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**The subcutaneously anchored  
sutureless device: the new gold  
standard for catheter securement**

**Mauro Pittiruti**

# The subcutaneously anchored sutureless device

About the Presenter: ***Mauro Pittiruti***



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Coordinator of a Multi-professional Vascular Access Team  
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of Venous Access Devices)

Co-founder of WoCoVA Foundation (World Conference on  
Vascular Access)

## Financial Disclosures

*I have no financial relationships to disclose.*

*In all my presentations I discuss the off label use of many devices, since we strongly believe (a) that wise and evidence-based clinical choices are often in contrast with the manufacturer's recommendations and (b) that the patient's benefit is our priority but it may not always be the manufacturer's priority.*

# Subcutaneously Anchored System= SAS

As with any new device, it is a question of

**Effectiveness**

**Cost-effectiveness**

**Safety**

# SAS

The safety and the cost-effectiveness of SAS have been defined only recently:

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

# SAS in our hospital

We 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.

# 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, some degree of pain in 5 patients (in 2/5 cases, signs of local inflammation).





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# 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 traditional sutureless device) 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
- Removal should be performed by trained operators

# Study B - results

- SAS was placed in 47 central lines (18 CICC, 4-7Fr + 29 PICC, 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.



CICC

## Elderly patients



Tunneled FICC

## CICCs in adult patients





Tunneled CICC in neonate





## Skin problems





Skin problems



?

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# 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%
- Removal should be performed by trained operators

# 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

# Cost effectiveness has been proven by a recent Italian study

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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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## Cost effectiveness has been proven by a recent Italian study

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

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

# Our latest study

## Study C

- We used SAS for all tunnelled central lines (CICCs and PICCs) in neonates and children. All catheters were inserted according to our insertion bundle for pediatric central lines (ultrasound guidance, modified Seldinger technique by micro-introducer, tip location by intracavitary ECG, cyanoacrylate glue for the closure of the puncture site and for the sealing of the exit site, transparent dressing).



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# Study C - results

- 85 central lines (3-4Fr power injectable polyurethane catheters: 48 CICC + 37 PICC) were secured with SAS in 73 patients (age range 20 days to 12 years).
- All SAS were easy to place and the duration of the line ranged from 5 day to 7 months (median 3 weeks).
- We had only one accidental removal (associated with skin erosion related to the SAS).
- SAS removal – performed by splitting in two halves with scissors - did not require sedation or local anesthesia and was easy and uneventful in all cases.

# Study C - comments

- SAS was effective in preventing dislocation in 99% of patients.
- Complications at insertion, during maintenance and at removal were negligible.

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



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# 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.



# Tip #4

When securing a PICC with a SAS, particularly in a very active child, it may be wise to add a standard sutureless device, so to avoid accidental traction on the SAS

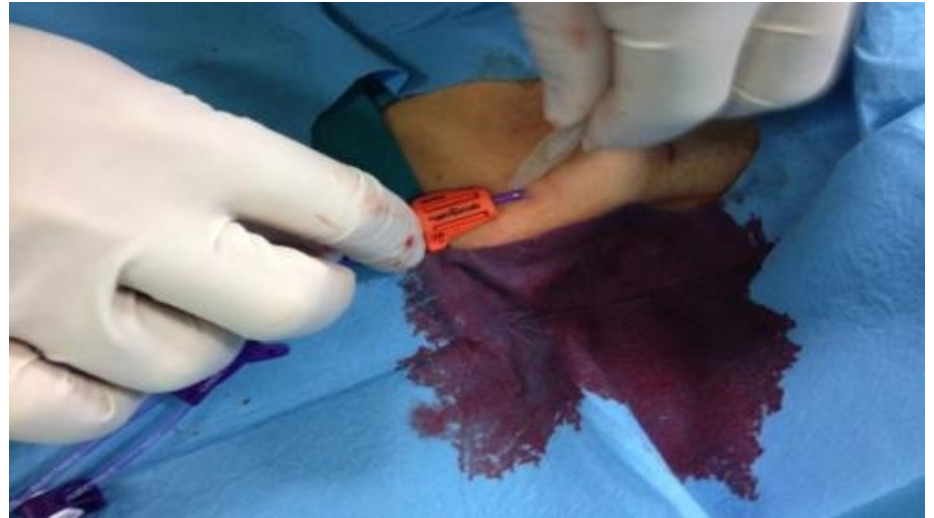


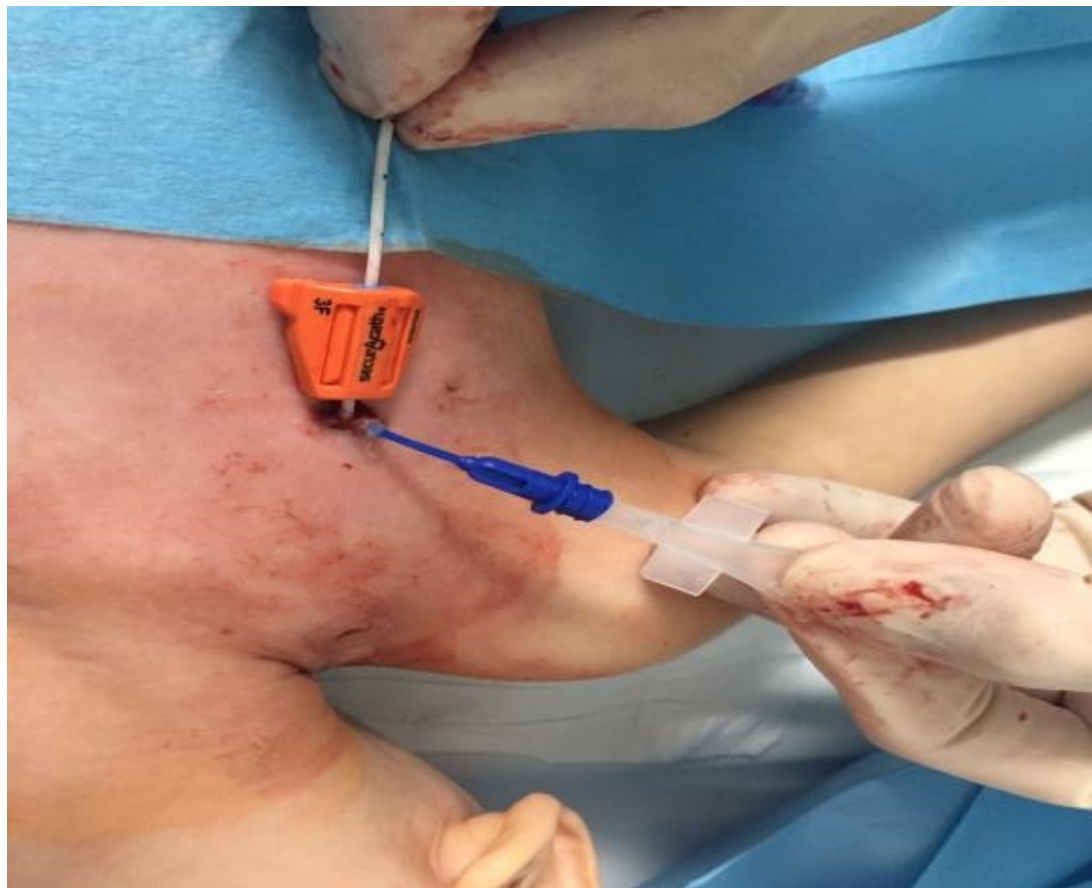
A few more considerations...



# Glue & SAS go together well

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





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# 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 dislocation
    - Glue for the first 7-10 days
    - SAS for the whole duration of the line

# SAS & kids go together well

SAS is 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 & kids go together well



Also in premature newborns

# 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





# Tunneled CICC in adult



Tunneled CICC in a child

# Tunnelled FICCs



# Tunnelled FICCs



# Another recent Italian study suggest that also tunnelled central lines should be secured by SAS in children

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ORIGINAL RESEARCH ARTICLE

## Potential role of a subcutaneously anchored securement device in preventing dislodgment of tunneled-cuffed central venous devices in pediatric patients

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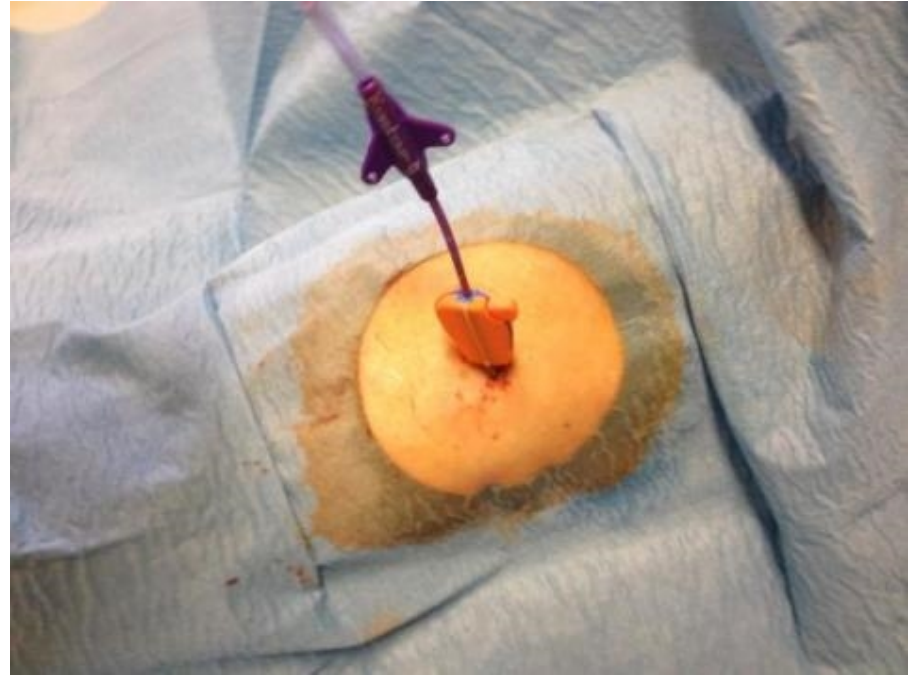
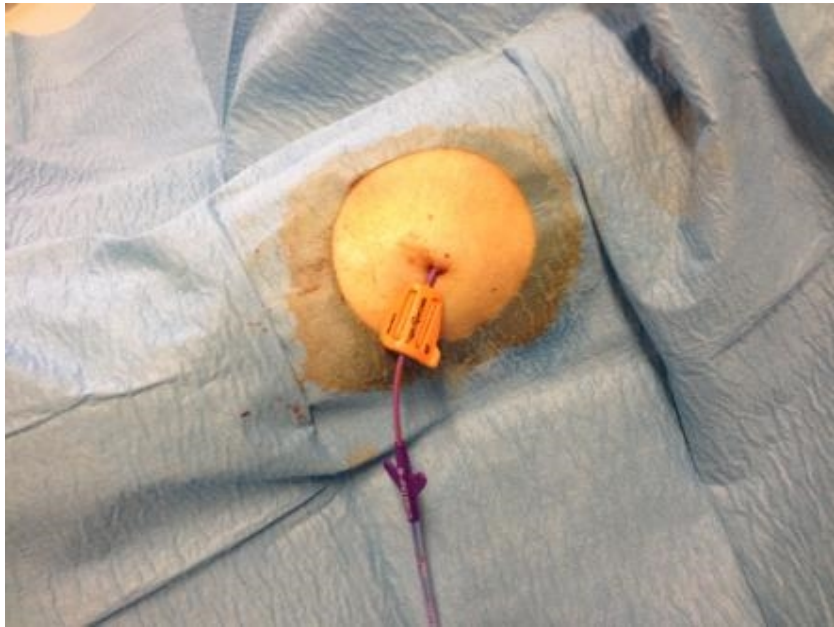
Another recent Italian study suggest that also tunnelled central lines should be secured by SAS in children

## **Conclusion**

In our study on children with CVCs, dislodgment was the complication confirmed to be the most frequently reported problem. The results of our series of patients suggest that the use of SAS significantly reduces the incidence of dislodgment in high-risk patients, particularly in the very first postoperative period. Based on these results, we strongly suggest that this new securement device be adopted for the whole life of every tunneled CVC and during the first 3 to 4 weeks after positioning for all cuffed CVCs, particularly in infants and toddlers.

# 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



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## SAS is ok also in patients with nichel allergy

- The anchor is nitinol (a metal alloy of nichel and titanium)
- The event of a cross-allergy between nichel and titanium is theoretically possible, but never described in the literature

# SAS is ok also in patients who need a MR

- The device is certified to be MRI-compatible

# SAS can be placed also days of weeks after insertion of the catheter

- In selected patients (typically: patients who show signs of intolerance to the traditional sutureless devices and/or to transparent dressing)
- It is feasible only if the external tract of the catheter is at least 2cm long
- Local anesthesia is recommended
- Pay attention not to damage the catheter
- Add glue around the exit site



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# The bottom line

In our hospital:

- We are currently using SAS in a vast variety of conditions, in different patient populations, as the gold standard for catheter securement

# Our policy (1):

We use SAS routinely in all central lines (PICC, CICC and FICC), either tunnelled or non-tunnelled placed **in all neonates and children**, with few exceptions (epicutaneo-caval catheters in neonates; emergency central lines; catheters with caliber > 8Fr).

# Our policy (2)

We use SAS for central venous catheters (PICC, CICC, FICC) in **selected adult patients:**

1. Patients with expected ineffectiveness of traditional sutureless devices because of skin issues (allergy, diffuse skin disease, burns, high perspiration, eritrodermia, etc.)
2. Patients whose central line (PICC, CICC, FICC) is expected to be used in an outpatient setting for more than 6 weeks
3. Patients at high risk of dislodgement (non-collaborative, restless, frequently mobilized, etc.)

# Our policy (3):

SAS is also used in neurosurgery (particularly in children) for the securement of cranial and spinal catheters.

*World Neurosurg. (2016) 93:1-5.*



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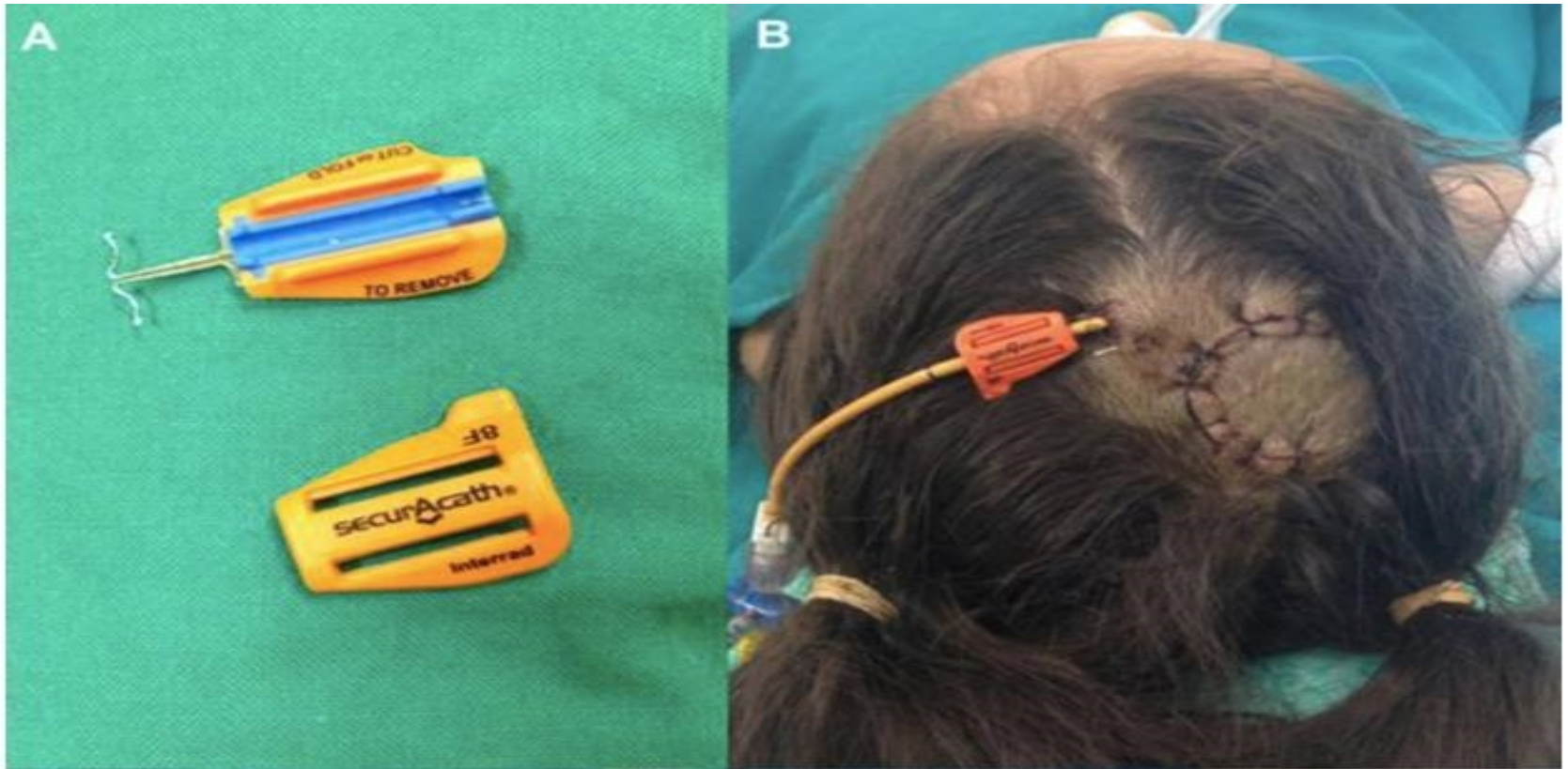
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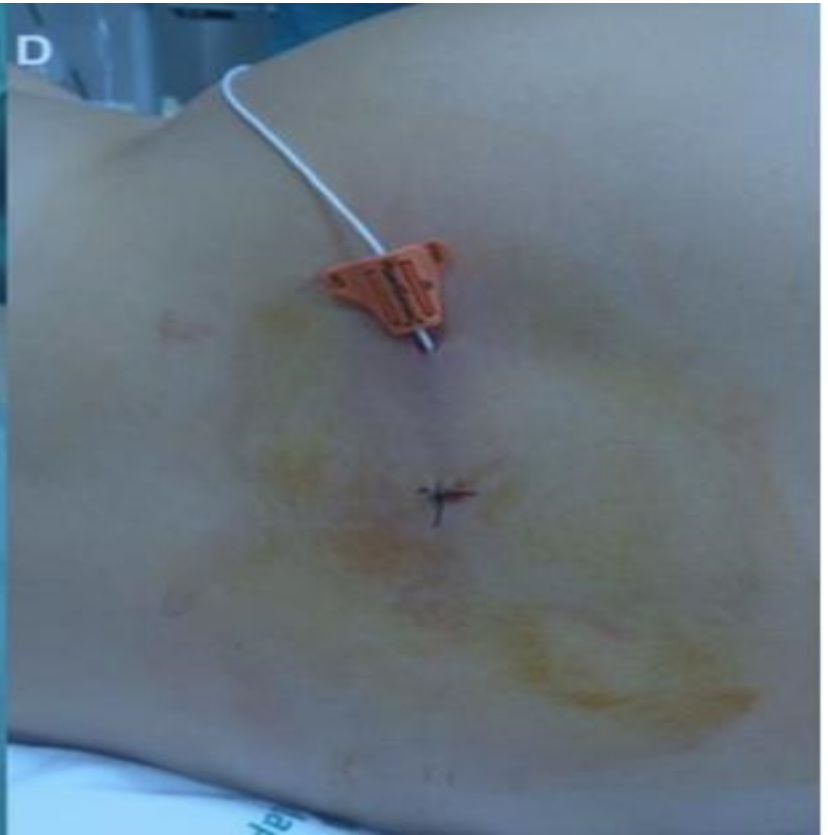
**A new Subcutaneously Anchored Device for Securing External Cerebrospinal Fluid Catheters: our Preliminary Experience**

***Paolo Frassanito<sup>1</sup>, Luca Massimi<sup>1</sup>, Gianpiero Tamburrini<sup>1</sup>, Mauro Pittiruti<sup>2</sup>, Francesco Doglietto<sup>3</sup>, Carlotta Ginevra Nucci<sup>3</sup>, Massimo Caldarelli<sup>1</sup>***



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B –ventricular catheter in a child



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C – bilateral ventricular catheter in a neonate  
D – spinal catheter in young woman



# Other future indications (?)

Nephrostomy tubes

Long term biliary drains

Peritoneal drainage for ascites

Thoracic tubes

Current limitation of SAS: only calibers between 3 and 8Fr are available

# Just beware !!!

*Use of SAS is habit forming...*

*Once you started using it, it is difficult to do without...*

# Thank you for your attention

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