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Subcutaneously anchored securement for peripherally inserted central catheters: Immediate, early, and late complications

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Abstract

Background: An adequate stabilization of a vascular device is an important part of insertion bundles and is an effective strategy in reducing complications. Dislodgment has a relevant clinical impact and an increase in healthcare costs.

Method: We have retrospectively investigated the safety and efficacy of Subcutaneously Anchored Securement (SAS) for Peripherally Inserted Central Catheters (PICC) in cancer patients.

Results: We analyzed 639 patients who had a PICC inserted and secured with SAS, over the past 3 years (2018–2020). No immediate complications during SAS placement were reported. In the first 24–48 h, a slight local ecchymosis was reported in 24 cases with rapid spontaneous resolution. No cases of bleeding or hematoma of the exit site were reported. The total number of catheter days was 93078. Dislodgment occurred only in seven cases (1.1%). In 16 patients, the PICC was removed because of catheter-related bloodstream infection (CRBSI): the overall incidence of CRBSI was 0.17 per 1000 catheter days. Symptomatic venous thrombosis was documented in 12 patients (1.9%) and treated with low molecular weight heparin without PICC removal. We had no cases of irreversible lumen occlusion. In 17 patients, local discomfort—including device-related pressure ulcers and painful inflammation—was reported: these cases were treated without SAS removal or PICC removal.

Conclusion: In this retrospective analysis, subcutaneously anchored securement of PICCs was a safe and effective strategy for reducing the risk of dislodgment.

Keywords

Oncology access, techniques and procedures, subcutaneously anchored securement, peripherally inserted central catheters, biomaterials

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Introduction

The optimal stabilization of the vascular device is part of all insertion bundles and is recognized as an important strategy to minimize the risk of complications. An adequate stabilization of a vascular access device must ensure the integrity of the device, minimize the movement of the catheter at the exit site, and prevent dislodgment of the catheter. Also, the method used to stabilize the catheter should not interfere with the assessment and control of the exit site.[1]

When stabilization is not optimal, the main risk is catheter dislodgment. The literature reports an incidence of dislodgment between 5% and 15%, depending on the type of securement and on the definition of dislodgment (total vs

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partial; accidental removal; with or without loss of function of the venous access).[2–5] It is a common complication, mainly related to peripheral venous access devices, though it affects, to a lesser extent, also Peripherally Inserted Central Catheters (PICCs) and Centrally Inserted Central Catheter (CICCs). The main causes of dislodgment are (a) factors dependent on the patient's cognitive status, (b) factors related to the actual efficacy/inefficacy of the securement, and (c) factors related to the active or passive mobilization of the patient. Dislodgment has a relevant clinical impact as it may be associated with loss of vascular access, forced interruption of therapy, unscheduled reposition of the access, increased discomfort for the patient, prolonged hospitalization, and increased health care costs.[6]

The introduction of sutureless devices has improved the possibility of effective and safe stabilization of vascular devices, as the previously adopted strategies of securement—that is sutures—were associated with relevant risk of local infection, dislodgment, and accidental puncture.[7]

Skin-adhesive sutureless devices (either separate from the dressing or integrated in the transparent membrane) are effective and safe but may have some limitations: they must be replaced weekly; they are not 100% effective in preventing dislodgment (in recent studies, their effectiveness does not reach 94%)[8]; they interfere with an adequate disinfection of the exit site; they allow "in and out" micromovements of the catheter at the exit-site; they might cause MARSI (Medical Adhesive-Related Skin Injury).[9]

Subcutaneously anchored sutureless devices allows a stabilization of the catheter through the use of nitinol bars anchored in the subcutaneous tissue, without any adhesion to the skin. They have many theoretical advantages: they do not require periodic replacement; they allow a complete, 360° disinfection of the exit site; "in and out" micromovements of the catheter at the exit site are virtually eliminated; their efficacy is not affected by characteristics of the skin and they do not cause MARSI.

As the actual rate of complications associated with the use of Subcutaneously Anchored Securement (SAS) is still under debate,[10] we have reviewed retrospectively our 3-year experience with such devices, when used for securement of PICCs.

Methods

Study design and setting

This is a retrospective cohort study conducted in the Unit of Anesthesia, Intensive Care Medicine and Vascular Access Team of CRO National Cancer Institute, a Clinical and Research Cancer Institute located in Aviano (PN), Italy. We analyzed all PICCs secured with SAS in cancer patients, during the last 3 years (2018–2020). The SAS device used was the only currently available for clinical use, Securacath (Interrad Medical).

This study received approval from our Ethics Committee.

Intra-procedural and routine follow-up information of these cases were drawn from clinical charts for all the patients who had previously given their consent to the use of clinical data for research purposes.

All patients over 18 years of age were included in this retrospective analysis. Patients who had not given informed consent to the use of their data for clinical and epidemiological research, and/or patients whose data of interest were not available in the medical record, were excluded from the analysis. Clinical data of interest present in the medical records of individual patients who meet the inclusion/exclusion criteria were collected. For each patient, data were collected from the time of PICC insertion until removal.

Technique of PICC insertion

PICC insertion was performed by experienced practitioners of our Vascular Access Team. In all patients, the procedure was performed according to our local insertion bundle for PICC insertion, which includes: pre-procedural ultrasound vascular assessment following the RaPeVA protocol (RaPeVA = Rapid Peripheral Vein Assessment),[11] measurement of vein diameter and respect for a catheter/vein ratio less than or equal to 1:3, skin antisepsis with 2% chlorhexidine, maximal barrier precautions, ultrasound-guided venipuncture, use of intracavitary electrocardiography method to verify the correct position of the tip of the catheter at the cavo-atrial junction, location of the exit site in Dawson's green zone (adopting tunneling from the yellow to the green zone, if necessary),[12] catheter securement with SAS, and sealing of the exit site with cyanoacrylate glue. Subsequent dressings and saline flushing of the PICC were performed weekly. The care and maintenance of the devices was entrusted to specialized nurses of our Access Vascular Team, according to institutional protocols.

Outcomes

Primary endpoints were (a) the efficacy of SAS, in terms of reducing the risk of dislocation and the need to reposition the vascular access device, (b) as well as its safety, evaluated investigating the incidence of immediate complications during SAS placement (difficulty, pain, etc.), early complications, that is, within 48 h (pain, local bleeding, etc.) and late complications (pain, malfunction, local or systemic infection, reversible or irreversible occlusion, catheter-related venous thrombosis, skin lesions due to the nitinol anchors, pressure ulcer of the device on the skin, etc.).

Statistical analysis

Descriptive analysis was performed by calculating the absolute frequency of the events of interest and relative proportion (%), with corresponding 95% confidence

Table 1. Patients included in the study (years 2018–2020).

PICCs secured with subcutaneously anchored sutureless system				
	2018	2019	2020	Total
Patients	115	232	292	639
M/F	61/54	117/115	149/143	327/312
Mean age (years)	69.2	66.9	67.6	67.7

Table 2. Early complications (within 48 h).

	N (%)	95% CI
PICC malfunction	0 (0.00)	—
Bleeding or hematoma at the exit-site	0 (0.00)	—
Skin ecchymosis	24 (3.8%)	2.4%–5.5%
Local pain at the exit-site	0 (0.00)	—
Early infection	0 (0.00)	—

intervals (95% CI). Numerical variables are expressed as means and standard deviation (SD). The cumulative incidence of infective complications was calculated as the number of events divided by the total number of catheter days and it was expressed per 1000 days of catheter stay with the relative 95% CI.

Results

A total of 639 patients had a PICC inserted and secured with SAS in the last 3 years (2018–2020) (Table 1).

PICCs of different brands and calibers were inserted: 254 Lifecath PICC Easy 4 Fr (Vygon), 114 Lifecath PICC Easy 5 Fr (Vygon), 97 HealthPICC 4 Fr single-lumen (Plan-1-Health), 153 HealthPICC 5 Fr single-lumen (Plan-1-Health), 21 HealthPICC 5 Fr double-lumen (Plan-1-Health). Indications for PICC insertion was chemotherapy in 120 patients, parenteral nutrition and chemotherapy in 410 patients, and parenteral nutrition in 109 patients.

As regards the effectiveness of securement with SAS, we recorded dislodgment only in seven patients (1.1%): three of these patients were non-collaborative patients with psychomotor agitation. In the remaining four cases, dislodgment occurred due to a mismatch between the size of the catheter and the size of the SAS. This was not related to an error of the operator but to an actual inconsistency of the caliber of the catheter as stated by the manufacturer. In fact, all four cases of dislodgment occurred with 4 Fr LifeCath PICC Easy (Vygon) secured with 4 Fr SAS or with 5 Fr LifeCath PICC Easy (Vygon) secured with 5 Fr SAS. In the early phase of our experience, noting this issue, we understood that the actual size of these catheters is slightly smaller than that the figure declared by the manufacturer. After these unexpected dislodgments, we have been using 3 Fr SAS for 4 Fr Lifecath PICC Easy and 4 Fr SAS for 5 Fr Lifecath PICC Easy, thus eliminating the risk of dislodgment.

No significant immediate complication during SAS placement was reported.

As regards early complications, in the first 24–48 h a slight local ecchymosis was reported in 24 cases (3.8%), with spontaneous resolution after 48–72 h. No cases of bleeding or hematoma of the exit site were reported (Table 2).

The total number of catheter days was 93078, with an average 154 days per patient (range 32–657 days); 302 PICCs, 47.2% of the total, had been tunneled from the yellow zone to the green zone of Dawson. In 16 patients (2.5%), the PICC was removed for catheter-related bloodstream infection (CRBSI) documented by the method of delayed time to positivity (blood culture from PICC becoming positive at least 2 h before peripheral blood cultures). The incidence of CRBSI was 0.17 per 1000 catheter days. Symptomatic catheter-related vein thrombosis was documented in 12 cases (1.9%) and treated with low molecular weight heparin therapy at therapeutic dose. Reversible lumen occlusion was reported in 15 cases (2.3%), treated and resolved with flushing maneuvers. In 17 cases (2.7%), some discomfort—including device-related pressure ulcers and painful inflammation—were reported, probably secondary to excessively tight dressing: these cases were treated with the application of a sterile gauze interposed between the SAS and the skin and proper application of dressings avoiding excessive compression. This latter complication did not imply SAS removal of PICC replacement in any of 17 patients (Table 3).

Discussion and conclusion

A recent consensus document on SAS has been developed by a panel of experts of GAVeCeLT and WoCoVA, aiming to analyze the current literature and propose future study directions. From the analysis of all available studies, it was suggested that SAS is highly effective in reducing the risk of dislodgment of the catheter, lowering this risk to 0%–3%. The data were not uniform, as in one study the incidence of dislodgment was higher.[10]

Some relevant issues should be discussed as regards the use of SAS: first, it is essential to choose the suitable size of the device, consistent with that of the catheter; second, the nitinol bars must be placed below the skin, as a superficial position may result in local inflammation, pain, and risk of dislodgment. This implies that a specific and adequate training is required before using SAS: in a recent study in which the clinical use of the device was preceded by a training period, the rate of complications was extremely low.[8]

One specific category of patients which may benefit of SAS is the population of non-cooperative patients with cognitive disorders: involuntary dislocation of the catheter is quite common, and SAS is highly recommended, even though it should be coupled with other strategies (such as tunneling the catheter so to place the exit site out of reach of the patient's hands).

Table 3. Late complications (analysis of 93,078 catheter days).

	N (%)	95% CI
Catheter-related bloodstream infection (CRBSI)	16 (2.5)	1.4–4.0
Symptomatic catheter-related venous thrombosis	12 (1.9)	1.0–3.3
Reversible lumen occlusion	15 (2.3)	1.3–3.8
Irreversible lumen occlusion	0 (0.00)	–
Pressure ulcers and painful inflammation	17 (2.66)	1.6–4.2
	Incidence/1000 catheter days	
Catheter-related bloodstream infection (CRBSI)	0.17	0.10–0.28

Another population of patients at high risk of catheter dislocation is represented by critically ill patients in Intensive Care Unit, and specially COVID patients. Since the beginning of the COVID-19 pandemic, both the Italian Group of Venous Access Devices (GAVeCeLT) and the Italian Society of Anesthesia, Resuscitation and Intensive Care (SIAARTI) have released documents, in which they recommend subcutaneous anchorage as securement of COVID patients, in particular if treated by pronation.[13–15]

There is no evidence in the literature that the use of SAS may reduce (or increase) the risk of infection or thrombosis.[10] A recent retrospective study on over 7700 PICCs suggests that the cumulative incidence of central line associated bloodstream infections (CLABSI) may be higher in PICCs secured with skin-adhesive sutureless devices than in PICCs secured with SAS.[16]

The cost effectiveness of SAS has been demonstrated by some studies. The cost of one single SAS is higher if compared to the average cost of a skin-adhesive sutureless device: though, as the SAS needs not to be replaced and effectively avoids expensive complications such as loss of the venous access, an economic advantage is easily demonstrated,[8,17] when the catheter is meant to remain in place for more than 5–6 weeks or when a high risk of dislodgment is anticipated.

In our experience with SAS, which began in 2018, the clinical use of the device was preceded by an adequate training so to guarantee proper knowledge of the characteristics of the device and the correct techniques of placement and management.

Our data confirm that subcutaneously anchored securement of PICCs is associated with very low risk of dislodgment and that this risk is limited to non-collaborative patients. In this population of patients, SAS must surely be used as securement, but they are not enough, since some other strategies should be addes, such as tunneling the catheter so to move the exit site far from the hands of the patient (e.g. to the back or to the knee)[18] away to an area not reachable by the patient and safer during mobilization.

Our data also show that the choice of a SAS of adequate size is a crucial point. A careful control of the actual correspondence of the catheter diameter as declared by the manufacturers and the possible use of SAS of smaller size for some catheters may be a further protection against the risk of dislodgment.

In our experience, we consistently use cyanoacrylate glue in association with SAS. This strategy was not associated with any complication, but—on the contrary—allowed us to obtain simultaneously an adequate catheter securement and an optimal protection of the exit site.

The use of the cyanoacrylate glue in association with the SAS could be a limitation of this study itself, but any effect of the glue (on dislocation, on early infection, etc.) could still be a bias only for the complications of the first week, since after this period it does not reapplied.

In our study, the incidence of infection and thrombosis was very low. Though there is no hard evidence in the literature that the use of SAS reduces catheter-related infection and thrombosis,[10] it is possible that an adequate stabilization of the catheter may have reduced the thrombotic risk and that the elimination of "in and out" micromovement of the catheter at the exit site, as much as an optimal disinfection all around the exit site, might have reduced the risk infection. In fact, as regards infection prevention, it is reasonable that SAS may have acted as part of a bundle of preventive strategies including not only SAS but also skin antisepsis with 2% chlorhexidine, maximal barrier precautions, tunneling (when needed), and—last but not least—sealing of the exit site with cyanoacrylate glue.

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