


# GAVeCeLT-WoCoVA Consensus on subcutaneously anchored securement devices for the securement of venous catheters: Current evidence and recommendations for future research

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## Abstract

**Background:** Subcutaneously anchored securement devices (or subcutaneous engineered securement devices) have been introduced recently into the clinical practice, but the number of published studies is still scarce. The Italian Group of Long-Term Central Venous Access Devices (GAVeCeLT)—in collaboration with WoCoVA (World Congress on Vascular Access)—has developed a Consensus about the effectiveness, safety, and cost-effectiveness of such devices.

**Methods:** After the definition of a panel of experts, a systematic collection and review of the literature on subcutaneously anchored securement devices was performed. The panel has been divided in two working groups, one focusing on adult patients and the other on children and neonates.

**Results:** Although the quality of evidence is generally poor, since it is based mainly on non-controlled prospective studies, the panel has concluded that subcutaneously anchored securement devices are overall effective in reducing the risk of dislodgment and they appear to be safe in all categories of patients, being associated only with rare and negligible local adverse effects; cost-effectiveness is demonstrated—or highly likely—in specific populations of patients with long-term venous access and/or at high risk of dislodgment.

**Conclusion:** Subcutaneously anchored securement is a very promising strategy for avoiding dislodgment. Further studies are warranted, in particular for the purpose of defining (a) the best management of the anchoring device so to avoid local

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problems, (b) the patient populations in which it may be considered highly cost-effective and even mandatory, (c) the possible benefit in terms of reduction of other catheter-related complications such as venous thrombosis and/or infection, and—last but not least—(d) their impact on the workload and stress level of nurses taking care of the devices.

## Keywords

Biomaterials, new devices, nursing, oncology access, central venous catheters

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## Introduction

Subcutaneously anchored securement (SAS) of venous access devices (VAD) has been introduced into the clinical practice few years ago (SecurAcath™, Interrad Medical, Inc.) (Figure 1). In terms of applicability, SAS requires that at least 2–3 cm of the extra-cutaneous tract of the venous catheter should be available, so that there might be space enough for the placement of the securing device. This implies that the main field of application of SAS is central VAD. In fact, the placement of SAS may be impossible in short peripheral intra-venous cannulas (<6 cm long) and in long peripheral cannulas (so-called “mini-midline” or extended dwell devices, 6–15 cm long), though it may theoretically viable for standard midline catheters (>15 cm long). Also, SAS are available of appropriate size for different catheter sizes, from 3 Fr to 12 Fr, so that they cannot be applied to catheters smaller than 3 Fr or larger than 12–13 Fr.

Although SAS are currently used in clinical practice, clinical studies are few and there are not yet clear evidence-based recommendations about their use in terms of effectiveness, safety, and cost-effectiveness.<sup>1</sup>

The effectiveness of SAS in reducing the risk of dislodgement has been addressed in a few clinical studies published in peer-reviewed journals<sup>2–9</sup> and in many unpublished studies presented at international conferences as posters or oral presentations. All these studies have apparently confirmed the efficacy of the device. Although, some concern exists around the safety of SAS, that is, the possibility of adverse effects such as allergy, pain at placement or at removal, skin injury, and infection; this topic has also been addressed in the literature,<sup>3,7,8</sup> though not systematically, so that there are no clear data about the actual incidence of adverse effects and about the possible strategies for preventing them. Finally, cost-effectiveness of SAS has been specifically addressed in a few studies,<sup>5,8,9</sup> which all concluded in favor of SAS. Still, considering the not irrelevant cost of the device, it appears that the actual cost-effectiveness may vary in different populations of patients, as it is dependent on the percentage risk of dislodgement as well as on the scheduled duration of the venous access. Furthermore, SAS is currently used for

securing central VADs both in adults and in pediatric patients; effectiveness, safety, and cost-effectiveness may be different in neonates versus children versus adults.

Considering that the published evidence on effectiveness, safety, and cost-effectiveness of SAS is still scarce, the Italian Group of Central Long-Term Venous Access Devices (GAVeCeLT)—in collaboration with WoCoVA (World Congress on Vascular Access)—decided to develop a Consensus document on SAS, with the main goal of examining systematically the available literature on this topic and proposing the direction for further clinical research.

## Methods

A literature search was done in PubMed and in the Cochrane library in August–September 2018, with a subsequent update in August 2019. Search terms used were as follows: subcutaneously anchored securement system, subcutaneous engineered securement device, subcutaneous ESD, SecurAcath™, subcutaneously anchored sutureless device. The search was limited to the period 2012–2019, as SAS was not commercially available before 2012.

Given the type of study, in agreement with Helsinki declaration, it was deemed not applicable in this case to involve our Internal Review Board for approval.

A panel of GAVeCeLT experts in the area of vascular access devices was selected, based on their competence as proven by the studies available in the literature. The panel consisted of Italian experts either in adult or in pediatric and neonatal venous access. This panel of experts was divided into two working groups, one focused on adults and one on children and neonates.

A group of international experts from WoCoVA, not included in the two working groups, was selected for the final peer review of the document. See Table 1 for the list of GAVeCeLT experts in each working group and the WoCoVA experts selected as peer reviewers.

A questionnaire was prepared for each group. All questions were mainly focused on central VADs, as the field of application of SAS does not cover peripheral VADs, with the possible exception of standard midline catheters (>15



**Figure 1.** SecurAcath™, Interrad Medical, Inc.

**Table 1.** Panel of experts.

GAVeCeLT panel of Italian experts

- Coordinators
  - Fulvio Pinelli (Firenze)
  - Mauro Pittiruti (Roma)
- Adult working group
  - Roberto Biffi (Milano)
  - Giuseppe Capozzoli (Bolzano)
  - Adam Fabiani (Trieste)
  - Cristina Garrino (Torino)
  - Luca Montagnani (Aosta)
  - Stefano Elli (Monza)
  - Daniele Elisei (Macerata)
  - Giancarlo Scoppettuolo (Roma)
  - Pietro Zerla (Melegnano)
- Pediatric working group
  - Giovanni Barone (Rimini)
  - Alessandro Crocoli (Roma)
  - Ugo Graziano (Napoli)
  - Alessio Pini Prato (Alessandria)
  - Nicola Zadra (Padova)
  - Clelia Zanaboni (Genova)

WoCoVA panel of international experts for peer review

- Matthew Jones (United Kingdom)
- Evangelos Kostantinou (Greece)
- Liz Simcock (United Kingdom)
- Hervé Rosay (France)
- Marguerite Stas (Belgium)
- Ton Van Boxtel (The Netherlands)

cm long). The four questions were the same for both the adults working group and the pediatrics working group:

1. Is there evidence on the effectiveness of SAS in reducing the risk of dislodgment of VADs? Is further investigation warranted in this regard?
2. Is there evidence on the effectiveness of SAS in reducing the risk of venous thrombosis and

infection associated with the use of VADs? Is further investigation warranted in this regard?

3. Which are the undesirable effects of SAS and do we know how to prevent them?
4. Is there evidence about the cost-effectiveness of SAS? In which population of patients?

Each working group was provided with the most relevant papers found by searching the published literature. Seven published papers on SAS<sup>2-8</sup> were considered to be relevant for both working groups (see Table 2). The panelists were provided also with 18 abstracts of oral presentations or posters on SAS discussed in international conferences on vascular access; such “grey” literature was offered for the purpose of providing a wider information on the clinical experience with SAS, though the panelists were invited to base their answers on the published papers and on their own personal experience rather than on such additional literature.

An additional paper,<sup>9</sup> published online during the revision of the present document, was later forwarded to the panelists. Answers from the individual experts on each specific question were combined together in a narrative form, leading to a number of final statements with a proper degree of Consensus from the whole working group. This final document was eventually forwarded to a group of international experts from WoCoVA for a peer review and edited by the panel.

## Results

### *Part 1: the use of subcutaneously anchored sutureless systems for securement of VADs in adult patients*

1. Is there evidence on the effectiveness of SAS in reducing the risk of dislodgment of VADs in adult patients? Is further investigation warranted in this regard?

**Discussion.** The use of SAS for securement of VADs in adults has been addressed in a relatively small number of published clinical studies over the last few years. Most of these studies are prospective observational studies, sometimes with a retrospective control; only one randomized clinical study is available,<sup>7</sup> comparing SAS with an adhesive engineered securement device (StatLock™, Becton Dickinson, Franklin Lakes, NJ, USA), but the main endpoint of this trial was not the effectiveness. While many studies have addressed the role of SAS in securing peripherally inserted central catheters (PICC) (Figure 2), a few studies have also included securement of centrally inserted central catheters (CICC) (Figure 3) and femorally inserted central catheters (FICC) (Figure 4); both tunneled and non-tunneled catheters, both in silicon and in polyurethane, have been included in these trials.

**Table 2.** Published studies on SAS.

Study	Design	Population/ no. of patients	Catheter type	Primary outcome	Results	Dislodgment N (%)	Success rate	Adverse events	Cost analysis
Cordovani and Cooper <sup>3</sup>	Multicentre Prospective Observational	Adult/74	CICC 7 Fr	Successful securement	72(97%)	2(2.7%)	100%	None	No
Egan et al. <sup>2</sup>	Multicentre Prospective Observational	Adult/68	PICC 5 Fr	Successful securement	62(91.2%)	None	100%	6(8.8%)	No
Hughes <sup>4</sup>	Observational	Adult/31	PICC	Successful securement	30(96.7%)	One moved out of 1 cm (3.3%)	100%	25% difficult removal; 22.5% other	Yes
Dolcino et al. <sup>6</sup>	Prospective Observational retrospectively controlled	Pediatric/ 51	Tunneled- cuffed CICC	Incidence of dislodgment within first 30 days	2(1.1%)	2(1.1%)	NR	NR	No
Zerla et al. <sup>5</sup>	Prospective Observational	Adult/30	PICC 4 Fr	Incidence of dislodgment	None	None	NR	NR	Yes
Goossens et al. <sup>7</sup>	RCT (StatLock™ vs Securacath™)	Adult/105	PICC 4–5 Fr	Nursing time for dressing change	7.3 vs 4.3 min ( $p < 0.0001$ )	2(4.3%) vs 3(5.9%) $p = 1$			No
Pittiruti et al. <sup>8</sup>	Prospective Observational	Neonatal; Pediatric; Adult/190	PICC; CICC; FICC Tunneled/ untunneled	Successful securement	187(98.4%)	3(1.6%)	99%	5(2.6%) Local inflammation	Yes

SAS: subcutaneously anchored securement; NR: not reported; CICC: centrally inserted central catheters; PICC: peripherally inserted central catheters; FICC: femorally inserted central catheters.



**Figure 2.** PICC secured with SAS + wing secured by skin adhesive securement (StatLock™).

Considering the overall results of the published studies, it appears that the SAS is highly effective, since the risk of dislodgment varies in most papers from 0%<sup>2,5</sup> to nearly 3%;<sup>3,8</sup> one paper has reported a minor dislodgment of 1 cm (3.3%),<sup>4</sup> while one randomized clinical trial has reported a 5.9% rate of failure.<sup>7</sup> Although, in this



**Figure 3.** CICC secured with SAS in a pediatric patient.

randomized study, the final result was that SAS was not inferior to the skin-adhesive sutureless securement.

The interpretation of such results is somewhat difficult, considering that the effectiveness of SAS in avoiding the dislodgment of the VAD depends also on factors independent from the device itself but related to the technique of insertion and to the training of the operator. For example, the erroneous placement of the nitinol bars of the SAS inside the layers of the skin and not—as recommended—in the subcutaneous tissue is associated with a high risk of



**Figure 4.** FICC secured with SAS.



**Figure 5.** SAS-related skin damage with exteriorization of nitinol bar.

decubitus of the bars (Figure 5) with subsequent local inflammation and dislocation of the SAS.

Also, the choice of an incorrect sized SAS for the catheters external diameter/French size may result in loss of the catheter by sliding through the SAS, while the SAS remains in place. In at least one paper<sup>8</sup> reporting three different prospective clinical studies in which the SAS was inserted by health operators—either trained or non-trained—the best results (zero dislodgements) were achieved in the study where all SAS were placed by competent staff. Another possible cause of failure is that the mismatch between the size of the catheter and the size of the SAS is not related to an error of the operator (e.g. use of a 4 Fr SAS for securing a 3 Fr catheter) but to some inconsistency of the caliber of the catheter as stated by the manufacturer.

However, failure may be also secondary to the use of SAS in a patient population with a very high risk of accidental dislodgment regardless of the type of securement;

for instance, in at least one of the published papers examined,<sup>8</sup> SAS was not always effective in non-cooperative aged patients with cognitive disorders, that is, in a category of patients with a very high risk of involuntary removal of VAD, even when secured with sutures. Probably, this is a patient population where the stabilization of the VAD should be obtained not just by the choice of securement but also by other strategies (e.g. tunneling the VAD so to obtain an exit site in a location out of reach of the hands of the patient; and/or choosing a totally implantable VAD).

Another bias of the few published studies is the very small number of patients (in most cases, 30–50) in each trial. However, at the time of the revision of the present document, a new clinical study was published<sup>9</sup>—a prospective observational study with a retrospective control group—where SAS was used in more than 1000 patients, with maximal efficacy (no dislodgment). The results of this large study are consistent with the results of all the clinical studies on SAS which have been published or presented in international conferences as posters or oral presentations in the last few years. In studies where different types of central VADs were considered, there was no difference between PICC, CICC, or FICC in terms of effectiveness of SAS.

Another problem is the definition of “dislodgment,” which ranges from the partial dislodgment of few millimeters or centimeters to the complete loss of the catheter. It appears from the literature, and from the clinical experience, that adhesive sutureless securement devices are particularly prone to “partial” or “minimal” dislodgment, whereas “dislodgment” of a device secured with a SAS is usually associated to the complete loss of the line. Partial or minimal dislodgments are usually tolerated, but a device like a SAS may have some additional advantage since it also avoids such minimal movements that may be potentially harmful.

Another critical point is the duration of effectiveness of SAS, which is still unclear. Different studies, both published and unpublished, report SAS staying in place for weeks and even for months; but no study has specifically addressed this aspect. This is particularly important in patients who have a PICC or other external VAD in situ for a prolonged period of time, as patients undergoing chemotherapy or receiving home parenteral nutrition.

In so far, as many of these issues require further definition by randomized clinical trials, it is also true that a comparison between SAS and securement by sutures is potentially illogical or even unethical. In this regard, the actual standard of securement to be compared with SAS should be more properly defined (Adhesive securement devices? And which type? With or without transparent semipermeable membranes? With or without cyanoacrylate glue? Other?).

**Conclusions of the panel.** Although the overall scientific quality of the clinical studies is poor, since in most cases

SAS has been tested in prospective non-controlled observational trials, all the literature works support the overall effectiveness of SAS in reducing the risk of dislodgment when used for securing PICCs and other types of central VADs in adult patients.

Further investigation is surely warranted in this area; future prospective controlled trials should be carefully designed taking care of different aspects:

- (a) Appropriate choice of the patient population, considering that SAS might be particularly indicated in some clinical situations (oncological patients with medium- to long-term central VADs, long-term parenteral nutrition, PICC dwell duration of more than 4–6 weeks, patients with skin abnormalities that limit the use of skin adhesive sutureless devices, etc.).
  - (b) The control group should be carefully defined: as securement by stitches should be generally avoided according to most recommendations,<sup>1</sup> controls should include a well-defined strategy of sutureless securement (e.g. skin adhesive sutureless system + cyanoacrylate glue + semipermeable transparent membrane).
  - (c) The endpoint should be carefully defined, including both partial dislodgment and complete dislodgment.
  - (d) The health operators participating to the study should be specifically trained in the management of SAS.
2. Is there evidence on the effectiveness of SAS in reducing the risk of venous thrombosis and infection associated with the use of VADs in adult patients?<sup>2</sup> Is further investigation warranted in this regard?

**Discussion.** From the analysis of the currently available literature, there is no evidence that the use of SAS might be associated with a reduction of the risk of catheter-related thrombosis and catheter-related infection (either infection of the exit site or bloodstream infection). The only data that suggest a low incidence of such complications in VADs secured with SAS are derived from observational non-controlled studies,<sup>4,5</sup> in which such benefit is more “perceived” by the clinician than demonstrated.

However, there are some theoretical basis for such potential benefits. In the majority of studies, SAS reduces the risk of minimal in-and-out movements of the catheter at the exit site, movements which are known to increase bacterial contamination by the extraluminal route.

Also, securement by SAS allows a more accurate antiseptics of the exit site during dressing change, and this might be effective in reducing bacterial contamination. Interestingly, SAS does not interfere with the utilization of other strategies for reducing extraluminal bacterial

contamination, such as skin antiseptics with 2% chlorhexidine in alcohol, semipermeable transparent dressings, chlorhexidine-releasing sponge dressings, tunneling of the catheter, or sealing the exit site with cyanoacrylate glue. In particular, the simultaneous use of SAS and glue may be highly advantageous, since cyanoacrylate will prevent any bleeding from the breach after placement of SAS and seal the exit site avoiding the entrance of bacteria into the skin.

Catheter-related thrombosis (CRT) is a complication caused by multiple factors, both patient-related and iatrogenic. The current strategies for reducing the risk of CRT include at least four recommendations that have a direct impact on the insertion technique of the catheter: (a) proper match between catheter caliber and vein diameter, (b) minimization of trauma to the vein wall using ultrasound guided venipuncture, (c) appropriate location of the tip of the catheter, and (d) maximal stabilization of the catheter at the exit site.<sup>10,11</sup> The use of SAS may have some impact on the risk of CRT by improving stabilization of the catheter.

**Conclusions of the panel.** There is no evidence about the effectiveness of SAS in reducing the risk of venous thrombosis and infection associated with the use of VADs. Since these beneficial effects are supported by a theoretical rationale, further studies are warranted in this area, preferably as randomized clinical studies with the following characteristics: (a) homogeneity of patient population in terms of risk of infection or CRT, (b) proper definition of the primary endpoint (reduction of complications such as infection of the exit site or CRBSI or CRT) and proper criteria of diagnosis of such complications, (c) proper definitions of the strategies used for preventing infection and/or CRT in the study group and in controls, and (d) proper definition of the securement adopted in the control group.

3. Which are the undesirable effects of SAS in adult patients and do we know how to prevent them?

**Discussion.** Several potential undesirable effects of SAS have been discussed in the literature: allergic reaction to the metallic component of the device, bleeding at the time of insertion, acute local inflammation, local granuloma at the site of insertion, local pain during placement or during maintenance or at removal.

The concern about allergy seems inconsistent: no case of allergy to nitinol (a metallic compound of nickel and titanium) is reported in the literature, and there is no cross-allergy reported between nickel and nitinol.

Bleeding at the exit site is not specifically reported in the literature and probably it may be completely prevented by the use of cyanoacrylate glue for sealing the exit site after SAS placement.

However, acute or chronic local inflammation at the site of insertion of SAS has been reported in the literature in a variable percentage of cases. Most authors correlate this

complication with an incorrect placement of the nitinol bars inside the layers of the skin and not—as recommended—deep in the subcutaneous tissue. This may happen because of insufficient training of the health operator or because of actual difficulties related to the patient (abnormalities of the skin and/or of the subcutaneous tissue). When the nitinol bars are located too superficially, inside the layers of the skin, local inflammation occurs, either chronic or acute, with the development of a local granuloma and/or infection of the exit site. It is also possible that an SAS—well-placed at first—may slowly migrate more superficially with the passing of time, possibly also as an effect of inappropriate traction during dressing change. The actual incidence of such complication ranges between 0% and 7% in different studies. Variability is obviously related to the different training of the operators, often not stated in the papers.

Local pain during SAS placement has not been described in the literature, since most insertions of central VADs in adult patients imply the infiltration of the puncture site/exit site with local anesthetic.

Local pain during maintenance has been rarely described. It may be secondary to local inflammation, or to the accidental traction of the SAS during dressing change, or to the pressure of the plastic body of the SAS against the skin. As regards the latter phenomenon, even if not recommended by the instructions for use (IFU), some clinicians place a gauze or some other soft sterile tissue under the body of the SAS, in order to relieve pressure to the skin (Figure 1): the actual effectiveness of this strategy is unknown. In one study,<sup>7</sup> the incidence of local pain was particularly high. As most studies offer little information about the level of training of the operators and about the details of SAS placement, no strong conclusion can be drawn about the incidence of this complication when SAS management is standardized and optimized.

Local pain at removal is a more common concern, which occurs in 2%–20% of cases<sup>4,5,8</sup> and it is often associated with local signs of inflammation.<sup>8</sup> The currently recommended technique of removal (splitting the body of the SAS in two halves using scissors) is effective in reducing pain at removal.<sup>4</sup> Nevertheless, this maneuver must be performed by trained clinicians for the risk of cutting the catheter. When there is evidence of local inflammation or granuloma, or when the patient is particularly sensitive, removal under local anesthesia (either by topical ointment or by local injection) may be warranted.

**Conclusions of the panel.** Several undesirable local effects related to SAS have been described, the most relevant being acute/chronic inflammation of the exit site and pain at removal. The real incidence of these local problems is difficult to quantify, because of the semi-anecdotal nature of the observations and the variety or uncertainty of the techniques used for SAS placement and SAS removal.

Further controlled clinical studies are needed, so to optimize the technique of SAS placement (local anesthesia, skin antiseptics, proper insertion of the nitinol bars deeply into the subcutaneous tissue, sealing with cyanoacrylate, etc.), the technique of SAS maintenance (avoidance of traction, definition of the role of gauze/tissue under the SAS, etc.), and the technique of removal (wise use of local anesthesia when needed, splitting the SAS in two, etc.).

4. Is there evidence about the cost-effectiveness of SAS in adult patients? In which population of patients?

**Discussion.** There is evidence supporting the cost-effectiveness of SAS if compared to skin-adhesive sutureless securement only in specific subsets of patients. All studies have compared SAS with adhesive securement; a comparison between SAS and securement by stitches would be illogical, considering that current guidelines<sup>1,12</sup> strongly recommend avoiding sutures as means of securement of VADs. The theoretical rationale for the cost-effectiveness of SAS is (a) avoidance of expenses related to VAD replacement after dislodgment; (b) cost saving in terms of material, since adhesive securement must be replaced weekly, while SAS stays in place indefinitely; (c) avoidance of potentially expensive complications related to adhesive securement (MARS = Medical Adhesive-Related Skin Injury); and (d) cost saving in terms of time when changing the dressing. This last issue has been specifically addressed in the only randomized controlled study currently available on SAS,<sup>7</sup> which has provided evidence for cost-effectiveness in terms of reducing nursing time and stress during exit site care.

Therefore, it is apparent that SAS will have a strong cost-effectiveness particularly when adopted (a) in patient populations at high risk for catheter dislodgment, (b) in patients who will probably use the VAD for long period of time, and (c) in patient populations at high risk for MARS.

The analysis conducted by NICE (National Institute for Clinical Excellence)<sup>13</sup> has demonstrated the cost-effectiveness of SAS over adhesive securement for VADs with medium- to long-term duration. Cost-effectiveness has also been demonstrated for PICCs in a small group of hospitalized patients<sup>5</sup> and more recently in a vast group of more than 1000 patients with PICC<sup>9</sup> in a paper published during the final revision of the present document. Cost-effectiveness has also been proven in oncology patients with PICC for more than 8 weeks, in non-compliant aged patients with different kinds of central VADs, in patients with skin abnormalities that may reduce the effectiveness of a skin adhesive sutureless securement, and in any patient with a high risk of VAD dislodgement.

Some uncertainty still exists about the actual cut-off of cost-effectiveness in terms of predicted duration of the

VAD: 2–4 weeks,<sup>13</sup> 8 weeks,<sup>8</sup> or otherwise. Also, it is likely that in the extra-hospital setting (home care, hospice, outpatients' clinic) the risk of dislodgment might be higher than in hospitalized patients, with a different cut-off time of cost-effectiveness.

Should the effectiveness of SAS in reducing infection and thrombosis be demonstrated by future clinical studies, as postulated by some authors, this fact may further change the analysis of cost-effectiveness.

**Conclusions of the panel.** There is evidence of cost-effectiveness of SAS if compared to skin adhesive securement, particularly in selected categories of adult patients such as patients with central VADs for more than 4 weeks (especially if not hospitalized), in non-collaborative older patients with cognitive disorders (even if, in such subsets of patients, the effectiveness of SAS might be lower than 100%), in patients with skin disorders that may reduce the applicability or effectiveness of adhesive securement, and in all patients with a high risk of VAD dislodgment.

## Part 2: the use of SAS for securement of VADs in children and neonates

1. Is there evidence on the effectiveness of SAS in reducing the risk of dislodgment of VADs in children and neonates? Is further investigation warranted in this regard?

**Discussion.** SAS have been used by several centers, particularly in Italy, both for children and for neonates (Figure 3). The available calibers of SAS (from 3 Fr to 12 Fr) make them appropriate only for central catheters of 3 Fr or more and not—for example—for the epicutaneo-caval catheters (ECCs) used in neonates, which have a caliber ranging from 1 Fr to 2.7 Fr.

Most of the evidence on the effectiveness of SAS in the pediatric population is based on extrapolation of results obtained in adult patients, on two published papers on pediatric patients,<sup>6,8</sup> on some reports presented as posters or oral presentation in international conferences, and on unpublished data from Italian clinical centers. Focusing exclusively on published literature, two papers are available. In the first paper,<sup>6</sup> SAS was used as an additional securement strategy in tunneled-cuffed long-term central VADs in children; SAS was 99% effective in reducing dislodgment. This was a non-controlled study comparing a double securement strategy (SAS + cuff) with a simple securement strategy (cuff).

The second paper<sup>8</sup> reported a prospective, observational, non-controlled study with some interesting specific features: both children and neonates were included, as long as they had a central VAD (PICC, FICC, or CICC) of 3 Fr or more; securement was achieved by SAS alone;

most of patients had also cyanoacrylate glue on the exit site, so to reduce local bleeding and extraluminal bacterial contamination. In this study, SAS effectiveness in preventing dislodgment was 99%.

**Conclusions of the panel.** Although good evidence is still missing, preliminary clinical experience suggests that SAS may be effective in reducing the risk of dislodgment in children and neonates, in both tunneled and non-tunneled, cuffed and non-cuffed central VAD, as long as SAS is applicable (caliber 3 Fr or more).

Further investigation in this regard is warranted; in particular, we need randomized clinical studies comparing SAS and adhesive securement. It is advisable that such studies should address different populations of pediatric patients, with a clear definition of the VAD under investigation (PICC vs FICC vs CICC; tunneled or non-tunneled; cuffed or non-cuffed; in silicon or in polyurethane) and a primary endpoint that should take into account both partial and total dislodgment.

2. Is there evidence of the effectiveness of SAS in reducing the risk of venous thrombosis and infection associated with the use of VADs in children and neonates? Is further investigation warranted in this regard?

**Discussion.** There is no evidence about the potential effectiveness of SAS in reducing the risk of venous thrombosis and infection related to central VAD, although the theoretical rationale (as explained above, in the adult section) is quite convincing.

Improved stabilization by SAS may be protective in preventing CRT and infection. Since the etiopathogenesis of these complications is multifactorial, it may be hard to design a study of appropriate statistical power to prove this contention.

**Conclusions of the panel.** Further investigation is warranted in this area. In particular, as mentioned in the adult section, we need randomized clinical studies with the following characteristics:

- (a) Homogeneity of patient population in terms of risk of infection or CRT.
- (b) Proper definition of the primary endpoint (reduction of complications such as infection of the exit site or CRBSI or CRT) and proper criteria of diagnosis of each complication.
- (c) Proper definition of the strategies used for preventing infection and/or CRT in the study group and in controls.
- (d) Proper definition of the securement adopted in the control group.

3. What are the undesirable effects of SAS in children and neonates and do we know how to prevent them?

**Discussion.** The two published studies on SAS in pediatric patients report a negligible incidence of undesirable effects. In one controlled, non-randomized study<sup>6</sup> about the use of SAS as additional securement in children with tunneled-cuffed catheters, no undesirable effects caused by SAS were reported.

In one prospective, non-controlled study<sup>8</sup> about the adoption of SAS as the only securement strategy for different central VADs in neonates and children, no difficulty or pain at SAS insertion was reported (which is logical, since most VAD insertions were performed under sedation or general anesthesia); pain or discomfort during maintenance was described in 5% of cases, of which one case had local inflammation; no pain or discomfort at removal was reported.

Discomfort during maintenance might also be related to inappropriate traction exerted on the SAS during dressing change; to avoid such traction, some authors secure the wing of the VAD (not included in the SAS securement) with an adhesive securement device (Figure 2).

Interestingly, both in the published and in the unpublished clinical experiences of SAS in pediatric patients, most clinicians have placed a sterile gauze or tissue below the body of the SAS, concerned by the risk of pressure ulcer on the fragile skin of neonates and infants. Whether this maneuver—not recommended by the IFUs—is useful or not, is still uncertain and it could form the basis of future investigations.

**Conclusions of the panel.** Preliminary reports suggest that undesirable effects of SAS appear to be negligible in children and in neonates. The experience in this field is still scarce, and most probably, we need detailed instructions for SAS management specifically tailored on neonatal and pediatric patients.

4. Is there evidence about the cost-effectiveness of SAS? In which population of patients?

**Discussion.** Considering that the event of catheter dislodgment implies higher costs in the pediatric patient when compared to adults, common clinical sense suggests that—since SAS is highly effective in children and in neonates—it should also be highly cost-effective. The non-controlled, observational study previously quoted<sup>8</sup> reported a clear cost-effectiveness, though a detailed cost-analysis was not performed.

More clinical trials are obviously warranted in this area, with special attention to special clinical conditions, which should be addressed separately and systematically (CICC in neonates, FICC in neonates, short term central VADs in children, long-term central VADs in children, etc.).

**Conclusions of the panel.** Although cost-effectiveness of SAS in children and neonates is intuitive, it is supported only by one published study, so that this area is open to future studies.

## Conclusion

Subcutaneously anchored securement devices (or subcutaneous engineered securement devices) have been introduced recently in the clinical practice, but the number of published studies addressing their effectiveness, safety, and cost-effectiveness is still scarce. The panel of our Consensus, after revising the available evidence, has concluded as follows:

SAS is effective in reducing the risk of dislodgment when used for securing PICCs and other types of central VADs in adult patients as well as in children and neonates.

There is no evidence that SAS may be effective in reducing other catheter-related complications such as venous thrombosis or exit site infection or bloodstream infection. There is no evidence either that they might increase the incidence of these or other major catheter-related complications.

SAS is associated with a low incidence of undesirable effects—most of them local and of low clinical relevance—which probably can be minimized by appropriate prevention and management.

Cost-effectiveness of SAS is demonstrated for central VADs staying in place for more than few weeks, and it is highly likely for all patients at high risk of dislodgment (children, neonates, non-compliant older patients, patients with skin abnormalities that makes them unsuitable for adhesive securement), independently from the expected duration of the VAD.

Efficacy and safety of SAS depend on their appropriate use by health practitioners; therefore, knowledge and training of personnel are crucial aspects.


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