BMI 30-34.9, n = 1 (3%).

Skin evaluation during routine maintenance was evaluated using visual exit-site (VES) score. In 709 observations during dressing change we found 499 cases with a VES score = 0 (70.4%), 190 with a VES score = 1 (26.8%), 19 with a VES Score 2 (2.7%), in 1 with a VES score = 3 (0.1%) (10).

SAS decreases the number of dressing steps (5 steps with SAS, 8 with adhesive), with consequent reduction of the nursing time: median 10 minutes with SAS (minimum 5, maximum 15 minutes), median 20 minutes with adhesive (minimum 10, maximum 30 minutes).

Finally, we evaluated patients pain using the numerical rating scale (NRS). The patient chose the number that better described his/her pain in different stages of the process "INSERTION", "MANAGEMENT" and "REMOVAL" (11).

Insertion pain data showed that device was well accepted with very low percentage of pain: 30% of patients had NRS = 0; 46.7% had NRS = 1; 13.3% had NRS = 2; 6.7% had NRS = 3 and 3.3% had NRS = 4.

During routine SAS maintenance, NRS pain evaluation was 0 or 1 in 81.5% of dressing changes (total number of dressings = 709). In detail, 19.9% of dressings had NRS = 0; 61.6% had NRS = 1; 13.4% had NRS = 2; 4.6% had NRS = 3; 0.3 had NSR = 4; 0.1% had NSR = 7.

Regarding pain at removal, of the 30 patients only 18 were evaluated because 5 patients died before removal and 7 still had the PICC in situ. Those 13 patients had a good response to pain (NRS <2) as shown in Table I (12-17).

Reasons for SAS removal: for 5 patients - death, 16 patients - the end of the treatment, in one patient (dwell time 212 days) - for total occlusion generated by blood products, and for one patient after 9 days - for pain. Seven patients were still active.

There were 0 dislodgements/4963 days, 0 infective complication/4963 days, 0 thrombotic complication/4963 days.

Economic analysis

We compared and assessed the economics of the adhesive stabilization device used in our hospital (StatLock™, Bard Access Systems) and the SAS system, considering that adhesive stabilization was replaced at each dressing change while SAS didn't need replacement until PICC removal (18). The comparison showed that for dwell time >30 days the cost of the SAS was amortized. The savings on the 30 patients studied are shown in Table II.

The SAS on this study eliminated the mechanical complications due to extra-luminal dislodgement. Our previous study on 793 PICCs stabilized with adhesive devices showed 63 extra-luminal dislodgements, 18 with an open-tip device, and 45 with a closed tip device (19). In all these cases, to ensure the continuity of care, we proceeded to a new PICC insertion with a consequence of substantial costs increase (Tab. III) and additional risks related to additional procedure.

TABLE I - Pain at removal

NRS removal pain	Patients (n)	%
0	6	20.00%
2	7	23.33%
4	3	10.00%
5	1	3.33%
7	1	3.33%
Died	5	16.67%
PICC still in situ	7	23.33%

NRS = numerical rating scale; PICC = peripherally inserted central catheter.

TABLE II - Cost comparison between adhesive stabilization and subcutaneously anchored sutureless device (SAS)

	SAS	Adhesive stabilization device
Maintenance performed	709	709
No. devices used	30	709
Device cost (€)	30	6
Stabilization total cost (€)	900	4.254
SAS savings (€)	3.354	

TABLE III - Dislodgement cost estimation (based on number of insertions from our previous study) (19)

Open tip devices		
Catheters	Insertion total cost (€)	Total cost (€)
18	197	3.546
Closed tip devices		
Catheters	Insertion total cost (€)	Total cost (€)
45	337	15.165
Total no. insertions 63	**Total cost €18.710**	

Discussion

SAS should be inserted, managed and removed by specifically trained healthcare professionals, to ensure that every maneuver is performed appropriately. This allows the achievement of targeting zero complications caused by facility and management.

Data collection and analysis are the key factor to understanding and improving the use and maintenance of vascular access devices, in order to achieve continuous improvement of the standard of care (19).

In our study, the use of a SAS device with its nitinol anchor was not associated with increased pain during insertion, management or removal.

We observed only one case where pain increased up to NRS scale of 7 associated with VES score of 3 where SAS was removed prematurely upon patient request.

In management, we found a decrease in the number of steps necessary to perform the dressing change with consequent saving of nursing time.

SAS indication is independent of age, sex, diagnosis and histology, adhesive allergies, BMI, type of device, type of vein, vein diameter, number of attempts for access to the vein, and the micro introducer staying time.

Vein depth >5 mm is recommended in order to insert SAS deep enough in the subcutaneous tissues.

Another critical point evaluated is the cost savings highlighted in Table III. The cost of the device after 30 days' dwell time is completely covered and the higher the indwelling time, the greater the gain in comparison to adhesive securement devices.

Conclusion

The SAS, in our experience, has demonstrated a viable alternative to traditional devices for securing PICCs.

With regard to safety, the SAS has contributed to reduction of mechanical complications showing a greater ability to prevent the extraluminal dislodgement, with consequent reduction of the number of PICC replacements and a net reduction of the risk of therapy interruption and cost savings.

The SAS, although used in the most difficult conditions, (i.e., oncology patients) and for long dwell times, has demonstrated a clear superiority in stabilizing PICCs.

The introduction of SAS in the PICC procedure gave our institution not only economic but also professional benefits. The staff gained the opportunity to practice an additional skill and clinicians' interactions were increased, resulting in improvement in patient care.

Disclosures

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Conflict of interest: None of the authors has financial interest related to this study to disclose.

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