



A multi center randomized controlled non-inferiority trial

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Disclosure

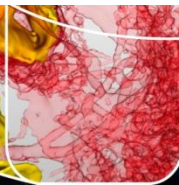
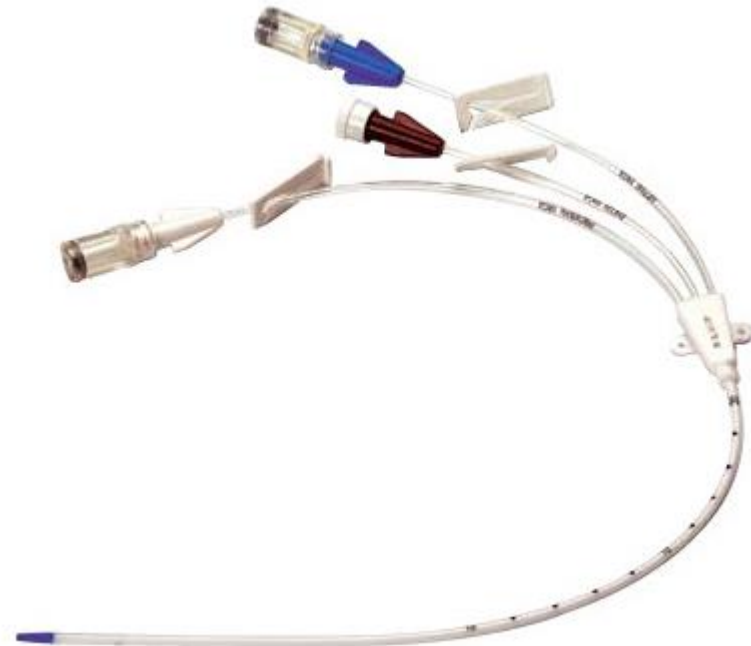
- Funding: Sanquin, NWO, ZonMw



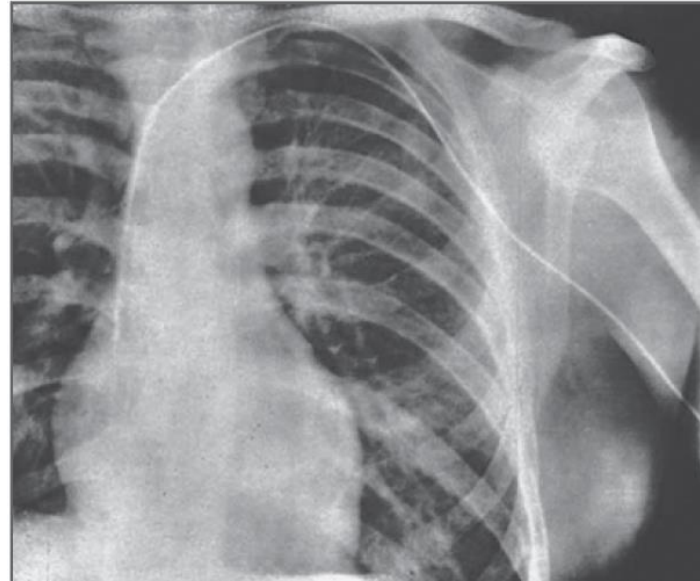
A randomized controlled trial on prophylactic platelet transfusion prior to central venous catheter placement in patients with thrombocytopenia



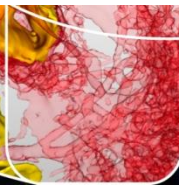
PACER trial



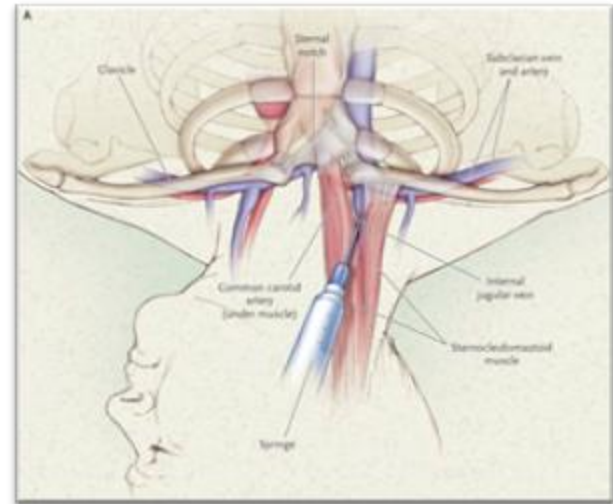
First Central Venous Line



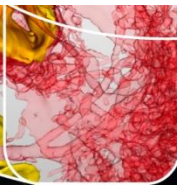
Werner Forßmann, 1904-1979



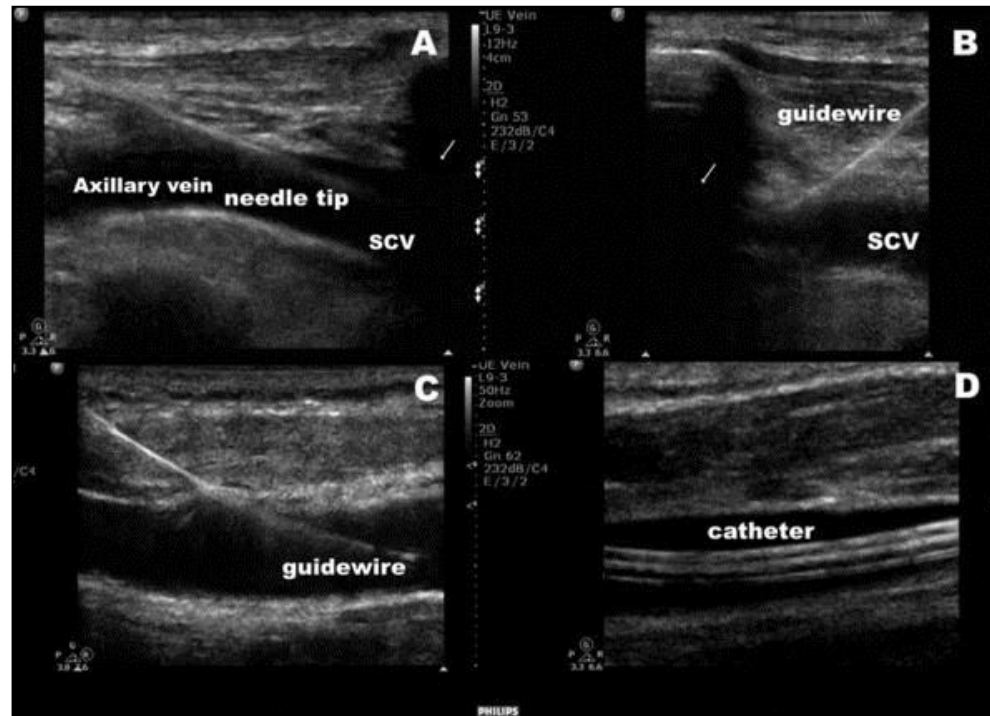
Ultrasound vs Landmark



HIND D et al. BMJ; 2003



Ultrasound



Fragou, 2011



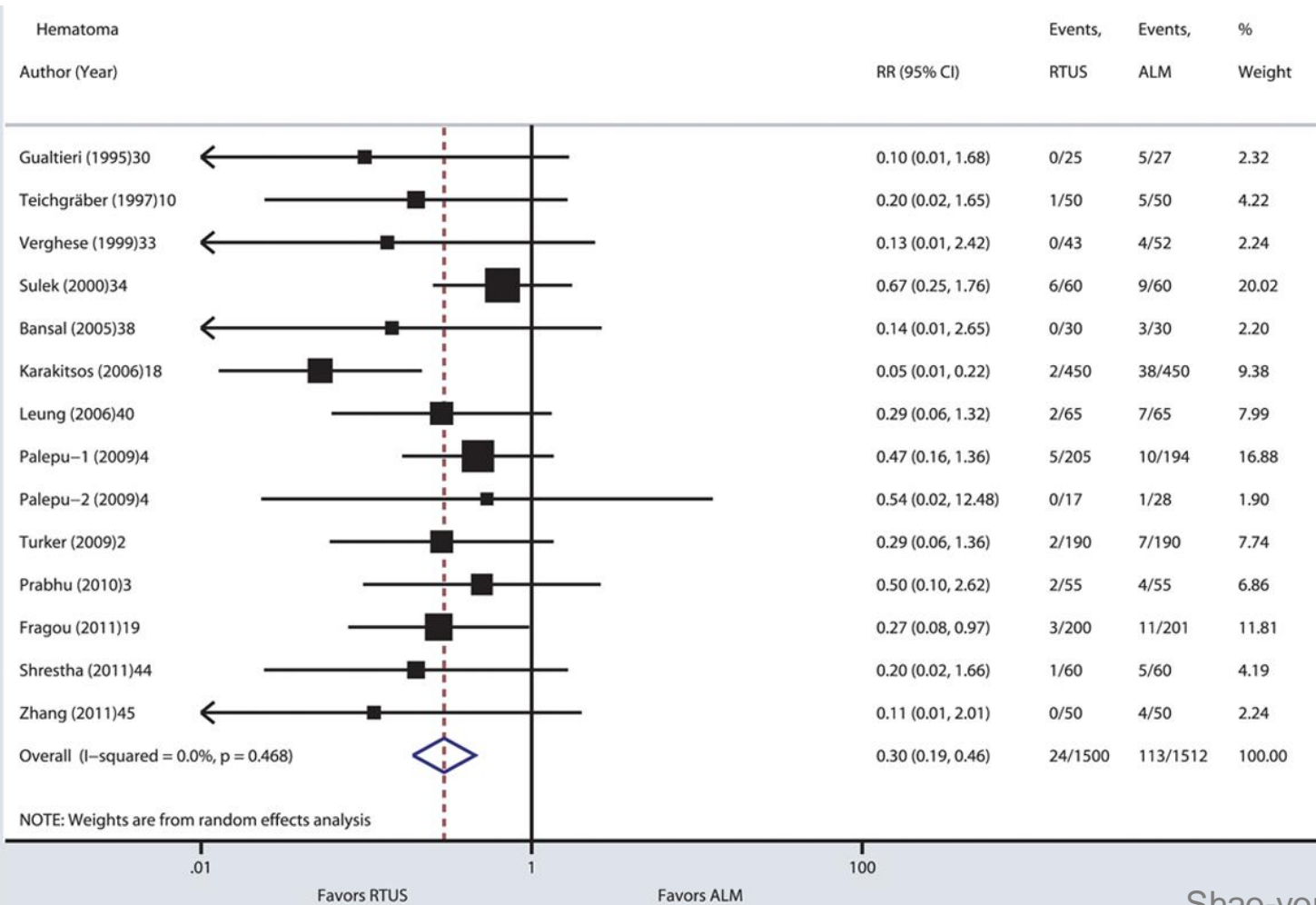
Ultrasound vs Landmark

Characteristics	Ultrasound group (n =100)	Landmark group (n=100)
Hematoma	3 (1.5%)	11 (5.4%)
Hemothorax	0 (0%)	9 (4.4%)
Artery puncture	1 (0.5%)	11 (5.4%)
Number of attempts	1.1 \pm 0.3	1.9 \pm 0.7

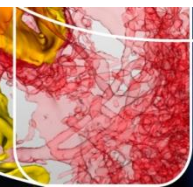
Fragou, 2011



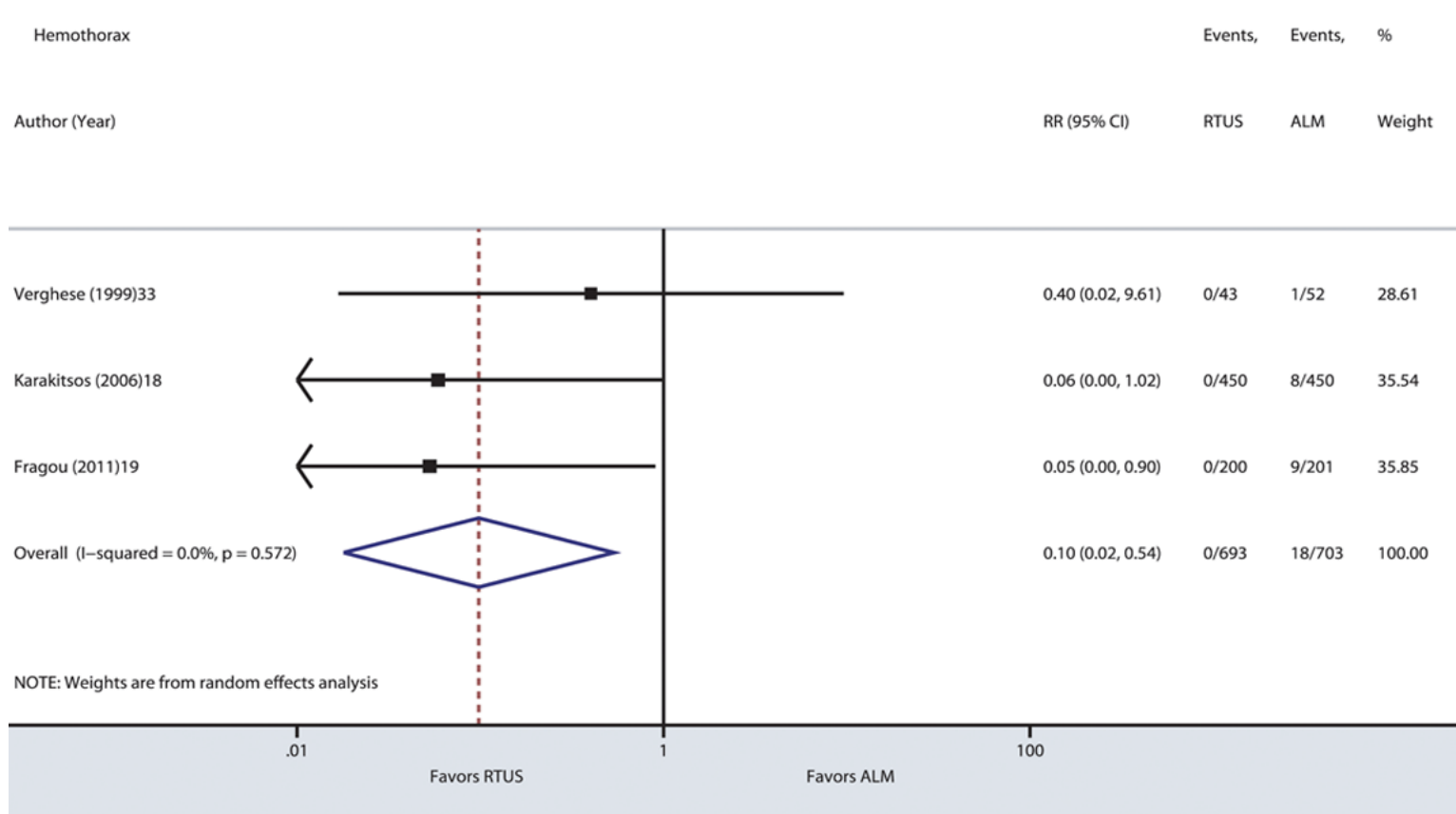
Hematoma



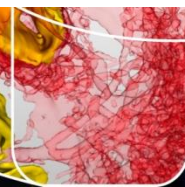
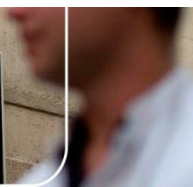
Shao-yong Wu, 2013



Hemothorax



Shao-yong Wu, 2013



CVC and thrombocytopenia

- Current guidelines
- Retrospective evidence
- Impact on healthcare costs



Platelet transfusion

- Allergic reactions
- TRALI
- Allo/auto-immunisation
- Contamination



Uptodate.com



Hypothesis

Not correcting thrombocytopenia prior to CVC placement in patients is safe



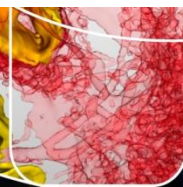
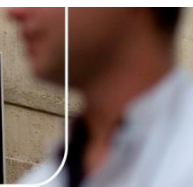
Objectives

- Clinical bleeding complications
- Transfusion complications and costs



Multi-center study

Radboudumc



Design

- Non-inferiority
- 231 patients per arm
- Cut off $<2.5\%$ complications



Involved departments

- Hematology
- Intensive Care
- Radiology
- Anesthesiology



Population

- Hematologic patients
- Intensive Care patients



Inclusion criteria

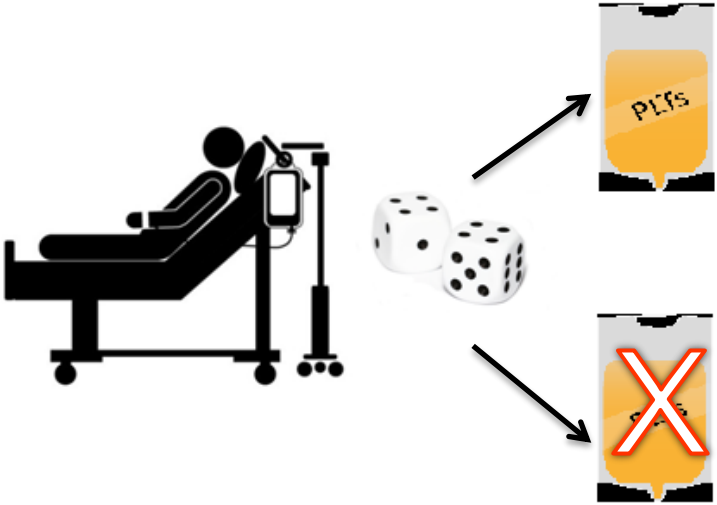
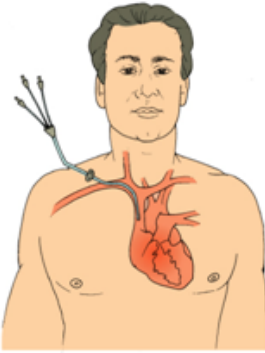

- Age > 18 years
- Need for CVC placement
- Platelet count: $10-50 \times 10^9/L$
- INR < 1.5, APTT < 1.5 ULN
- Informed consent

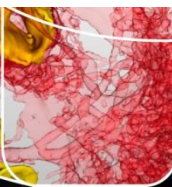


Exclusion criteria

- Use of therapeutic anticoagulant therapy
- Contra-indication for PC transfusion
- Previous randomization in the current trial
- Patients with a history of congenital or acquired coagulation factor deficiency or bleeding diathesis



Before placement	CVC	Measurements
		<p>T1: Directly T2: 1 hour T3: 24 hours</p> 



Primary Endpoint

- Central Venous Catheter related bleeding complications (WHO grade 2-4)



Secondary endpoints

- Not significant bleeding (WHO 1)
- Transfusion reactions
- Hb drop
- Costs



Workflow Intensive Care

- Deferred Consent
- Randomisation by researcher
- CVC Placement by experienced intensivist
- Consent by researcher



CVC Placement

- Ultrasound guidance
 - Placement by experienced physician
- > 50 previous CVC placements



Prolonged bleeding

1. Manual compression
2. Suture
3. Rescue platelets
4. Radiological / surgical intervention





A Randomized Controlled Trial on
Prophylactic Platelet Transfusion Prior to Central
Venous Catheter Placement in Patients with
Thrombocytopenia

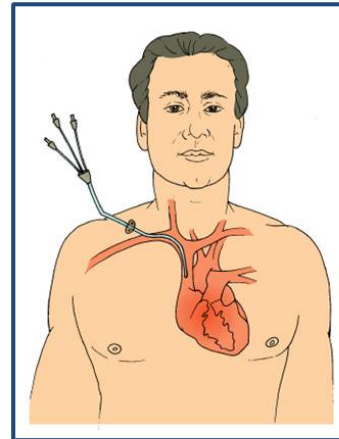
Het nut van trombocytentransfusie voor het plaatsen van een
Centraal Veneuze Lijn, bij patiënten met trombocytopenie.

Inclusie criteria:

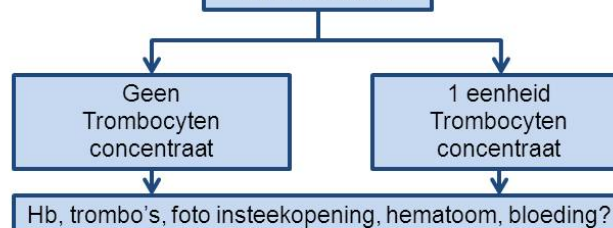
- Trombocytengetal $10-50 \times 10^9/L$.
- Indicatie voor centraal veneuze lijn (geen PICC-lijn)
- Ouder dan 18 jaar.
- $INR < 1.5$.
- Informed consent.

Exclusie criteria:

- Therapeutische antistolling, met uitzondering van enkele plaatjesremming, en (tijdelijk) gestaakte therapeutische heparine.
- Contra-indicatie voor trombocyten transfusie (TTP, IgA deficiëntie)
- Eerdere deelname aan de huidige studie.
- Patiënten met een aangeboren of verworven factor deficiëntie.



Randomisatie



Tijdpunten

- Direct na plaatsing
- 1 uur
- 24 uur

Onderzoeker:

- Vraagt Informed Consent
- Randomiseert
- Verzamelt gegevens

Participation

- Please contact:

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Questions?

