



Milano 2022

30 - 31 maggio



La colla in cianoacrilato

Vito D'Andrea



IV Convegno Nazionale GAVePed

Il fissaggio ideale:

- Ridurre i movimenti dell'accesso vascolare all'interno del vaso (pistoning; "in and out")
- Ridurre i movimenti dell'accesso vascolare all'esterno (mantenendolo nella vena)
- Fornire una barriera alla contaminazione batterica
- Facilitare la traspirazione della cute (alto MVTR specie nel neonato pretermine)
- Prevenire il sanguinamento
- Garantire una chiara e semplice valutazione del sito di inserzione
- Minimizzare il trauma sulla cute
- Essere confortevole
- Poco costoso
- Facile da applicare

La colla: cianoacrilato

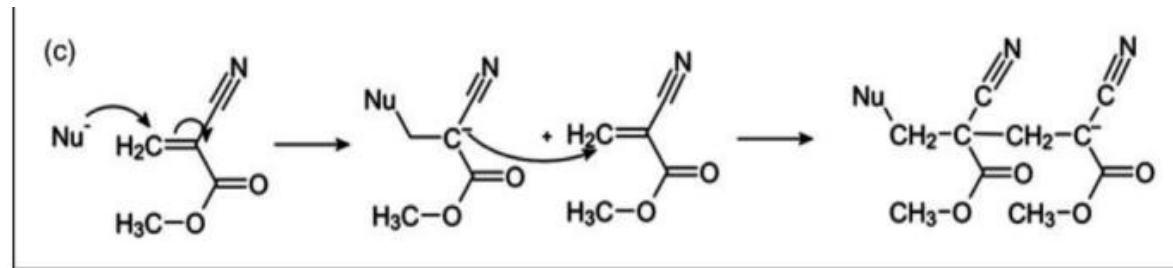


Figure 2. Molecular structure of cyanoacrylate and the polymerization process (adapted from Pollak and White¹⁸). (a) Monomeric cyanoacrylate $\text{CH}_2=\text{C}(\text{CN})-\text{COOR}$. The R represents an alkyl group. (b) *n*-Butyl-2-cyanoacrylate (*n*-BCA). The carboxyl ethyl ($-\text{COOH}-\text{CH}_2-\text{CH}_2$) group is the antigenic component of the molecule. (c) Polymerization process of cyanoacrylate (CA). Exposure of CA monomers to an anion, such as the hydroxyl ($-\text{OH}$) group in water initiates the polymerization process with bonding of the ethylene units.

La polimerizzazione è una reazione esotermica. Durante la formazione del polimero si genera calore con temperature che possono arrivare anche a 40-45°C

La colla: cianoacrilato

- Possiede un'alta resistenza alla trazione (tensile strength)
- Stabilizza il catetere riducendo i movimenti "in and out"
- Potenzialmente reduce il danno endoteliale e il rischio di trombosi
- Sigilla il sito di inserzione prevenendo il sanguinamento e l'ingresso dei microrganismi (colonizzazione extraluminale)
- Proprietà batteriostatica

Cyanoacrylate tissue adhesives for securement have been studied in vitro, in animals, and in small pilot trials of peripheral venous and arterial catheters. Tissue adhesive plus a standard transparent dressing have shown a slight trend toward reduction in catheter failure with these adhesives in combination with a standard transparent membrane dressing; however, larger trials are needed to confirm these findings and identify patients for whom this might not be suitable.^{5,15-17} (III)

INS 2021

Tissue adhesive for vascular access devices: who, what, where and when? Amanda Corley. British Journal of Nursing, 2017

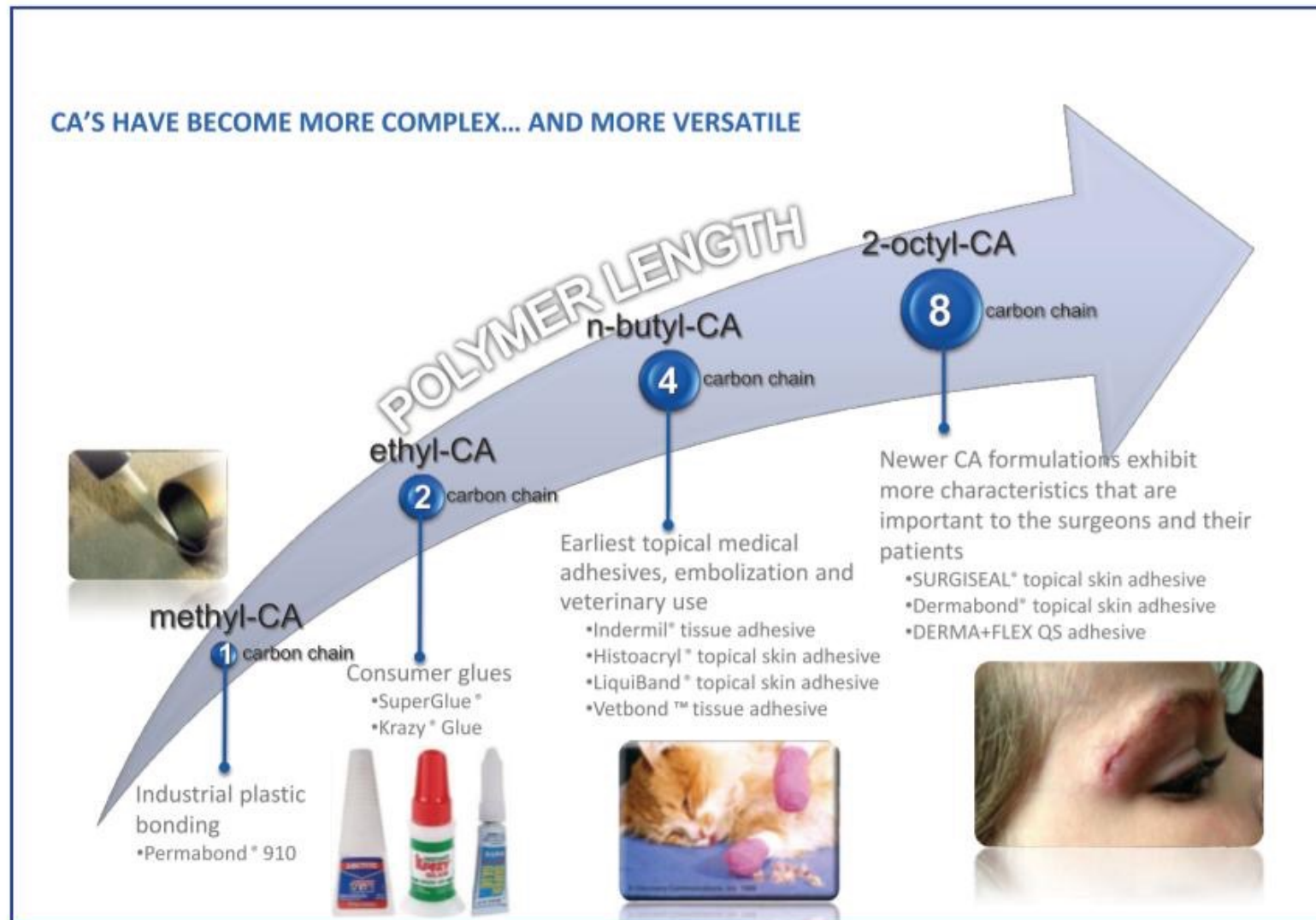


Figure 1. Cyanoacrylate development

Table 1. Comparison of older and newer cyanoacrylate tissue adhesives

First generation	Second generation
Butyl-cyanoacrylate (BCA)	2-octyl-cyanoacrylate (OCA)
Quick drying	Longer drying time
Rigid/brittle	Higher tensile strength and more flexible
More cytotoxic	Less cytotoxic
Stronger thermal reaction	Reduced thermal reaction
Requires minimum 24 hours before fully water resistant	Immediately water resistant

Source: Internal testing by Adhezion Biomedical

Table 1. A selection of tissue adhesives used for skin closure or with vascular access devices*

Brand name (manufacturer)	Chemical constitution	Presentation (ml)	Storage (Celsius)	Time to degradation (days)	Properties
Histoacryl/Histoacryl Blue (B.Braun, Melsungen, Germany)	NBCA	0.5	< 22	7–10	■ High tensile strength ■ Microbial barrier ■ Quick setting time
Histoacryl Flexible (B.Braun, Melsungen, Germany)	NBCA + softener	0.5	< 25	7–10	■ High tensile strength ■ More flexible than NBCA ■ Less heat production on application ■ Microbial barrier
Dermabond (Ethicon, Somerville, NJ, USA)	OCA	0.36, 0.7	< 30	5–10	■ Higher tensile strength than NBCA ■ More flexible than NBCA ■ Microbial barrier
Surgiseal/SecurePortIV (Adhezion Biomedical, Wyomissing, PA, USA)	OCA	0.35, 0.5 (Surgiseal) 0.15 (SecurePortIV)	< 30	5–10	■ Higher tensile strength than NBCA ■ More flexible than NCBA ■ High moisture vapour transmission rate ■ Microbial barrier
Glubran Tiss2 (GEM, Viareggio, Italy)	NBCA + OCA	0.25, 0.35, 0.5	0–4	5–8	■ Improved flexibility ■ High tensile strength ■ Breathable ■ Less heat production on application ■ Microbial barrier
Indermil flexifuse (Connexicon, Dublin, Ireland)	NBCA + OCA	0.75	4–30	5–8	■ Flexibility ■ High tensile strength ■ Minimal heat produced ■ Microbial barrier

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

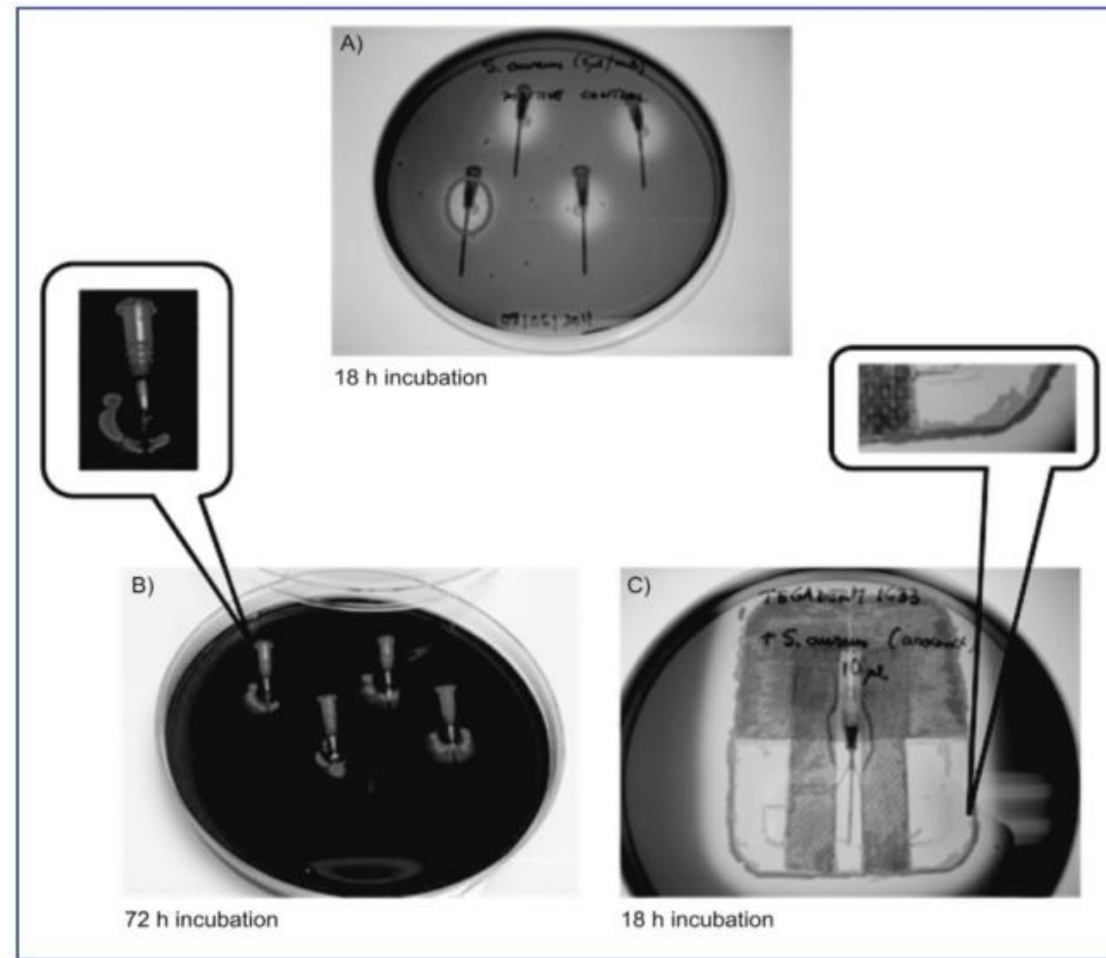
510(k) Number (*if known*)
K170505

Device Name
SecurePortIV Catheter Securement Adhesive

Indications for Use (*Describe*)

SecurePortIV™ catheter securement adhesive is to be applied as a film forming securement and sealant at the point of vascular access catheter skin entry. The film holds the catheter to the skin to reduce catheter movement, migration, and/or dislodgment. It is used to protect the catheter skin entry site by creating a sealant that immobilizes surface bacteria, preventing them from entering into the catheter skin entry site while also providing a moisture barrier. SecurePortIV™ is intended to be used with a transparent film dressing on short-term and long-term vascular access catheters including peripheral IVs, PICCs, and CVCs.

Azione antibatterica...BCA



Simonova G. Cyanoacrylate tissue adhesives—effective securement technique for intravascular catheters: in vitro testing of safety and feasibility. *Anaesth Intensive Care*. 2012;40(3):460–466

Azione antibatterica...OCA

Table 1

Antibacterial effect of the uninitiated product after a 3-minute contact time: detailed results versus *Pseudomonas aeruginosa*

Replicate No.	Log 10 survivors	Log 10 reduction	Neutralization challenge
1-19	0	8 - 0 = 8	+
20	1.48 = 1	8 - 1 = 7	+

P aeruginosa versus negative control

Dilution	Count
10 ⁻⁴	TNTC, TNTC
10 ⁻⁵	>200, >200
10 ⁻⁶	27, 58
10 ⁻⁷	5, 3
cfu/10 mL	4.3 × 10 ⁷
Log 10	7.63 = 8
Summary of kill against 7 clinically relevant organisms	Average (n = 20) log 10 reduction
Methicillin-resistant <i>Staphylococcus aureus</i>	8
<i>Escherichia coli</i>	8
<i>P aeruginosa</i>	8
<i>Klebsiella pneumoniae</i>	7
<i>Staphylococcus epidermidis</i>	7
<i>Corynebacterium pseudodiphtheriticum</i>	8
<i>Staphylococcus aureus</i>	8

NOTE. The filtrates were also plated and had no growth. The results for all organisms were equivalent as shown above. On challenge with <100 cfu, all dilution tubes were positive, meaning no carryover residual cyanoacrylate was present in the dilution tubes. The results for all the eight organisms tested were equivalent having ≥7 log kill.

+, positive; cfu, colony forming units; TNTC, too numerous to count.



Prince D, Solanki Z, Varughese R, Mastej J, Prince D. Antibacterial effect and proposed mechanism of action of a topical surgical adhesive. Am J Infect Control. 2017.

Azione emostatica

- Incidenza di sanguinamento nel posizionamento dei PICC: 40% ad 1 h, e 15% a 25 h.
- L'uso costante della colla in cianoacrilato abbatte l'incidenza di sanguinamento (0%) ad 1 e 25 h dal posizionamento del CVC
- Questo ha un notevole impatto logistico e sui pazienti.



Elimination of the 24-hour dressing: a quick win

be inspected. It is, however, common practice to apply gauze over the insertion site initially to absorb any post-insertion bleeding. A 24-hour, post-insertion dressing would then be applied (Royal College of Nursing, 2016). By using tissue adhesive, it is possible to eliminate the need for this 24-hour, post-insertion dressing as haemostasis can be achieved before the transparent film dressing is applied.

A Revolutionary, Proven Solution to Vascular Access Concerns: A Review of the Advantageous Properties and Benefits of Catheter Securement Cyanoacrylate Adhesives

Sheng Zhang, PhD • Bethany S. Lingle, BS • Shannon Phelps, BS

Catheter type	Securement method	Securement strength (N)
BD Autoguard catheter	CSCAs	12.473
	Tegaderm 1683	8.283
	Opsite	3.216
	HubGuard	2.905
	Durapore	3.381
BD Nexiva catheter	CSCAs	13.380
	Tegaderm 9525HP	7.090
	Opsite	1.392
	HubGuard	1.552
	Durapore	1.348
Abbreviations: CSCAs, catheter securement cyanoacrylate adhesives; N, newton.		

Catheter Type	Securement Method	Securement Strength (N)
BD Autoguard catheter	CSCAs + Tegaderm 1683	19.501
	CSCAs + Opsite	15.453
	CSCAs + HubGuard	12.451
	CSCAs + Durapore	12.362
BD Nexiva catheters	CSCAs + Tegaderm 9525HP	14.893
	CSCAs + Opsite	16.000
	CSCAs + HubGuard	10.840
	CSCAs + Durapore	15.035
Abbreviations: CSCAs, catheter securement cyanoacrylate adhesives; N, newton.		

Ten years of clinical experience with cyanoacrylate glue for venous access in a 1300-bed university hospital

Mauro Pittiruti, Maria Giuseppina Annetta, Bruno Marche, Vito D'Andrea and Giancarlo Scoppettuolo

Table 1. Italian Group of Long-Term Venous Access Devices recommendations on the use of glue in venous access

1. Use cyanoacrylate glue

- As an additional securement of peripheral venous access devices at a high risk of dislodgement
Particularly in peripheral catheters with expected duration >48 hours
- For sealing the exit site of any central venous access device soon after insertion to avoid post-procedural local bleeding, prevent unscheduled dressing changes and protect the exit site from bacterial contamination during the first week
Use chlorhexidine-releasing sponge dressing (in non-tunnelled central catheters) after the first week
- For closing any skin incision related to venous access procedures (skin incisions for tunnelling or for subcutaneous port placement)
Never use stitches

2. Remember to prefer butyl-cyanoacrylate or octyl-butyl-cyanoacrylate

3. Use a minimal amount of cyanoacrylate glue and only at the time of insertion

Targeting zero catheter-related bloodstream infections in pediatric intensive care unit: a retrospective matched case-control study



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2018, Vol. 19(2) 119–124
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TABLE I - Insertion and maintenance bundle adopted in the group of cases

Insertion and maintenance bundle	Cases	Controls
1. Hand washing and maximal barrier precautions	Yes	Yes
2. Skin antisepsis with 2% chlorhexidine	Yes	Yes
3. Ultrasound pre-puncture evaluation through RaCeVA	Yes	No
4. Ultrasound guided venipuncture	Yes	Yes
5. Tunneling of the catheter so to obtain an exit site in the infraclavicular area	Yes	No
6. Sealing of the exit site with glue	Yes	No
7. Securement with sutureless device	Always	Inconsistently
8. Coverage with transparent semipermeable dressing	Yes	No
9. Chlorhexidine-impregnated sponges	After the 1 st week	Since insertion
10. Use of neutral NFC and port protectors	Yes	Yes
11. Simulation-based standardized training program	Yes	No

RaCeVA = rapid central vein assessment; NFC = needle free connectors.

Targeting zero catheter-related bloodstream infections in pediatric intensive care unit: a retrospective matched case-control study



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TABLE III - Punctured veins at different sites

Veins	Cases	Controls
Right internal jugular vein at mid-neck, n (%)	0 (0%)	40 (62.5%)
Low lateral right internal jugular vein, n (%)	2 (3.12%)	11 (17.2%)
Left internal jugular vein at mid-neck, n (%)	0 (0%)	13 (20.3%)
Left brachiocephalic vein, n (%)	2 (3.12%)	0 (0%)
Right brachiocephalic vein, n (%)	52 (81.25%)	0 (0%)
Right axillary vein, n (%)	4 (6.25%)	0 (0%)
Left subclavian vein, n (%)	2 (3.12%)	0 (0%)
Right external jugular vein, n (%)	2 (3.12%)	0 (0%)

TABLE IV - Complication rates from insertion to PICU discharge

		Cases	Controls
Indwelling time (d)	Total	648	503
	Mean ($\pm$ SD)	9.7 $\pm$ 3.1	7.5 $\pm$ 3.5
CR-BSI	No	1	8
	per 1000 catheter days	1.5	15
CR-DVT	No	0	1
Accidental dislodgements	No	0	3

CR-BSI = catheter-related bloodstream infections; CR-DVT = catheter-related deep vein thrombosis; PICU = pediatric intensive care unit; SD = standard deviation.

....e nel neonato???

ECC

CICC/FICC

CVO



1
2
3

Use of cyanoacrylate glue for the sutureless securement of epicutaneo-caval catheters in neonates

**Vito D'Andrea¹ , Lucilla Pezza¹, Giovanni Barone²,
Giorgia Prontera¹, Mauro Pittiruti³  and Giovanni Vento¹**

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1–4

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Table 1. Demographics population and Epicutaneo-Caval Catheters characteristics.

	Intervention	Control	
Infants (<i>n</i>)	92	80	
Gestational age weeks	29	29	
Birth weight grams	1280	1200	
Catheters (<i>n</i>)	134	124	
Day of life at the insertion	6	6	
Weight at insertion grams	1230 (520–3000)	1180 (480–3270)	
Days ECC in place	10.4	11	
Elective ECC removal <i>n</i> (%)	95 (70.8)	89 (71.7)	
Dislodgement <i>n</i> (%)	1 (0.7)	14 (11.3)	0.0003

- L'uso del CA non è stato associato ad alcun effetto avverso.
- La colla si è dimostrata sicura, facile da applicare e efficace nel 100% dei casi nel prevenire sanguinamenti nel sito di venipuntura.
- La rimozione si è dimostrata semplice e senza complicanze.

Cyanoacrylate Securement in Neonatal PICC Use

A 4-Year Observational Study

Matheus van Rens, RN, MaANP, NNP; Nuha Abdelghafar M. A. Nimeri, MD, CABP;
Timothy R. Spencer, RN, APRN, BHSc, DipAppSc, IntCare Cert, VA-BC;
Kevin Hugill, PhD, RN, BSc, PGCE, MSc; Airene L. V. Francia, RN, BSc;
Tawa Olayemi Olukade, MBBS, MSc, MPH; Mohamad Adnan Mahmah, MD, CABP

TABLE 3. Reasons for Device Removal, Dwell Time, and Therapy Failure

	Tissue Adhesive			P Value
	Total (N = 1842) n (%)	No (n = 975) n (%)	Yes (n = 867) n (%)	
Reason for removal				
1.Therapy completed	1313 (71.3)	637 (65.3)	676 (78.0)	<.001
2.Therapy failure ^a				
Catheter-related complications ^b	43 (2.3)	24 (2.5)	19 (2.2)	
Extravasation/infiltration	50 (2.7)	47 (4.8)	3 (0.3)	
Maintenance-related complications ^c	75 (4.1)	53 (5.4)	22 (2.5)	
Phlebitis	56 (3.0)	42 (4.3)	14 (1.6)	
Suspected sepsis	118 (6.4)	87 (8.9)	31 (3.6)	
Death (CLABSI)	8 (0.4)	6 (0.6)	2 (0.2)	
3. Administrative censoring				
Death (other causes)	44 (2.4)	31 (3.2)	13 (1.5)	
Transferred	135 (7.3)	48 (4.9)	87 (10.0)	
Dwell time, median, (IQR), d	11 (7-16)	11 (7-17)	10 (7-14)	.074
Therapy failure ^a	350 (20.5)	259 (27.9)	91 (11.7)	<.001



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ECC

CICC/FICC

CVO

Clinical trial protocol

JVA | The Journal of
Vascular Access

A GAVeCeLT bundle for central venous catheterization in neonates and children: A prospective clinical study on 729 cases

**Mauro Pittiruti¹ , Davide Celentano², Giovanni Barone³ ,
Vito D'Andrea⁴ , Maria Giuseppina Annetta⁵ and Giorgio Conti²**

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Securement of central venous catheters by subcutaneously anchored sutureless devices in neonates

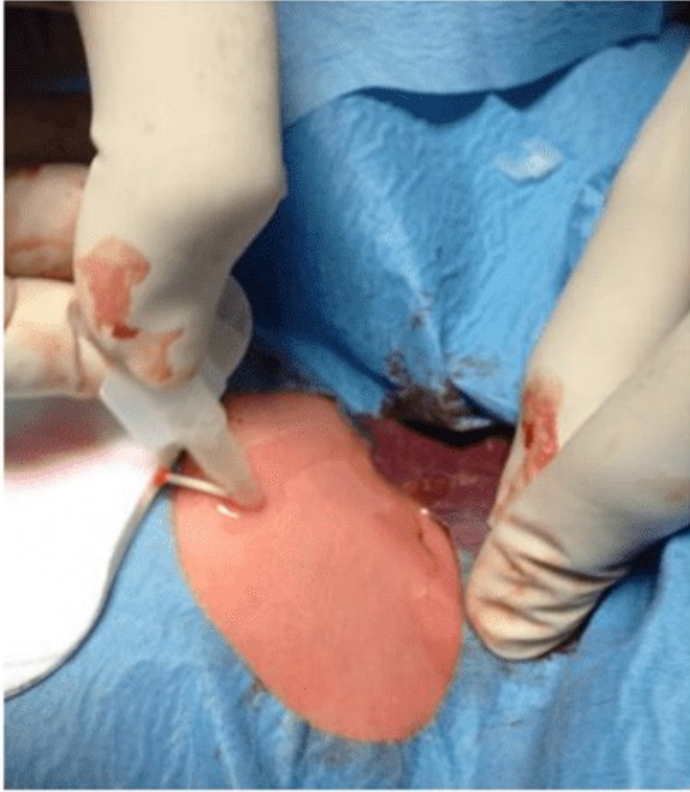
Mauro PITTIRUTI, Giovanni BARONE, Vito D'ANDREA

Catholic University Hospital, Rome and Rimini Hospital (Italy)

Results

72 central venous catheters were inserted in 70 preterm and term neonates (3-4Fr power injectable polyurethane catheters; 62 CICC + 10 FICC) and they were all secured with SAS. Mean postmenstrual age at the time of insertion was 31 weeks (range 25 - 41 weeks) and mean weight was 1400 grams (range 580 - 4100 grams). SAS was easy to place in all cases. The median duration of the line was 5 weeks (range 10 days - 3 months). No accidental dislodgement of CICC or FICC was recorded. All SAS but one were left in place until elective removal of the catheter; only in one patient, early removal of SAS was necessary because of a skin ulcer caused by the device. In all patients, SAS removal was easy and uneventful, and it did not require any sedation or local anesthesia.









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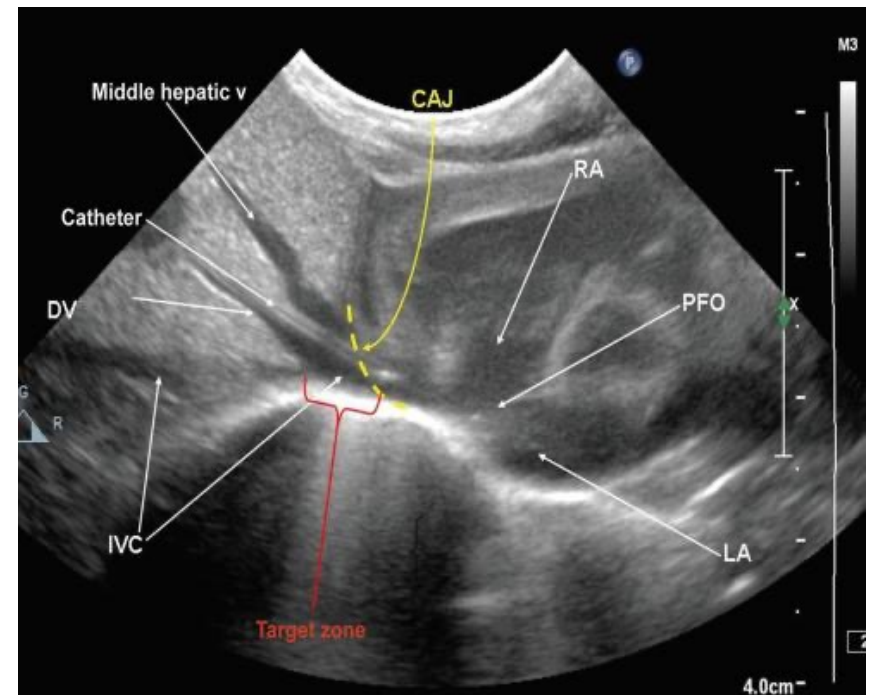
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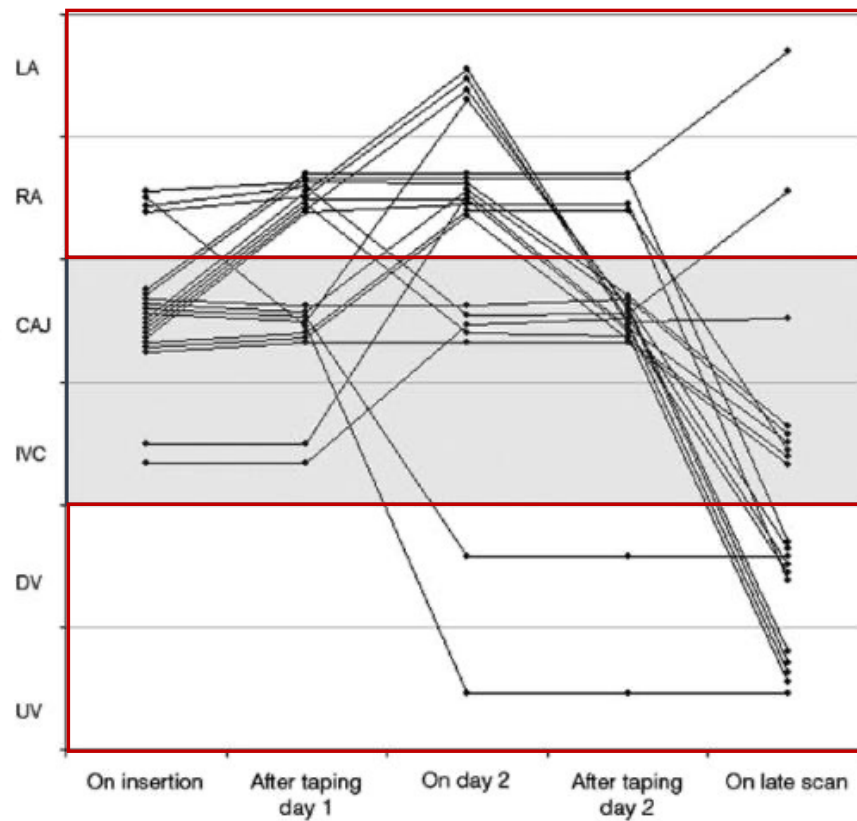
CICC/FICC

CVO

“Can we do it better?”...fissaggio CVO

GLUUV Trial





- Retrazione cordone
- Espansione polmonare
- Distensione addominale
- Management CVO

Hoellering A. et al. Study of movement of umbilical venous catheters over time. Observational Study J Paediatr Child Health. 2018

INS 21

Standard 38 – Vascular Access Securement (Gorski et al., 2021, pp. S108-S111)

This standard indicates that ALL vascular access devices (VADs) should be secured to prevent complications associated with movement at the insertion site and unintentional loss of access. The standard also recommends that the securement technology not interfere with the ability to routinely assess and monitor the access site.

- **Tissue adhesive** is listed as one of the four approved securement technologies (Level I).
- All securement devices are seen as an adjunct to the primary dressing. The effectiveness of combining securement technologies is still unclear.
- **Tissue adhesive** in addition to the primary dressing for peripheral IV's (PIVCs) is recommended to improve catheter dwell times and decrease failure rates (Level II). Use a securement technology for long PIVCs and midline catheters (Committee Consensus).
- Use of **tissue adhesive** as an alternative to sutures for PICCs is considered to be a safer alternative and reduce risks of complications, including infection and dislodgement (Level I).
- Consider the benefits of **tissue adhesive** as an adjunct to the primary method of dressing and securement to provide immediate hemostasis at the insertion site, which can prolong intervals between dressing changes (Level II).
- **Tissue adhesive** has been demonstrated to create a barrier to microorganism growth in the catheter tip (Level II).
- Tissue adhesive along with sutures or other securement technologies may reduce failure rates with nontunneled CVADs in the neck and groin (Level III).
- Tissue adhesive should be reapplied at each dressing change (Level I).
- Dressings should be changed at least every 7 days, or immediately if dressing integrity is observed e.g., visibly soiled, presence of moisture, drainage, or blood (Level III).
- **TA** has shown promising effects in promoting hemostasis post-VAD insertion (Level III).

European recommendations on the proper indication and use of peripheral venous access devices (the ERPIUP consensus): A WoCoVA project

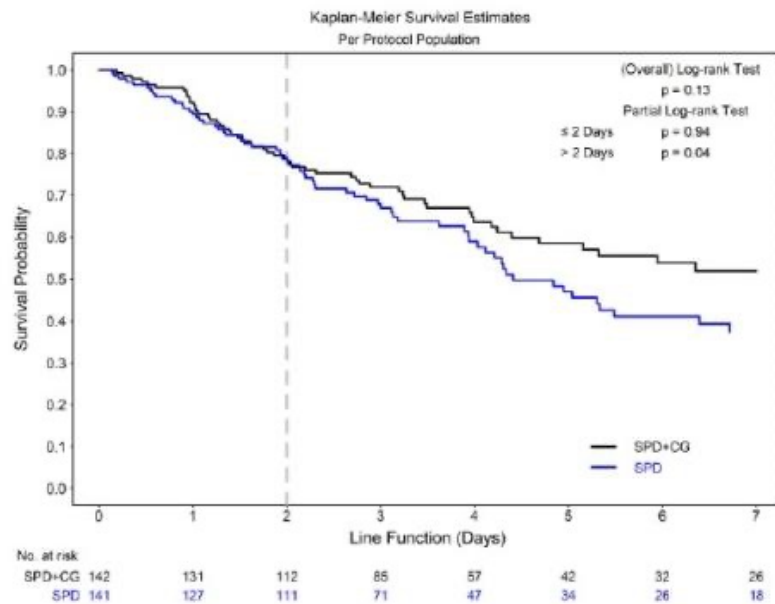
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Short peripheral intravenous catheter securement with cyanoacrylate glue compared to conventional dressing: A randomized controlled trial

Amit Bahl , S. Matthew Gibson, David Jankowski and Nai-Wei Chen

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	Analysis	Time	Study Group		p-Value
			SPD + CG	SPD	
Intention-to-treat	IV failure (event) [‡] , n (%)	Overall	55/171 (32.1%)	66/174 (37.9%)	0.065
	Restricted mean survival duration [§] , days	≤2 days (48 h)	1.84	1.83	0.81
		>2 days (48 h)	5.97	5.43	0.05
	Hazard ratio (95% CI) on IV failure [¶]	≤2 days (48 h)	1.05 (0.63 to 1.77)	1 [reference]	0.85
		>2 days (48 h)	0.57 (0.34 to 0.97)	1 [reference]	0.04
Per Protocol	IV failure (event) [‡] , n (%)	Overall	55/142 (38.7%)	66/141 (46.8%)	0.04
	Restricted mean survival duration [§] , days	≤2 days (48 h)	1.82	1.80	0.71
		>2 days (48 h)	5.97	5.43	0.05
	Hazard ratio (95% CI) on IV failure [¶]	≤2 days (48 h)	1.02 (0.60 to 1.71)	1 [reference]	0.95
		>2 days (48 h)	0.57 (0.34 to 0.97)	1 [reference]	0.04

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- Previene il sanguinamento
- Batteriostatica
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SUKSAMA
EKHMET
ATTO
MAAKE
GRAZIE
MEHRBANI
PALDIES
KOMAPSUMNIDA
HERASTANY
GAEJTHO
GOZAIMASHITA
EFCHARISTO
AGUYJE
FAKAAUE
TINGKI
BIYAN
SHUKRIA
MAKETA
MINHOCHAB
BOLZIN
MERCI
SHALCHESH
YUSPAGABATAM
HUI
SPASSIBO
DEKKAUJA
NEHACHALHYA
MAKETA
SHAKOHO
ENOLJU
GUR
MATUR
MAKETA