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Defining the indications of subcutaneously anchored securement devices: a European point of view

Mauro Pittiruti

Catholic University Hospital, Rome - Italy

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Securement power hour

Probably, glue and subcutaneously anchored sutureless devices (SAS) have been the two most important novelties to change our clinical practice in the management of the exit site of VADs in the last few years.

Glue & SAS

- They are both highly effective
- They may act synergistically in reducing all the potential complications of the exit site:
 - Bleeding
 - bacterial contamination
 - dislodgement

Glue...

The safety and the cost-effectiveness of the cyano-acrylate glue is obvious and easy to prove:

- The event of allergic reactions to glue is more theoretical than real
- Glue is safe, even on the skin of premature newborns
- There is no known interaction between glue and the material of the VADs
- The cost of one 0.25ml vial of glue - in our Hospital - is approximately \$ 3,00

... SAS

The safety and the cost-effectiveness of SAS still requires some investigation:

- There are some concerns about the safety (pain at insertion/pain at removal/skin lesions)
- There are some concerns about the cost-effectiveness (in our hospital, the cost of one SAS is approximately \$ 35,00)

SAS (SecuraCath)

We recently carried out two separate prospective clinical studies:

Study A: Use of SAS in all cancer patients candidate to PICC insertion for > 2 months of chemotherapy in a extra-hospital setting.

Study B: Use of SAS in selected groups of patients which may potentially benefit from SAS (high risk of central line dislodgement)

Study A

We prospectively enrolled 50 oncological patients candidate to 4Fr or 5Fr power injectable PICCs for chemotherapy (extra-hospital use, expected duration > 2 months). All PICCs were inserted according to the SIP protocol and managed according to the hospital policies.

PICC Insertion protocol (SIP protocol)

1. Hand washing, aseptic technique and maximal barrier protection
2. Bilateral US scan of all veins at arm and neck
3. Choice of the appropriate vein at midarm (vein mm = or > cath Fr)
4. Clear identification of median nerve and brachial artery
5. Ultrasound guided venipuncture
6. US scan of IJV during introduction of the PICC
7. EKG method for assessing tip position
8. Securing the PICC with a sutureless device

Hospital policies for PICC maintenance

Care of the exit site

transparent dressings only

dressing change every 7 days

skin antisepsis with 2% CHG

Care of the infusion line

flush with saline, before and after each infusion

lock with saline only

port protectors for disinfection of the hubs

Study A - results

- SAS was placed in 48 PICCs.
- In 28/48, glue was also used on the exit site.
- Results:
 - no pain or difficulty at SAS insertion;
 - duration of PICCs: 2-9 months (26 pts), > 9 months (18 pts), < 2 months (4 pts);
 - one case of skin irritation (no glue);
 - no SAS was removed because of SAS-related complications;
 - at PICC removal, we saw some degree of pain in 5 patients (in 2/5 cases, signs of local inflammation).



Study A - comments

- SAS was effective in **100%** of cases
- SAS was also cost-effective, considering that (a) it saved \$ 6,00 per week (cost of one Statlock) and (b) it avoided an expected rate of dislodgement of 8-10% (previous experience in similar group of patients)
- In > 50% of cases, SAS was used in association with glue, with no apparent problem

Study A – comments (2)

- If placed by expert clinicians, insertion is easy and painless
- During maintenance, no significant complications are expected
- At removal, local anesthetic might be indicated, in selected cases

Study B - results

- SAS was placed in **47** central lines (18 CICC, 4-7Fr + 29 PICCs, 4-5Fr):
 - **11** non-collaborative elderly patients (71-87 y.o)
 - **22** patients with history of previous accidental removal of central lines
 - **8** pediatric patients (3-12 y.o.)
 - **6** patients with special skin problems such as hyperhidrosis, allergy, etc.
- In 17/47, glue was also used on the exit site.
- 6 PICCs were tunneled.

Elderly patients



CICC



Tunneled FICC



Tunneled CICC in neonate





Skin problems

Study B – results (2)

Results:

- duration of the line 1 day – 3 months (median 2 weeks);
- two cases of difficulty at insertion;
- two accidental removals (both in dementia elderly patients);
- At removal, some degree of pain in 5 patients (in 2/5 cases, signs of local inflammation).

Study B – comments

- SAS was effective in 100% of children and in 100% of adult collaborative patients – though, it may not 100% effective in dementia patients.
- SAS was highly cost-effective, considering that the expected risk of dislodgement in this group of patients was 50%
- At removal, we hypothesize that local anesthetic might be indicated, in selected cases

Conclusions for Studies A+B

- SAS was effective in preventing dislodgement in 98% of patients
- SAS was cost effective in both studies
 - Cost effectiveness should be maximal in patients with high expected risk of dislodgement (>10%) and/or for central lines expected to stay in place for > 6 weeks

Conclusions for Studies A+B (2)

- Complications at insertion, maintenance and removal were minimal
- Still, placement and removal should be done by expert clinicians
- In selected cases (specially in presence of inflammation of the exit site), local anesthetic might be indicated during removal

A few tips we learned from the field...

Tip #1

Placement of SAS is easier if the incision at the exit site is not too small:

- To place the SAS properly, you must put the 'anchor' as deep as possible under the skin
- Do not worry about the risk of bleeding: put glue



Tip #2

During maintenance, make sure that the 'shell' of the SAS is not at direct contact with the skin (specially in neonates and infants)

Also, make sure that shell is slightly higher than the anchor, so that the anchor does not exert pressure on the skin from below



Tip #3

Removal by splitting the shell in two (cutting with scissors) is faster and less painful.

If there are local signs of chronic inflammation, use local anesthesia.





A few more considerations...

Glue & SAS go together well

- SAS should be placed BEFORE placement of glue at the exit site



Glue & SAS go together well

- Synergistic effect?
 - Glue stops bleeding
 - SAS & glue reduce the risk of bacterial contamination
 - Glue seals the exit site
 - SAS avoid stitches and allows accurate antisepsis of the exit site
 - SAS & glue reduce the risk of dislodgement
 - Glue for the first 7-10 days
 - SAS for the whole duration of the line

SAS & kids go together well

SAS was extremely well tolerated by children and neonates:

- No problem at insertion (sedation/anesthesia)
- No skin reactions or any other problem during maintenance
- No pain or difficulty at removal (no local anesthesia needed)

SAS & kids go together well



SAS & tunneling go together well

- The simultaneous adoption of SAS (stabilization) and tunneling (prevention of extraluminal contamination) changes the VAD into a long term VAD !!!
- Tunneled CICC (or PICC) secured with SAS = equivalent to a tunneled-cuffed CICC (or PICC)

SAS & tunneling go together well



Tunneled PICCs

SAS & insertion bundles go together well

- SAS is ideal with insertion bundles to prevent infection
 - SAS avoids stitches
 - SAS prevents movements of the catheter inside the skin breach at the exit site
 - SAS allows accurate skin antisepsis all around the exit site; can be used with biopatch, too
- SAS is ideal with insertion bundles to prevent thrombosis
 - SAS prevents movements of the catheter inside the vein

The bottom line

In our hospital:

- We are currently using SAS in all central lines of neonates or children at potential risk for dislodgement
- We are currently using SAS in patients with skin problems which may prevent the use of traditional sutureless devices
- We are currently planning to include into the hospital policy the recommendation of using SAS in all PICCs inserted in extra-hospital patients, with expected duration > 6 weeks

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Thank you for your attention!

mauro.pittiruti@rm.unicatt.it

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