



Evidence Overview for Tissue Adhesive on Vascular Access Devices.

Who, What, Where and When?

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Who, What, Where and When?

About the Presenter: Amanda Corley



Amanda is an intensive care nurse with 25 years experience and specialties in cardiac surgical and respiratory critical care. She is an Adjunct Research Fellow with AVATAR at Griffith University; and a Nurse Researcher at the Critical Care Research Group, The Prince Charles Hospital.

Amanda has published >25 peer reviewed research articles and held several research grants. She is Masters prepared in research methods and commenced her PhD this year.

Amanda has particular expertise and interest in the largest of all vascular access devices - ECMO (Extra Corporeal Membrane Oxygenation) cannulae, and is one of a small few of researchers globally in this area. She has also published research on the care of arterial and central venous catheters in the

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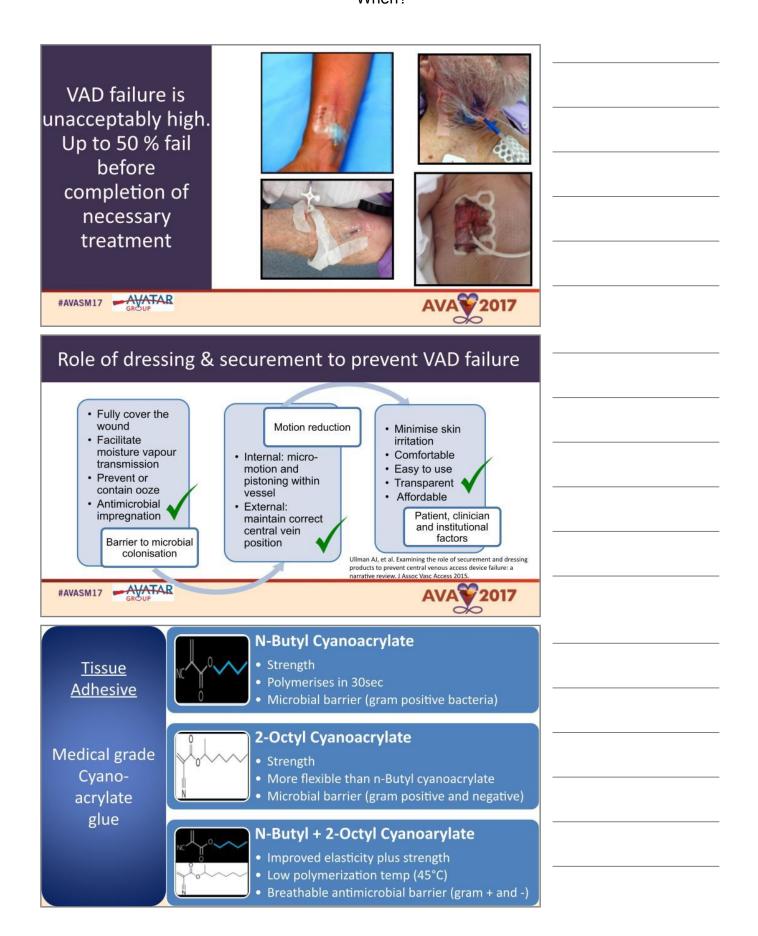
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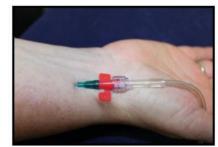




Peripheral VADs: Evidence overview



Peripheral intravenous catheters (PIVs)



Peripheral arterial catheters (ACs)





Preliminary invitro testing

Cyanoacrylate tissue adhesives - effective securement technique for intravascular catheters: in vitro testing of safety and feasibility

G. SIMONOVA*, C. M. RICKARD†, K. R. DUNSTER‡, D. J. SMYTH§, D. MCMILLAN**, J. F. FRASER††

Preliminary work involved:

- 1. Testing removal solutions -Remove™, Paraffin, Acetone
- 2. Pull-out force of 4 securement options (including TA - Dermabond & Histoacryl)
- 3. Antimicrobial properties of TA

Assessment of tissue adhesives and removal agents for chemical compatibility with IVCs

Tensile strength (N), mean±SD

Removal agents

50.23±2.44 Paraffin 46.17±2.28

24.94±1.59* Acetone

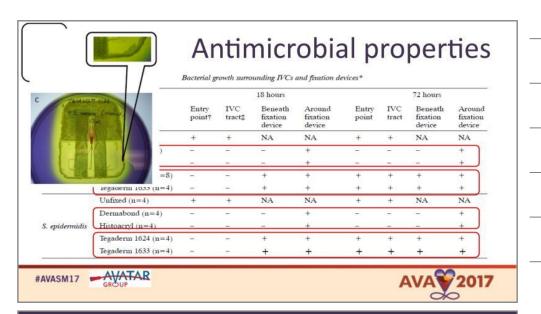
Data expressed as mean \pm SD. The control was a plain intravascular catheter (IVC) without use of any chemical agent. *P <0.05 control vs chemical agent.

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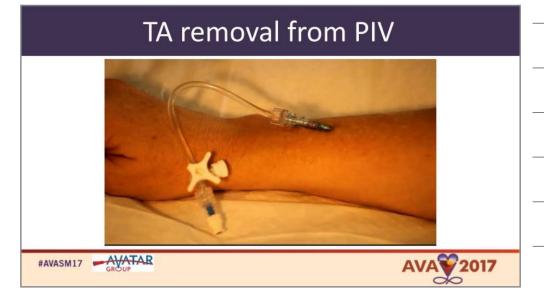




Pull-out force to dislodge PIV Pull-out force, N Securing method #AVASM17 AVATAR







Randomised controlled trials in PIVs

- 1. PIVs in acute care adults (Marsh et al, 2015)
- 2. PIVs inserted in emergency department (Budgen et al, 2016)
- 3. PIVs in acute care adults (unpublished) [HOTOMFTHE PRESS]



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1. PIV in acute care adults (Pilot RCT)

- 4 arm, non-blinded, single centre pilot RCT
- · Primary outcome: PIV failure
- Compared:
 - 1. Tissue adhesive
 - 2. Standard transparent dressing JVA



3. Bordered transparent dressing Securement methods for peripheral venous catheters 4. Sutureless securement device to prevent failure: a randomised controlled pilot trial

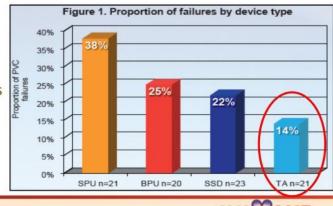
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1. PIV in acute care adults (Pilot RCT)

RESULTS

- n=85
- 5305 PIV hours
- · 4 adverse skin events all in TA group
 - 1 skin tear
 - 2 rashes
 - 1 blister



PIV inserted in emergency department

- 2 arm non-blinded RCT in metropolitan ED
- Primary outcome: PIV failure at 48 hours
- Compared:
 - 1. Tissue adhesive
 - 2. Bordered transparent dressing

THE PRACTICE OF EMERGENCY MEDICINE/ORIGINAL RESEARCH

Skin Glue Reduces the Failure Rate of Emergency Department-Inserted Peripheral Intravenous Catheters: A Randomized Controlled Trial



Simon Bugden, MBChB, FACEM+; Karla Shean, RN; Mark Scott, MBBS, FACEM; Gabor Mihala, MEnglMech), GradCert(Bios Sean Clark, MBBS, FACENt Christopher Johnstone, MBChB, FACENt; John F, Fraser, MD, PhD; Claire M, Rickard, PhD, RN





PIV inserted in emergency department

RESULTS

- Standard Care. Skin Glue. Difference n= 369
- No adverse skin reactions
- Occasional feeling of 'pulling' noted during removal

	No. (%)	No. (%)	(95% CI), %	
Primary outcome PIVC failure	52 (27)	31 (17)	-10 (-18 to -2)	10%
Secondary outcomes Infection	0	0	0	absolute reduction
Phlebitis	9 (5)	6 (3)	-1 (-5 to 3)	
Occlusion	20 (11)	15 (8)	-2 (-8 to 4)	
Dislodgement	26 (14)	13 (7)	-7 (-13 to 0)	P=0.02
Cl, Confidence interval.				

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PIVs in acute care adults (large RCT)

- 2 site, 4 arm, single blinded definitive RCT
- Primary outcome: PIV failure (dislodgement, occlusion, phlebitis, and primary bloodstream or local infection)
- Compared:
 - 1. Tissue adhesive and standard transparent dressing
 - 2. Simple transparent dressing
 - 3. Bordered transparent dressing
 - 4. Sutureless securement device and standard transparent dressing

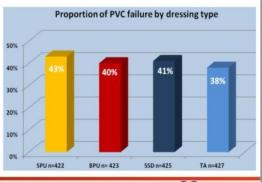




3. PIVs in acute care adults (large RCT)

RESULTS

- n=1697/115,408 PIV hours
- Compared to control (SPU), TA group had:
 - significantly less occlusion (56 vs 79/1000 days, p=0.03)
 - less dislodgement (24 vs 35/1000 days, p=0.07)
 - Highest staff rating for acceptability and performance



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3. PIVs in acute care adults (large RCT)

- In all study arms:
- Important
- High failure rates
- Adverse skin reactions occurred (highest rate TA group 7.4%, lowest BPU 2.8%)
- High rate of additional dressing and securements

Securement of PIVs requires further product and/or practice innovation





Updated Systematic Review: Polyurethane (PU) vs Tissue Adhesive (TA) + Polyurethane Risk Ratio Cochrane Fixed, 95% CI Library secure peripheral venous catheters PU TA+PU s (Review) 3 RCTs N=1081 N=632 Failure 38% 31% 7% reduction in PIV failure 01 Relative Risk 0.86, P= 0.03 Favours TA Favours PU #AVASM17 AVATAR 2017

Randomised controlled trials in peripheral arterial catheters (ACs) 1. ACs in adult ICU (Edwards et al, 2014) 2. ACs inserted in adult operating theatre and maintained in ICU (Reynolds et al, 2015) AVATAR #AVASM17 TA application to AC #AVASM17 AVATAR AVA 2017 1. ACs in adult cardiac and general ICU 4 arm, single centre, unblinded pilot RCT Primary outcome: AC failure (complete dislodgement, occlusion, pain or any infection) Crit Care Resusc 2014; 16: 175-183 Compared: A pilot trial of bordered polyurethane dressings, 1. Tissue adhesive tissue adhesive and sutureless devices compared with 2. Bordered polyurethane dressing standard polyurethane dressings for securing short-term arterial catheters 3. Sutureless securement device 4. Standard polyurethane dressing #AVASM17 AVATAR

ACs in adult cardiac and general ICU

Results

- n=195
- 7147 AC hours
- Patient and staff satisfaction high in all groups
- · Anecdotally, TA degraded over ~ 3 days

	SPU n=47	BPU+ SPU n=43	SSD + SPU n=49	TA + SPU n=56
AC failure	10 (21%)	2 (5%) *	8 (16%)	6 (11%)
Adverse skin events	0	0	1	2
Dressing costs	\$3.48	\$5.07*	\$10.90*	\$17.70*

SPU - Standard polyurethane dressing; BPU - Bordered polyurethane dressing; SSD - Sutureless securement device; TA - Tissue adhesive * p<0.05 when compared with control (SPU)





2. ACs in adult OT and general ICU

- · 4 arm, single centre, unblinded pilot RCT
- Primary outcome: AC failure (complete dislodgement, occlusion, phlebitis or any infection)
- Compared:
 - 1. Tissue adhesive
 - 2. Bordered polyurethane dressing
 - 3. Sutureless securement device
 - 4. Standard polyurethane dressing



Novel technologies can provide effective dressing and securement for peripheral arterial catheters: A pilot randomised controlled trial in the operating theatre and the intensive care unit

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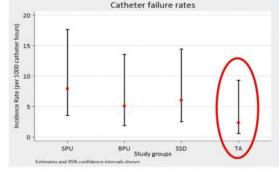




2. ACs in adult OT and general ICU

Results

- n=195
- 7147 AC hours
- · 14% reduction in failure with TA when compared with control (SPU)
- · Patient satisfaction highest in TA group



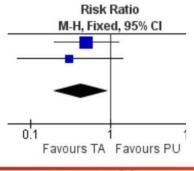
SPU - Standard polyurethane dressing; BPU - Bordered polyurethane dressing; SSD - Sutureless securement device; TA - Tissue adhesive



Meta-analysis: Polyurethane (PU) vs Tissue Adhesive (TA)

	PU	TA+PU
2 RCTs	n=77	n=88
AC Failure	21%	9%

12% reduction in AC failure Relative Risk 0.43, P= 0.04







Take home message for TA use in PIVs and ACs

Peripheral venous catheters

• 7% reduction in failure compared to standard polyurethane dressing

Arterial catheters

 12% reduction in failure compared to standard polyurethane dressing

Adverse skin events

• Requires further investigation to ensure appropriate patient selection





Central VADs (CVADs): Evidence overview



Peripherally inserted central catheters (PICCs)





Non-tunnelled CVADs



Tunnelled CVAD

Randomised controlled trials in CVADs

- 1. PICCs in acute care adults (unpublished)
- 2. PICCs in paediatrics (Kleidon et al, 2017)
- 3. Jugular non-tunnelled CVAD in adult post-cardiac surgery patients (Rickard et al, 2016)
- 4. Non-tunnelled CVAD in paediatric ICU (unpublished)
- 5. Tunnelled CVAD in paediatrics (Ullman et al, 2017)

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Application of TA to PICC



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1. PICCs in acute care adults MITCH THE PRESS 1



- · 4 arm, single centre, single blinded pilot RCT
- Primary outcome: PICC failure (infection, dislodgement, occlusion, and/or catheter fracture)
- Compared:
 - Standard polyurethane dressing + Sutureless securement device + CHG disc
 - Polyurethane with Absorbent Lattice pad dressing + CHG disc
 - Combination Securement-Dressing (Sorbaview™) + CHG disc
 - Tissue Adhesive + Standard polyurethane dressing

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2017

1. PICCs in acute care adults MITTHEMESS						
Results • n=121		Sample Size n=121	Failure Rate (%)	Incident rate/1000 cath days	Skin events* (%)	
1132 PICC daysPAL group – ceased	Standard polyurethane + Sutureless securement + CHG disc	39	4 (10%)	9	12 (30%)	
recruitment due to safety concerns	Integrated Securement- Dressing + CHG disc	42	3 (7%)	9	10 (23%)	
 High incidence of adverse skin events in all groups 	Tissue Adhesive + Standard polyurethane	35	3 (8%)	10	13 (36%)	
	Polyurethane absorbent lattice dressing + CHG	5	1 (20%)	17	1 (20%)	
#AVASM17 AVATAR	* any of rash, bli and bruising at a			AVA\2	2017	

1. PICCs in acute care adults | MICCS IN OF THE PRESS

Lessons learned from this trial

- · Positive feedback by clinicians regarding TA to control haemostasis (but not formally tested)
- TA easily removed from skin but built up++ on PICC, threatening skin injury
- Manual removal of TA from PICCs risked dislodgement, and was time consuming
- TA has potential benefits at insertion, its use for repeated dressings during PICC dwell was not feasible





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2. PICCs in paediatrics

- · 3 arm, single centre RCT
- Primary outcome: PICC failure (cessation of function prior to completion of therapy)
- · Compared:
 - 1. Bordered polyurethane dressing + sutureless securement device
 - 2. Integrated securement dressing
 - 3. Tissue adhesive + bordered polyurethane dressing



2. PICCs in paediatric ICU					
Resultsn=95Low overall		BPU + SSD n=32	ISD n=31	TA + BPU n=32	
failure rate (5%) Cost of TA higher but fewer dressing changes	PICC failure	2 (6%)	2 (6%)	1 (3%)	
	Incident rate/1000 catheter days	8	8	3	
	Adverse skin events*	5 (16%)	3 (10%)	10 (31%)	
	Parental satisfaction (0-10)	7.6	9.7	8.5	
	*Itchiness, rash, skin tear, blist	ter or bruising	g at any time o	luring study	
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2. PICCs in paediatric ICU

Lessons learned from this trial

- Excessive application of TA on insertion may lead to skin tears
- Less is more → 2 drops at insertion site and 2 drops to securement wings
- TA was removed easily from skin but difficult to remove from PICC resulting in residual build up → maybe not a long-term securement option
- TA could be useful as an adjunct to other dressings, to provide immediate haemostasis, reduce post-operative bleeding, and the need for early dressing change

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TA application to jugular CVL #AVASM17 AVATAR GROUP #AVASM17 AVATAR GROUP

Jugular non-tunnelled CVAD in adult 3. cardiac ICU

- · 4 arm single centre pilot RCT
- Primary outcome: CVAD failure
- · Compared:



C.M. Rickard, RN. BN. Grad Dip Crit Care Nurs. PhD: FACN, FAAHMS 44.

- 1. Bordered polyurethane + suture (control)
- 2. Absorbent dressing + suture
- 3. Sutureless securement device x 2 + standard polyurethane dressing
- 4. #1 Tissue adhesive + standard polyurethane dressing #2 Tissue adhesive + standard polyurethane dressing + suture

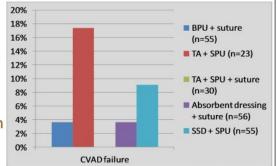
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Non-tunnelled jugular CVAD in adult 3. cardiac ICU

Results

- n=221
- 15 479 CVAD hours
- TA without a suture in jugular CVADs was unsafe
- TA Less patient and staff satisfaction, and more pain on removal



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Non-tunnelled jugular CVAD in adult cardiac ICU

Lessons learned from this trial

- Factors likely to be associated with TA failure:
 - Diaphoretic coagulopathic post-cardiac surgical patients
 - CVAD position (internal jugular vein)
 - Early mobilisation
 - 'Drag' from multiple infusions
 - Beard regrowth in males





4. Non-tunnelled CVAD in paediatric ICU



- · 3 arm, single centre pilot RCT
- · Primary outcome: CVAD failure
- Compared:
 - 1. Bordered polyurethane dressing + sutures + CHG disc (control)
 - 2. Tissue adhesive + control
 - 3. Integrated dressing securement + sutures + CHG disc





4. Non-tunnelled CVAD in paediatric ICU

Results

- n=180
- Similar levels of acceptability for each group
- TA most difficult to apply

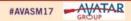
	BPU+suture +CHG (control) n=54	ISD+suture +CHG n=56	TA + control n=59
CVAD failure	3 (6%)	1 (2%)	6 (10%)
Non-routine dressing change	28%	13%	10%

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5. Tunnelled CVAD in paediatrics

- 4 arm, 2 centre pilot RCT
- Primary outcome: CVAD failure
- Compared:
 - 1. Bordered polyurethane dressing + suture
 - Sutureless securement device + suture + bordered polyurethane dressing
 - 3. Tissue adhesive (at exit wound and under catheter bifurcation) + bordered polyurethane dressing
 - 4. Integrated securement-dressing + suture



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5. Tunnelled CVAD in paediatric ICU

Results

- n=48
- · High staff approval on application
- High parental satisfaction on removal but not staff satisfaction

	ISD+ suture n=12	SSD+suture +BPU n=13	BPU+suture (control) n=11	TA+BPU n=12
CVAD failure	2 (17%)	1 (8%)	0	0
Adverse skin event*	2 (17%)	1 (8%)	2 (18%)	0

*rash, blister, itchiness





Non-randomised reports in CVADs

Practice review of >30 CVCs (Wilkinson et al, 2007)

Application less time-consuming than sutures & line securement a 'complete success'

Practice review in 20 non-tunnelled CVCs (Lawrence & Hacking, 2014)

- Application process easier than sutures
- But 3 CVC accidental removals; 6 CVCs ineffectively secured → TA NOT ADOPTED





Non-randomised reports in CVADs

Cohort study of CVADs in adult patients (Scoppettuolo et al 2013)

- In 45 PICCs, 11 dialysis catheters and 9 CVCs, no bleeding at 1 or 24 hrs post -insertion
- No adverse events/No damage to polyurethane catheters detected

Cohort study of CVADs in adult & paediatrics (Pittiruti 2016)

- 348 PICCs; 165 CVCs; 114 tunnelled PICCs & CVCs; 802 ports & PICC ports
- 100% effective in haemostasis; in PICCs, in preventing extra-luminal bacterial contamination; and, in paediatric CVCs, achieved a tenfold reduction in CLABSI



2017

Non-randomised reports in CVADs

Cohort study of CVADs (and midlines) in adult patients (Ariotti 2016)

- >200 patients had TA applied to insertion site immediately after insertion, then compression bandage applied
- No need for dressing change within 24 hrs of catheter insertion
- Economic savings for hospital; and reduced discomfort for patient

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Take home message for TA use in CVADs

PICCs

- TA reduced failure rates
- Build-up of TA over repeated applications was problematic

CVADs

- In non tunnelled CVADs, TA ± suture may be effective in preventing failure → more evidence required
- In tunnelled CVADs, TA appears to be effective in reducing CVAD failure and providing haemostasis

Adverse events

- · Adverse skin events need to be investigated further
- · Patient/device factors need to be considered





Clinical practice guidelines



or Intravenous Ca Panel Using the



Guidelines for the Prevention of Intravascular Catheter-Related Infections, 201

VeCeLT* consensus s

Infusion Nursing plantable venous acco Standards of Practice

'Use of cyanoacrylate products ("super glue") to prevent oozing or discharge from the exit site or to secure catheters was rated as neutral by the panelists, who noted lack of substantial evidence or experience to support this recommendation'

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Challenge for manufacturers

- To supply TA in a form suitable for VAD securement
 - Smaller volume at a lower price point
 - More suitable applicators for VAD securement
 - VAD manufacturers could provide vials prepacked with insertion pack





Where to now?

- More large RCTs investigating TA use in all VADs are necessary, particularly:
 - PIV securement in paediatrics
 - PICC securement in all populations
 - Tunnelled and non-tunnelled CVADs in all populations
 - Testing of haemostatic and antimicrobial properties
- Adverse skin events associated with TA need to be explored further

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