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Administration sets/infusion tubing: How often should they be changed to prevent CRBSI?

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Disclosures

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3M, Adhezion, Angiodynamics, Bard, Baxter, BBraun, BD, Carefusion, Centurion, Cook, Entrotech, Flomedical, Hospira, Mayo, Medtronic, ResQDevices, Smiths, Teleflex, Vygon

This presentation is independently prepared and reflects no commercial entity nor promotes particular products unless these are supported by research data

This study:

Intravascular device administration sets:
Replacement after Standard Versus Prolonged use
(The RSVP trial)

V3 02/05/2017

NHMRC project grant 2011-2015, AUD\$1.7 million



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Background



- IVDs used extensively worldwide. Many use AS to deliver fluids, medication and pressure monitoring
- Since 1971, AS have been time limited for use (firstly 24 hours, then longer)
- Replacing AS may remove contaminated sets, or may instead allow contamination by breaking a closed circuit
- Routine AS change: equipment, nursing time costs, and medical waste, profits for manufacturers.



Background



Cashrana Database of Systematic Boylous

Optimal timing for intravascular administration set replacement

New search Conclusions changed Review Intervention

Amanda J Ullman M. Marie L Cooke, Donna Gillies, Nicole M Marsh, Azlina Daud, Matthew R McGrail, Elizabeth O'Riordan, Claire M Rickard

First published: 15 September 2013

Editorial Group: Cochrane Anaesthesia, Critical and Emergency Care Group

DOI: 10.1002/14651858.CD003588.pub3

Wewtsave citation

- A Cochrane systematic review (2013) included 16 RCTs (5001 pts) Most papers included were of moderate to high risk of bias (or unclear)
- Cochrane has determined <u>"There are currently an inadequate numbers of trials to examine the effect of AS use beyond 96hrs"</u>
- Australian Infection Control Guidelines (2010): "Leave AS that do not contain lipids, blood/blood products in place <u>up to 4 days</u>"
- CDC Guidelines 2011: "In patients not receiving blood, blood products or fat emulsions, replace AS no more frequently than at 96-hour intervals, but at least every 7 days." Category 1A



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The Team



Professor Claire Rickard Chief Investigator



Ms Nicole Marsh Project Manager

- (Other) Site Investigators:
 - o Professor Joan Webster
 - Professor Jeanine Young
 - o Professor John Fraser
 - Professor Geoffrey Playford
 - O Dr Evan Alexandrou
 - O Dr David McMillan
 - O Dr Matthew McGrail
- o Dr Fenella Gill
- o Dr Bradley Wibrow
- o Dr Naomi Runnegar
- O Dr Adrian Regli
- O Dr Stuart Baker
- o Dr John Gowardman
- o Tim Spencer
- Claire Reynolds

+ 26 Research Nurses over a period of 6 years. An amazing team!



Research Question



Aim: To compare the impact of 4 vs 7day administration set (AS) replacement on infective, clinical and cost outcomes?

Hypotheses:

- 7 day use is non-inferior (no worse) to 4 day for IADs for CRBSI - Sample: 680 IADs (baseline CRBSI 0.8%)
- ➤ 7 day and 4 day use is equivalent (+/- 2%) CVADs (all) for CRSBI - Sample: 2,220 CVADs (baseline CRSBI 1.9%)

PRIMARY OUTCOME: CRBSI (matched tip/blood; or differential time to positivity criteria) CDC 2011, IDSA 2009





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Design



- Multi-centre, RCT of 2,941 patients
- Pragmatic design of 4 day vs 7 day policy for crystalloid based infusions and non-lipid PN
- Centralised, stratified, block randomisation (concealed)
- Not blinded to patients, clinical or research staff, but blinded primary endpoint CRBSI assessments (ID physician)
- One device per patient. Intention to Treat approach
- Data Safety Monitoring Committee

Inclusion criteria

✓ Any inpatient/any age

Update! Waiver of consent

- ✓ CVAD or IAD in situ with AS
- ✓ Device *in situ* >24 hours
- ✓ Device expected ≥7 days

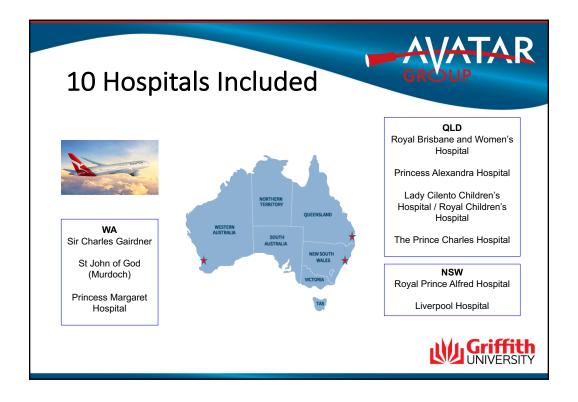
Exclusion criteria

- X Current bloodstream infection
- X Device removal ≤24 h
- X Device in situ >96 h
- X Original AS replaced



Study Population Clinical Setting Population **Devices** • Adults Intensive Care Arterial Lines • Paediatrics (IALs) Cancer Care Services • Central Venous Catheters (CVCs) Medical/Surgical Peripherally **Inserted Central** Catheters (PICC) Cuffed Catheters Implanted Ports

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Approvals



Human Research Ethics Committees:

Update: Children's Health Queensland Hospital and Health Services Human Research Ethics Committee (HREC) (5 Hospitals - from 2013-2016)

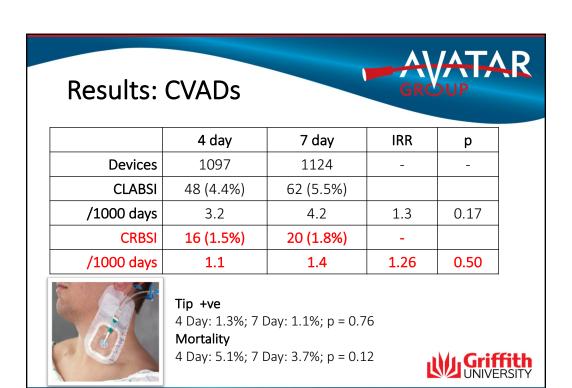
- New South Wales (NSW): Royal Prince Alfred Hospital HREC (2 Hospitals)
- Western Australia (WA):
 - Princess Margaret Hospital Hospital HREC (1 Hospital)
 - Sir Charles Gairdner and Osborne Park Health Care Group HREC (1 Hospital)
 - St John of God Health Care HREC (1 Hospital)
- Site Specific Approvals (for each hospital)
- QCAT (QLD Civil and Administrative Tribunal) and NCAT (NSW Civil and Administrative Tribunal)
- Public Health Act approval (permission to access confidential health information)
- · Registered on the Australian and New Zealand Clinical Trials Registry

....lots of paperwork....



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Study Population GROUP				
	4 day	7 day		
Age	49 yrs	50 yrs		
Females	37%	37%		
ICU / PICU	52% / 10%	51% / 9%		
Med/Surg	4% / 11%	4% / 12%		
Onc / Haem	4% / 20%	5% / 19%		
Diabetes	16%	16%		
Leucopenic	5%	5%		
Griffit				



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Results: IALs



	4 day	7 day	IRR	р
Devices	363	357		
CLABSI	10 (2.8%)	6 (1.7%)		
/1000 days	3.8	2.4	0.63	0.38
CRBSI	0 (0%)	1 (0.28%)		
/1000 days	0	0.4	N/A	0.49



Tip +ve

4 Day: 0%; 7 Day: 0.8%; p=0.08

Mortality

4 Day: 6.6%; 7 Day: 7.3%; p=0.72



Interpretation



Now:

- ✓ 4 day & 7 day AS replacement equivalent for CVADs
- ✓ Day 7 is not worse than Day 4 for arterial devices
- ✓ Policies can change to 7 day AS replacement for crystalloid-based infusions and non-lipid PN
- ✓ Less AS replacement procedures reduce work and costs

Future:

- ✓ Many ICU (and other units) have CLABSI >1/1000 days
- ✓ Focus needed on highly prevalent ICU device failure
- ✓ Why are so many ICU devices removed "routinely"?
- ✓ Why are so many ICU and CCS "suspected CLABSIs" not confirmed?

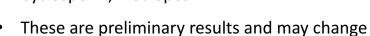


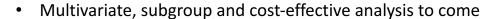
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Limitations



- Only outcome assessors were blinded
- PICC & CVCs unable to be powered separately
- Not generalizable to lipids, blood, chemotherapy,
 Cyclosporin, inotropes









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