CATETERI VENOSI NOVITA' IN AFERESI

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GAVeCeLT
Gli Accessi Venosi Centrali a Lungo Termine

UNIVERSITÀ CATTOLICA DEL SACRO CUORE

Cosa è cambiato nel nuovo millennio

- Nuova filosofia ‘patient oriented’ anziché ‘physician oriented’
- Crescente ruolo infermieristico in tutti gli aspetti dell’accesso venoso
- Pratica clinica non più empirica ma orientata su linee guida e raccomandazioni internazionali ‘evidence based’
- Nuove tecnologie per l’impianto e per la gestione
- Nuovo atteggiamento: ricerca di ciò che è ‘più costo-efficace’ piuttosto che ciò che è ‘meno costoso’

Cosa è cambiato nel nuovo millennio

- Novità “procedurali”
  - Proactive Vascular Planning e ruolo dell’infermiere
  - Targetting Zero Complications e i “bundles”
    - Complicanze immediate
    - CR-BSI
    - Trombosi
- Novità “tecniche”
  - Eco-guida
  - ECG-guida
- Novità “tecnologiche”
  - Power-PICC in aferesi e ultrafiltrazione (dialisi ?)
  - Cateteri “ibridi” (anche “power”)
  - Cateteri “trattati”
  - Port bicamerali (aferesi cronica) con tecnologia “Vortex” (+ “power”)

1.
NOVITA' "PROCEDURALI"

Proactive Vascular Planning

Proactive Va

Kathy K

Journal of Infusion Nu

Cost Containme

Th
grams in the United State
nutrition, patient fall, and
tients receive vascular ac
proactive planning proces

- Reduce the prices paid for resources[7]
  - Decrease the number of unsuccessful PICC insertions
  - Decrease the number of PICC insertions referred to the interventional radiology department
  - Maintain an 80% or higher insertion success rate for the first attempt at all conventional peripheral venipunctures
  - Declot rather than replace occluded central catheters
- Reduce the patient's hospital LOS[7]
  - Place a PICC at admission rather than discharge to encourage early discharge planning for alternate site infusion
  - Reduce the cost of incomplete drug infusions or late drug delivery by providing a reliable infusion device
  - Decrease the risk of nosocomial catheter-related bloodstream infection (CR-BSI)
- Reduce the intensity of service provided[7]
  - Reduce the number of unnecessary peripheral starts and restarts by providing a reliable vascular access device at patient admission rather than on the day of discharge
- Improve production efficiency[7]
  - Implement a vascular access planning program
  - Use tools to decrease the time for placement of a PICC and improve insertion proficiency
  - Reengineer infusion teams, dedicating specialized staff to high-tech procedures full-time rather than task-oriented site checks, multiple repetitive peripheral catheter reinsertions, and repetitive timed dressing changes.

Promuovere la professionalità infermieristica

Sheryl McDiarmid, RN, BScN, MEd, MBA, AOCN, ACNP
Linda Hamelin, RN, BScN
L. B. Huebsch, MD

Leading Change

Retrospective Evaluation of a Nurse-led Initiative in Vascular Access Options for Autologous Stem Cell Transplant Recipients Ranging From Hickman Catheters to Peripherally Inserted Central Catheters

Journal of Infusion Nursing

Vol. 29, No. 2, March/April 2006

Targeting zero complications

USA: NESSUN RIMBORSO PER COMPLICANZE PREVENIBILI

Negli USA, dal gennaio 2008, Medicaid non rimborsa più i seguenti eventi avversi in quanto giudicati **PREVENIBILI**:

- EMBOLIA POLMONARE (in pazienti non già portatori di TVP)
- DECUBITI (se non pre-esistenti)
- SEPSI URINARIE DA CATETERE VESCICALE (in pazienti non già portatori di CV)
- CORPI ESTRANEI ritenuti in seguito a procedure invasive
- **SEPSI BATTERIEMICHE DA CATETERE VASCOLARE**

Institute For Healthcare Improvement's **100k** lives Campaign

PRESUPPOSTO

- **≤ 98,000** decessi l'anno per errore medico (*Institute of Medicine, 1999)*
- **195,000** decessi l'anno per errore medico (*HealthGrades, 2004)*

Institute For Healthcare Improvement's **100k** lives Campaign

1. Teams dell'emergenza efficienti
2. Efficace intervento per gli infarti del miocardio
3. Prevenire le reazioni avverse da farmaci
4. Prevenire le infezioni della ferita chirurgica
5. **Prevenire le infezioni degli accessi venosi centrali**
6. Prevenire le polmonite associate a ventilazione meccanica

PREVENZIONE DELLE CR-BSI
LE STRATEGIE "SEMPLICI"

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 28, 2006 VOL. 355 NO. 26

An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU

Peter Pronovost, M.D., Ph.D., Dale Needham, M.D., Ph.D., Sean Berenholtz, M.D., David Sinopoli, M.P.H., M.B.A., Haitao Chu, M.D., Ph.D., Sara Cosgrove, M.D., Bryan Sexton, Ph.D., Robert Hyzy, M.D., Robert Welsh, M.D., Gary Roth, M.D., Joseph Bander, M.D., John Kepros, M.D., and Christine Goeschel, R.N., M.P.A.

Thus, 103 ICUs reporting data for 1981 ICU-months and 375,757 catheter-days were included in the final analysis. The characteristics of the

tion.[1] The recommended procedures are hand washing, using full-barrier precautions during the insertion of central venous catheters, cleaning the skin with chlorhexidine, avoiding the femoral site if possible, and removing unnecessary catheters.

PREVENZIONE DELLE CR-BSI
LE STRATEGIE "SEMPLICI"

Table 3. Rates of Catheter-Related Bloodstream Infection from Baseline (before Implementation of the Study Intervention) to 18 Months of Follow-up.*

Study Period	No. of ICUs	No. of Bloodstream Infections per 1000 Catheter-Days				
		Overall	Teaching Hospital	Nonteaching Hospital	<200 Beds	≥200 Beds
		median (interquartile range)				
Baseline	55	2.7 (0.6–4.8)	2.7 (1.3–4.7)	2.6 (0–4.9)	2.1 (0–3.0)	2.7 (1.3–4.8)
During implementation	96	1.6 (0–4.4)†	1.7 (0–4.5)	0 (0–3.5)	0 (0–5.8)	1.7 (0–4.3)†
After implementation						
0–3 mo	96	0 (0–3.0)‡	1.3 (0–3.1)†	0 (0–1.6)†	0 (0–2.7)	1.1 (0–3.1)‡
4–6 mo	96	0 (0–2.7)‡	1.1 (0–3.6)†	0 (0–0)‡	0 (0–0)†	0 (0–3.2)‡
7–9 mo	95	0 (0–2.1)‡	0.8 (0–2.4)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.2)‡
10–12 mo	90	0 (0–1.9)‡	0 (0–2.3)‡	0 (0–1.5)‡	0 (0–0)†	0.2 (0–2.3)‡
13–15 mo	85	0 (0–1.6)‡	0 (0–2.2)‡	0 (0–0)‡	0 (0–0)†	0 (0–2.0)‡
16–18 mo	70	0 (0–2.4)‡	0 (0–2.7)‡	0 (0–1.2)†	0 (0–0)†	0 (0–2.6)‡

Pronovost - New England Journal of Medicine - 2006

Targeting zero infections

- Possibilità REALE di azzerare il rischio infettivo..
  - Concetto di ***TARGETING ZERO***
- Utilizzando in maniera sistematica un insieme di poche ma efficaci norme comportamentali basate sulla EBM
  - Concetto di ***'bundle'***

Targeting zero infections

IL “BUNDLE”

- Igiene delle mani
- Massime precauzioni di barriera
- Antisepsi cutanea con clorexidina
- Scelta ottimale per il posizionamento del catetere
- Verifica quotidiana della necessità del catetere con rimozione immediata in caso di non necessità

'*Bundle*' GAVeCeLT per la prevenzione delle infezioni associate a cateteri venosi centrali non tunnellizzati a breve e medio termine

2008

1. Massime precauzioni di barriera durante l'impianto del catetere venoso
2. Scelta appropriata del sito di inserzione (in ordine di preferenza: metà braccio, zona sottoclaveare, zona sopraclaveare, collo, inguine)
3. Impianto ecoguidato, ovunque possibile, sia per i cateteri a inserzione centrale che per i cateteri a inserzione periferica
4. Utilizzo di clorexidina al 2% per la disinfezione cutanea prima della inserzione, nonché per la disinfezione continua o discontinua dell'exit site
5. Utilizzo di "sutureless devices" per il fissaggio del catetere, ovunque possibile
6. Impiego di medicazioni semipermeabili trasparenti, ovunque possibile
7. Rimozione immediata del catetere venoso centrale non più indispensabile

Have we forgotten the most important thing to prevent bacteremias associated with tunneled hemodialysis catheters?

M. Albalate[1], R. Pérez García[1], P. de Sequera[1], R. Alcázar[1], M. Puerta[1], M. Ortega[1], A. Mossé[1], E. Crespo[2]

[1] Nephrology Department. Infanta Leonor Hospital. Madri
[2] Nephrology Radiology. Infanta Leonor Hospital. Madrid,

Nefrologia 2010;30(5):573-7

Table 2. Summary of connection/disconnection TC protocol in the HD unit

A. CONNECTION

1. Inform the patient on the technique to be used and place the patient in supine or Trendelemburg position.
2. Facemask placement (nurse, patient, and other personnel involved in the connection).
3. Wash hands and place non-sterile gloves for dressing removal.
4. Prepare the sterile area and place below the catheter.
5. Change to sterile gloves in order to clean the insertion point, first with saline solution and then with disinfecting gauze. Dry with sterile gauze and cover with a sterile dressing.
6. Change to new sterile gloves.
7. Drip clorhexidine on the connection points and cap.
8. Remove the arterial line cap and clean with a sterile gauze impregnated with disinfectant. Immediately connect to the different syringes in order to test function and clean the line. Do not leave the connection open to the air at any point, leaving the syringe to one side until the moment of connecting to the arterial line. Repeat the sequence identically with the venous branch.
9. Avoid at all times that the connection touch any non-sterile surface.
10. Avoid losing sterility in the HD lines.
11. Proceed with the arterial and venous connections.
12. Surround the connections with gauzes impregnated with disinfectant solution.
13. Secure the lines to avoid traction or kinks.

B. DISCONNECTION

1. Follow the same precautions using facemask, gloves, and sterile workspaces.
2. Following the disconnection, again clean the catheter connection point with a sterile gauze and disinfectant, and follow the same precautions to not expose the connection to the open air or allow it to touch non-sterile surfaces until putting the caps in place.

NOTES AND OBSERVATIONS:

1. It is advisable to perform the disinfection and catheter connection with the help of another member of the nursing staff. If this is not possible, change the sterile gloves after touching any non-sterile foreign object or material before coming into contact again with the catheter or insertion point.
2. Move the TC as little as possible in order to avoid eroding the insertion point or antagonizing the internal tissues.
3. Whenever alterations are observed in the insertion point, the skin around it, and/or the permeability of the catheter, immediately notify the attending physician and head nurse.

Targeting zero complications

NESSUN RIMBORSO PER COMPLICANZE PREVENIBILI

In Francia il ministero della sanità ha PROSCRITTO l'approccio alla vena succlavia per via sottoclaveare per i cateteri venosi centrali a lungo termine (PREVENZIONE del pinch off e del PNX)

Il protocollo ISALT

ISALT = Impianto Sicuro degli Accessi a Lungo Termine (port e tunnellizzati)

1. Massime precauzioni di barriera
2. Venipuntura ecoguidata
3. Verifica intraoperatoria della posizione della punta, mediante fluoroscopia o mediante metodo EKG
4. Gestione accurata della guida metallica
5. Appropriata stabilizzazione dei cateteri tunnellizzati
6. Scelta appropriata della sede di impianto del reservoir

Obiettivi del protocollo ISALT

- Minimizzare le complicanze da venipuntura:
  - Fallimento, tentativi ripetuti, PNX, puntura arteriosa
- Minimizzare il rischio infettivo
- Minimizzare le malposizioni
- Minimizzare il rischio trombotico
- Minimizzare il rischio di dislocazione
- Minimizzare il rischio di aritmie

Il protocollo ISP

ISP = impianto sicuro dei PICC

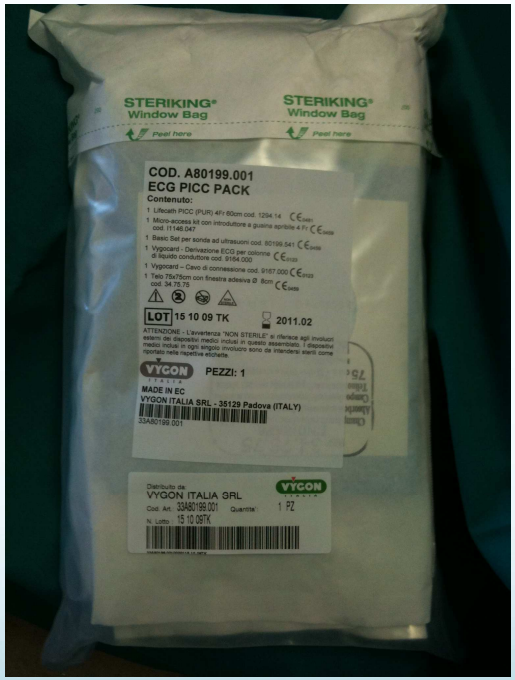
1. Lavaggio delle mani, asepsi e massime protezioni di barriera
2. Esame ecografico bilat. di tutte le vene del braccio e del collo
3. Scelta della vena appropriata a ½ braccio (mm vena = o > Fr cat.)
4. Identificazione del n.mediano e della arteria brachiale
5. Venipuntura ecoguidata
6. Controllo ecografico della v.giugulare interna durante la progressione del PICC
7. Verifica della posizione centrale della punta con metodo ECG
8. Fissaggio del PICC con un sistema ‘sutureless’

Obiettivi del protocollo ISP

- Minimizzare le complicanze da venipuntura:
  - Fallimento, punture ripetute, puntura del nervo, puntura/incannulamento dell'arteria
- Minimizzare le malposizioni
- Minimizzare il rischio trombotico
- Minimizzare il rischio di dislocazione
- Minimizzare il rischio infettivo

Importante: utilizzo di ‘pack’ con tutti gli elementi necessari alla manovra

- Cfr linee guida SHEA/IDSA 2008
  - ‘pack’ pronto = riduzione rischio infettivo



Catetere

Introduttore MST

Grip-lok

Bionecteur

- Coprisonda + gel sterile
- Telino traforato
- Cavo per tecnica ECG
- Siringhe
- ……

2.
NOVITA' "TECNICHE"

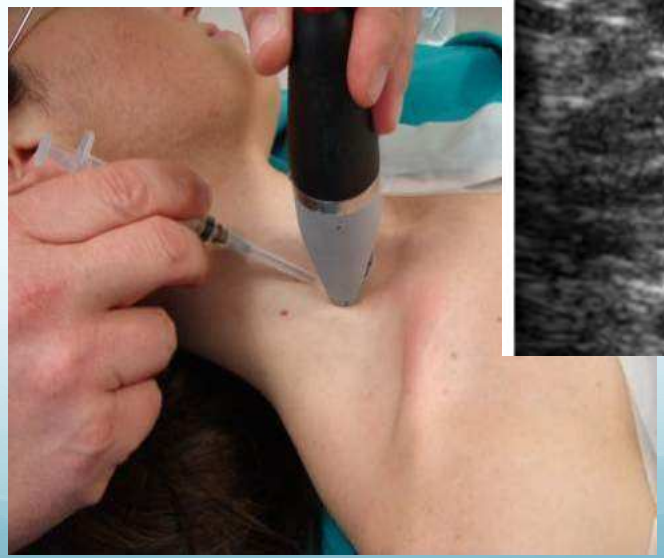
Ecografia ed accessi vascolari

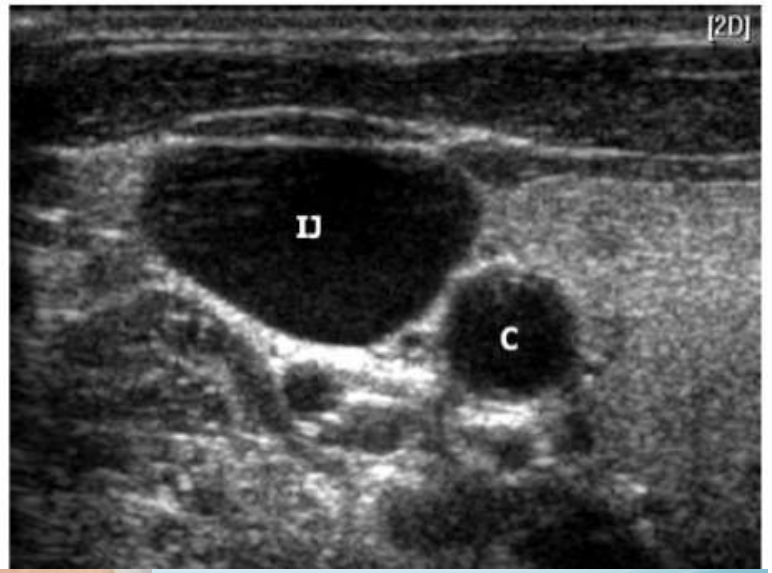
Negli ultimi 10 anni una gran quantità di Letteratura ha dimostrato che la guida ecografica migliora i risultati del cateterismo vascolare in termini di:

- Tasso globale di successo della manovra e tasso di successo al primo tentativo
- Tempo medio per il completamento della procedura
- Tasso di complicanze
- Numero di tentativi
- Costi

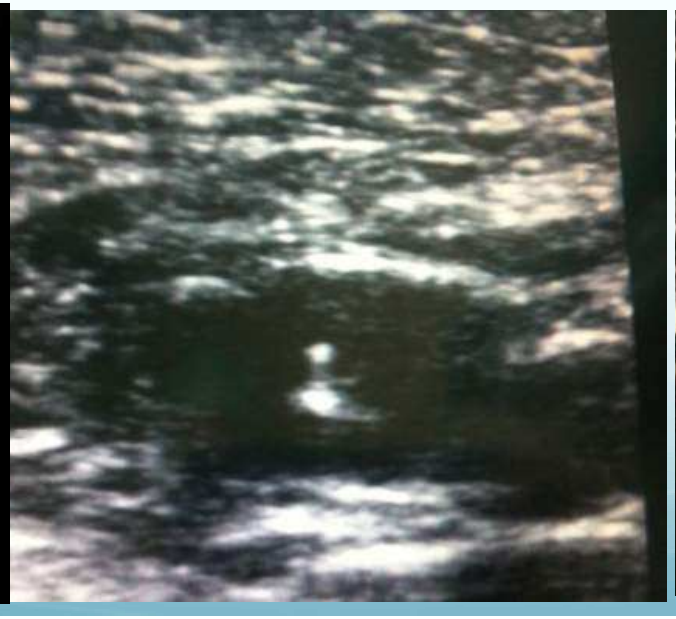
- Studi randomizzati "storici"
- Metanalisi
  - Randolph 1996
  - Rothschild 2001
  - Keenan 2002
  - Calvert 2003
- Studi randomizzati recenti
- Position papers (ACS 2008, AVA 2008)
- Linee guida internazionali: AHRQ 2001, NICE 2002, BCSH 2006, EPIC 2007, ESPEN 2009, INS 2011, CDC 2011, WoCoVA 2012

Scelta della vena

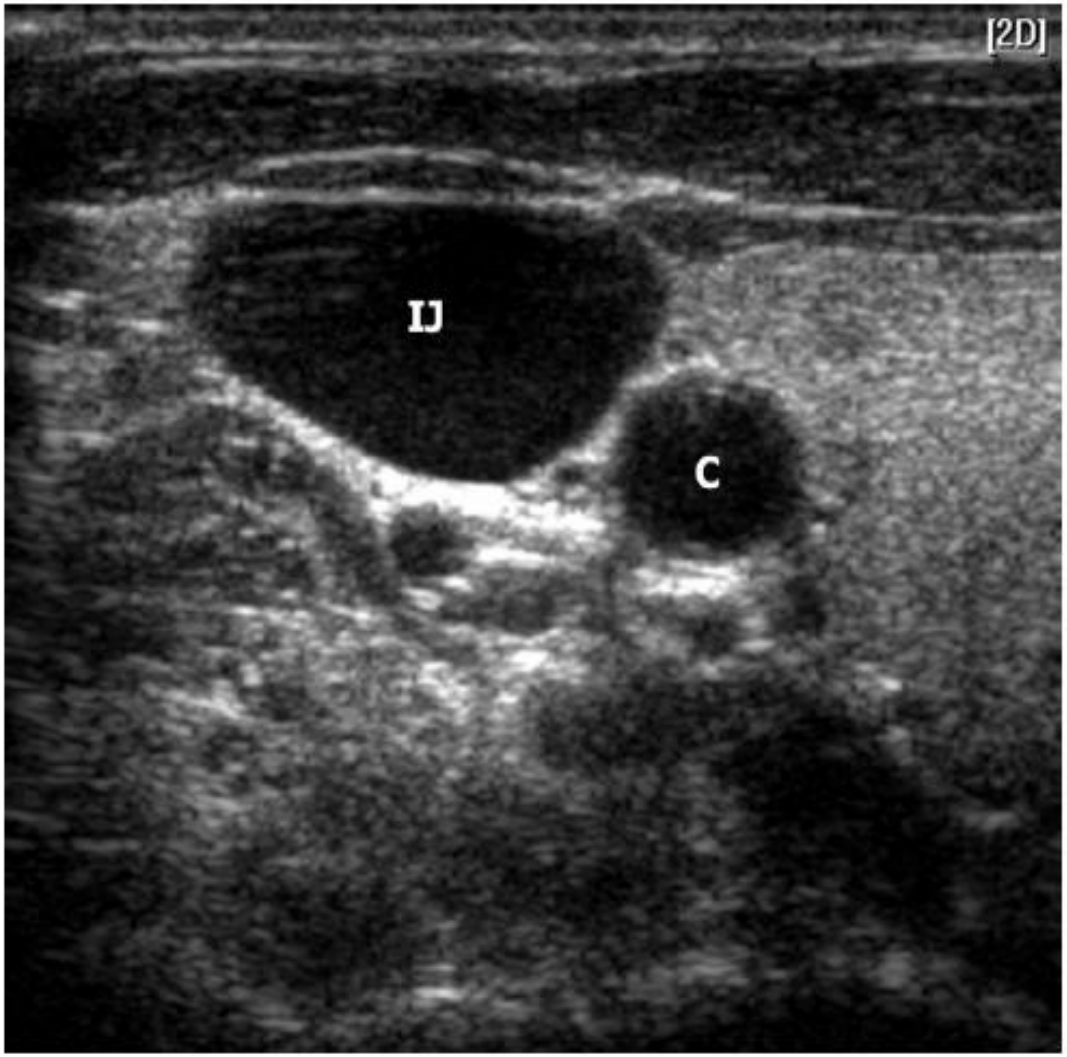




Venipuntura centrale “diretta” (CICC)



Evitando …



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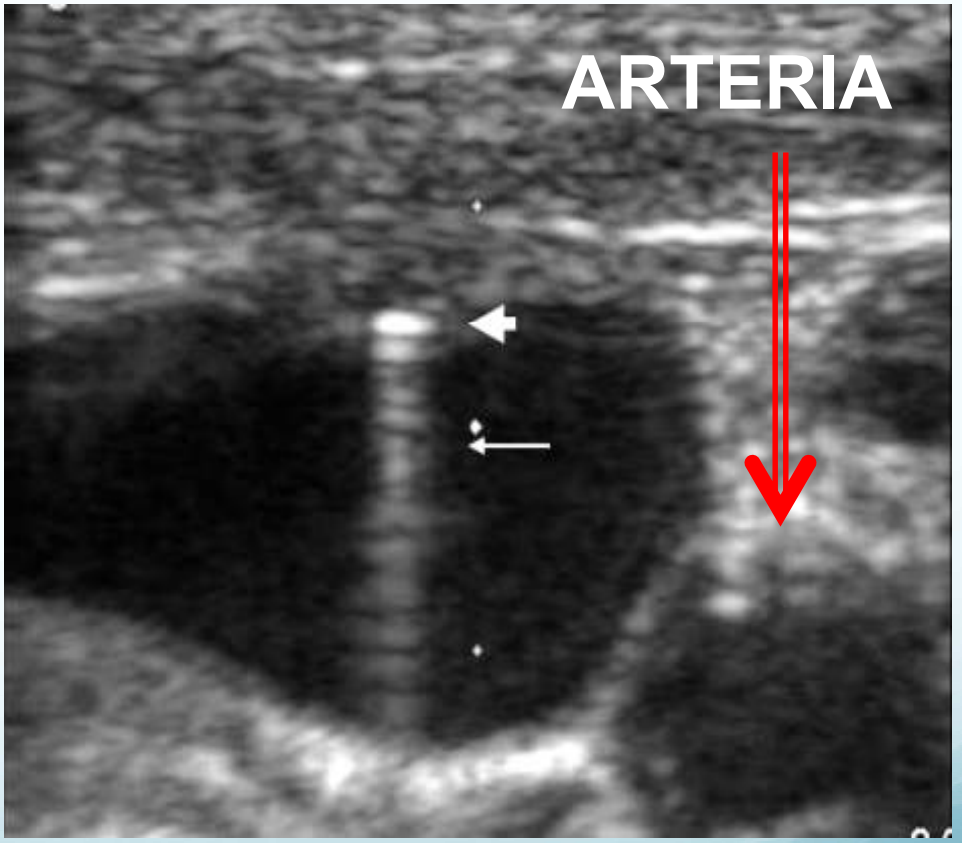
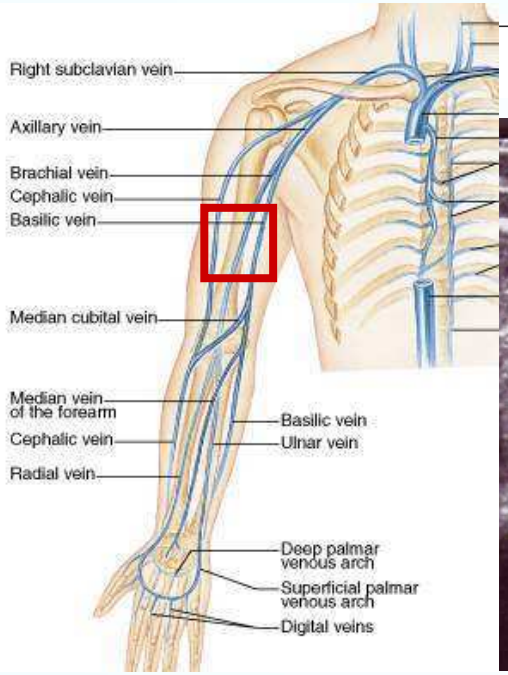
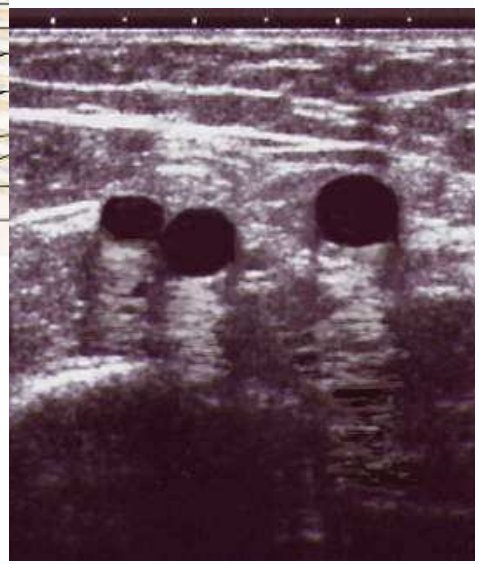


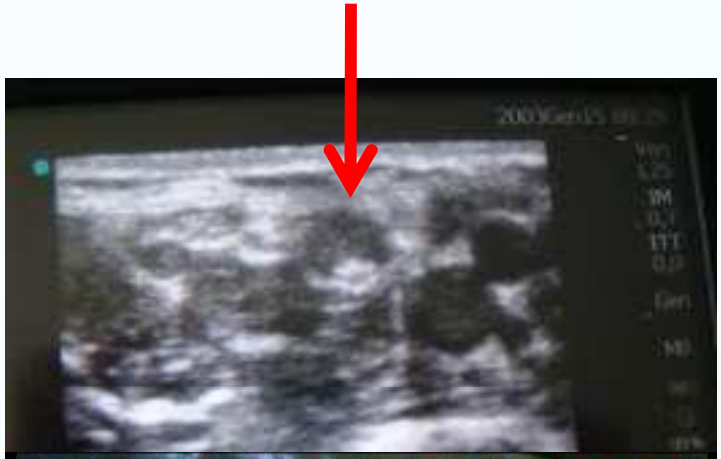


JAVA | Vol 8 No 3 | 2003



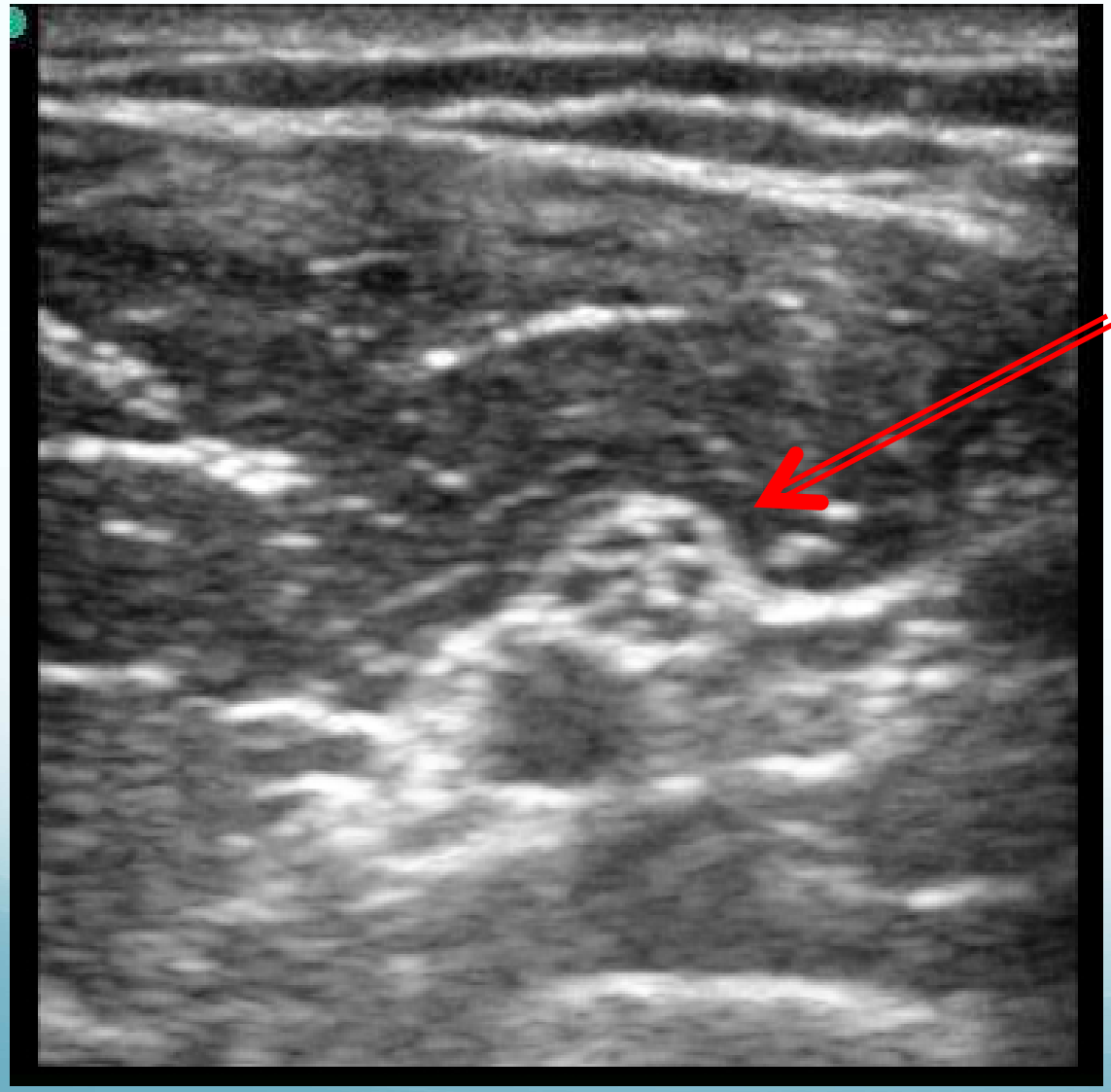
The Impact of Ultrasound on PICC Placement

Michael Anstett, RN, CRNI
Timothy Ian Royer, BSN, CRNI



Venipuntura PERIFERICA per accesso venoso CENTRALE (PICC)

Evitando …



PICC:
NERVO
MEDIANO

Ecoguida: effetti sulla CR-BSI…

Real-time ultrasound-guided catheterisation of the internal jugular vein: a prospective comparison with the landmark technique in critical care patients

D. Karakitsos et al - *Critical Care* 2006, **10**:R162

Table 2

Outcome measures in the ultrasound group versus the landmark group of patients

Outcome measures	Ultrasound group ($n = 450$)	Landmark group ($n = 450$)
Access time (seconds)	17.1 ± 16.5 (11.5 to 41.4)[a]	44 ± 95.4 (33.2 to 77.5)
Success rate	450 (100%)[a]	425 (94.4%)
Carotid puncture	5 (1.1%)[a]	48 (10.6%)
Haematoma	2 (0.4%)[a]	38 (8.4%)
Haemothorax	0 (0%)[a]	8 (1.7%)
Pneumothorax	0 (0%)[a]	11 (2.4%)
Average number of attempts	1.1 ± 0.6 (1.1 to 1.9)[a]	2.6 ± 2.9 (1.5 to 6.3)
CVC-BSI	47 (10.4%)[a]	72 (16%)

[a]Comparison of the outcome measures between the ultrasound group and the landmark group of patients ($p < 0.001$). Access time and average number of attempts are expressed as mean ± standard deviation (95% confidence interval). Success rate, carotid puncture, haematoma, haemothorax, pneumothorax, and CVC-BSI are expressed as the absolute number of patients and percentage of their group. CVC-BSI, central venous catheter-associated blood stream infection.

Ecoguida: effetti sulla TVC

CE Test Material

Catheter-Related Central Venous Thrombosis: The Development of a Nationwide Consensus Paper in Italy

Costantino Campisi, MD, Roberto Biffi, MD, and Mauro Pittiruti, MD
on behalf of the GAVeCeLT Committee for the Consensus

38 | JAVA | Vol 12 No 1 | 2007

- **Q2 - Is there an ideal insertion technique for minimizing the risk?**

- No randomised trials have so far investigated the relationship between different insertion techniques in the long-term setting (percutaneous vs venous cut-down, US guided vs anatomic landmark techniques) and central venous thrombosis rate.

- Prospective studies suggest a relationship between minimal insertion damage to vein wall and low rate of thrombosis.

Strength C Recommendation

Il documento più recente e completo….

Intensive Care Med
DOI 10.1007/s00134-012-2597-x

CONFERENCE REPORTS AND EXPERT PANEL

Massimo Lamperti
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International evidence-based recommendations on ultrasound-guided vascular access

2012

Consensus GAVeCeLT - WINFOCUS - WoCoVA

Raccomandazioni nell'adulto…

Ultrasound vascular access in adults		
Domain code	Suggested definition	Level of evidence
D4.SD2.S1	Ultrasound guidance should be routinely used for short-term central venous access in adults	A
D4.SD2.S2	Ultrasound guidance should be routinely used for long-term central venous access in adults	A
D4.SD2.S3	PICCs should be routinely inserted at mid arm level by ultrasound guidance using micro introducer technique	A
D4.SD2.S4	Use of ultrasound guidance should be taken into consideration for any kind of peripheral intravenous line when difficult access is anticipated	B
D4.SD2.S5	Ultrasound-guided arterial catheterization improves first-pass success and should be used routinely in adults	A
D4.SD2.S6	Ultrasound can accurately detect pneumothorax and should be routinely performed after central venous catheter cannulation when the pleura could have been damaged	B
D4.SD2.S7	CEUS (contrast-enhanced ultrasound) is a valid method for detecting a central venous catheter tip in the right atrium	B
Cost-effectiveness of the use of ultrasound for vascular cannulation		
D5.S1–3	Ultrasound-guided vascular access has to be used because it results in clinical benefits and reduced overall costs of care makes it cost-effective	A

Nel bambino e nel neonato…

Ultrasound vascular access in neonates and children

Domain code	Suggested definition	Level of evidence
D4.SD1.S1–2	Ultrasound guidance should be routinely used for short- and long-term central venous access in children and neonates	A
D4.SD1.S3	Ultrasound vessel imaging with ultrasound assistance as "a minimum" should be routinely performed before internal jugular vein puncture in neonates	A
D4.SD1.S4	In neonates, ultrasound screening should be used before subclavian vein puncture. Ultrasound-guided puncture should be considered for catheterization using the supra-clavicular route, but this technique requires experienced operators	C
D4.SD1.S5	Ultrasound vessel screening should be routinely used before femoral vein puncture. Ultrasound-guided femoral puncture is recommended to decrease inadvertent arterial puncture	B
D4.SD1.S6	Ultrasound guidance can be considered when difficult peripheral venous access is required in areas such as the antecubital fossa and ankle. Blind deep antecubital fossa puncture should disappear	C
D4.SD1.S7	Ultrasound-guided arterial catheterization improves first-pass success and should be used routinely in children and neonates	A
D4.SD1.S8	After central venous catheter placement in paediatric patients including neonates, the ultrasound equipment should remain easily accessible at the patient's bedside to detect early life-threatening catheter-related complications such as pneumothorax, cardiac tamponade and hemothorax	B
D4.SD1.S9	There is no ideal site for cannulation in children; the best site should be determined after ultrasound examination	A

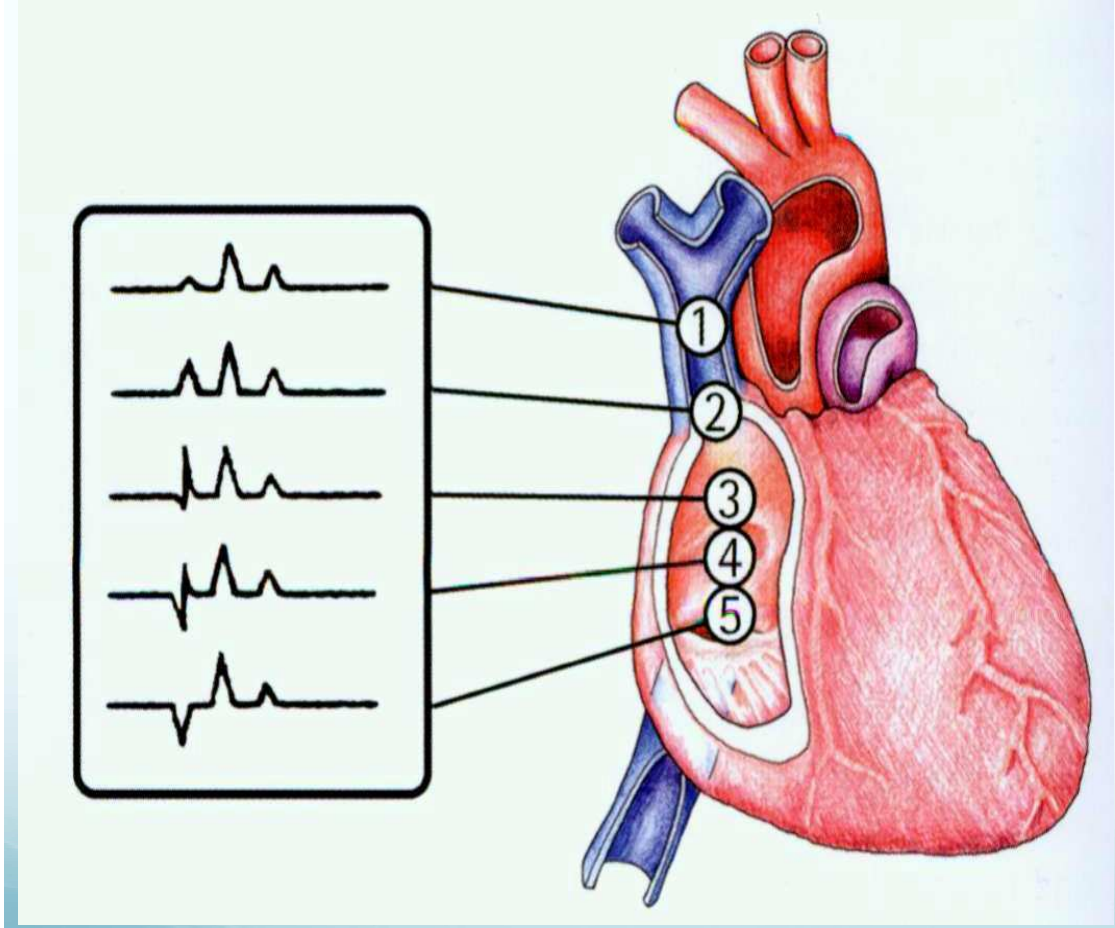
Il nuovo concetto che emerge dalla pratica clinica è:

USO ‘ GLOBALE’ DELL’ECOGRAFO

Ovvero:

- Per la scelta della vena
- Per la venipuntura
- Per la corretta direzione del catetere
- Per la esclusione di complicanze da venipuntura
- Per la verifica della posizione della punte
- **Per incannulare qualunque tipo di vaso con qualunque tipo di catetere**

Controllo della punta: ECG guida

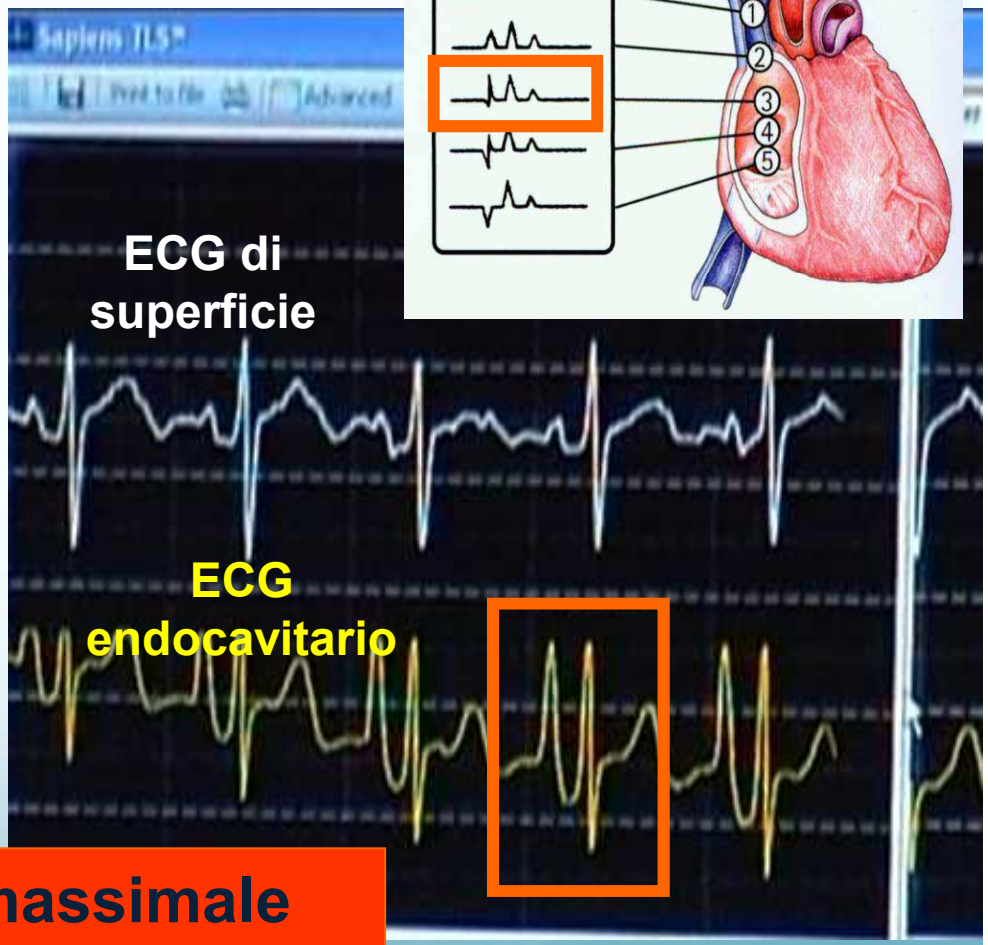


- ECG intracavitario
- Modificazioni onda P durante progressione dell'elettrodo intracavitario dalla periferia al cuore
- Elettrodo intracavitario "solidale" con il catetere
- Identificazione forma d'onda P corrispondente alla posizione voluta della punta
- GIUNZIONE ATRIO-CAVALE:
  inizio della p massimale (Stas, Yeon, Schummer, Pittiruti/La Greca)

GUIDA ECG ENDOCAVITARIA

Punta alla giunzione atriocavale - ingresso atrio dx

(crista terminalis)

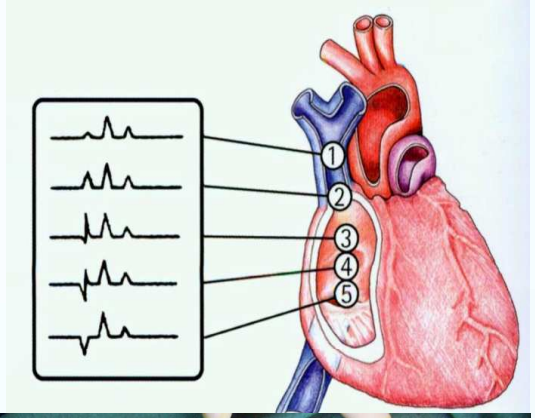


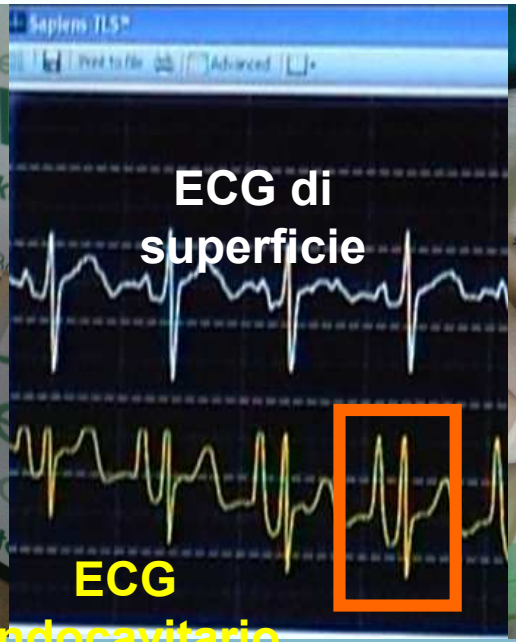
Onda P endocavitaria = massimale

Controllo della punta: ECG guida

Applicabile a qualunque accesso venoso centrale, preferibilmente utilizzando la tecnica della colonna di liquido e standardizzando la metodica

- Azzeramento malposizioni
- Basso costo
- Massima efficienza





J Vasc Access 2012; 13 (3): 357-365
DOI: 10.5301/JVA.2012.9020

ORIGINAL ARTICLE

The intracavitary ECG method for positioning the tip of central venous catheters: results of an Italian multicenter study

Mauro Pittiruti[1], Daniele Bertollo[2], Ermanno Briglia[3], Massimo Buononato[4], Giuseppe Capozzoli[5], Luigi De Simone[6], Antonio La Greca[1], Cecilia Pelagatti[7], Pier Sandro Sette[8]

TABLE II - OVERALL ACCURACY **1444 paz**

P – Perfect match	1199	83.0%	**95.4%**
C – Correct match	179	12.4%	
S – Mismatch	55	3.8%	
NA – Not applicable	11	0.7%	

J Vasc Access 2011; 12 (4): 280-291
DOI: 10.5301/JVA.2011.8381

REVIEW

The electrocardiographic method for positioning the tip of central venous catheters

Mauro Pittiruti[1], Antonio La Greca[1], Giancarlo Scoppettuolo[2]

Intra-procedural methods for verifying the location of the tip are to be preferred, since they avoid the risks, delays and costs of repositioning the tip. Among the intra-procedural methods, the EKG method has many advantages: it is as accurate as fluoroscopy, but simpler, more readily available, less expensive, safer and more cost-effective. In addition, it has the additional advantage of being applicable for post-positioning control of the tip (even weeks or months after insertion). The only contraindication for utilizing the EKG method is the difficulty in identifying the standard P-wave on a surface EKG (this happens - usually because of severe arrhythmias, such as atrial fibrillation - in only approximately 7% of cases: although such patients are easily identified before the procedure and referred for other methods of tip positioning); in conclusion, the EKG method is applicable - on average - to 93% of patients.

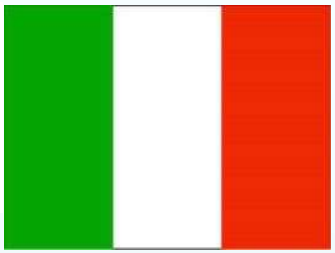
GUIDA ECG ENDOCAVITARIA

Letter to the Editor

The Journal of TRAUMA® *Injury, Infection, and Critical Care*
April 2008

Procedural and Clinical Data plus Electrocardiographic Guidance Greatly Reduce the Need for Routine Chest Radiograph Following Central Line Placement

Vittorio Antonaglia, MD
Giuseppe Ristagno, MD
Giorgio Berlot, MD
Cattinara University Hospital
Trieste, Italy



correct placement of the central line. We, therefore, truly encourage the development of a decision model based on the association of procedural and clinical data and ECG guidance, which may greatly decrease the need for routine chest radiographs. We believe this procedural approach to be appropriate for a number of reasons. As well as being reliable, cost-effective, and timesaving, it may allow for a reduction in radiation exposure and an increase in hospital efficiency without decreasing patient safety.

UN BUNDLE "RX FREE" ?

ECG GUIDA

In tutti gli accessi centrali:

- Abbattimento del rischio di malposizioni
  - Complicanze correlate (costi)
  - Costi del riposizionamento
- Riduzione dei costi “bruti” della procedura
- Snellimento dei percorsi:
  - Procedura in mano ad un unico operatore
  - Inizio precoce delle terapie senza “gap radiologici”

ECG: è già linee guida …

- *Ideally, the position of the tip should be checked <u>during the procedure, either by fluoroscopy or by the ECG method</u>.*
- *If the position has not been checked intraoperatively, a post-procedural chest X-ray should be performed to check the position of the tip.*

ESPEN 2009

Clinical Nutrition 28 (2009) 365–377

Contents lists available at ScienceDirect

Clinical Nutrition

journal homepage: http://www.elsevier.com/locate/clnu

ESPEN Guidelines on Parenteral Nutrition: Central Venous Catheters (access, care, diagnosis and therapy of complications)

Mauro Pittiruti [a], Helen Hamilton [b], Roberto Biffi [c], John MacFie [d], Marek Pertkiewicz [e]

[a] Catholic University Hospital, Roma, Italy
[b] John Radcliffe Infirmary, Oxford, United Kingdom
[c] Division of Abdomino-Pelvic Surgery, European Institute of Oncology, Milano, Italy
[d] Scarborough Hospital, Scarborough, United Kingdom
[e] Medical University of Warsaw, Poland

Romedex International K093775

JUL 1 5 2010

510(k) Summary

Proprietary Name: Sapiens™ Tip Location System also known as evGuide™ Tip Location System

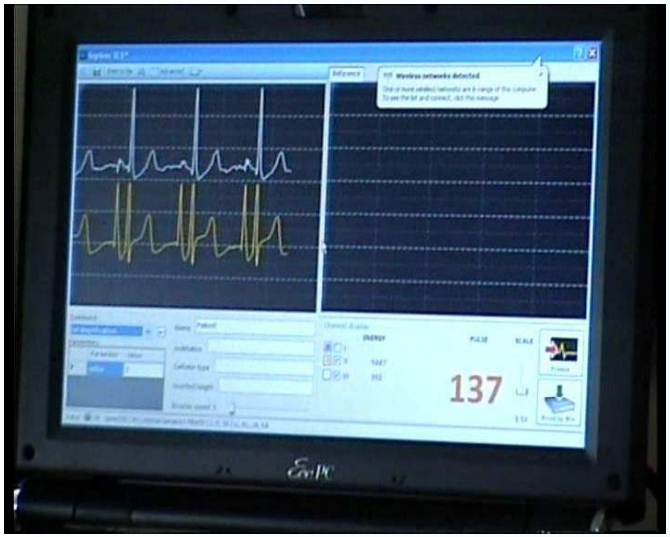
Device Trade name: Sapiens™ Tip Location System (TLS)

Device Description: The Sapiens™ TLS consists of the following elements: sterile electrical adaptor, ECG module and cable, laptop running Sapiens™ TLS software, label printer (optional), and remote control (optional). A stylet or a guidewire inserted in a central venous catheter can be connected to the Sapiens™ TLS system via the Sapiens™ TLS Electrical Adaptor establishing a direct electrical connection to the catheter distal tip for ECG signal measurement. A different ECG signal measurement method – the column of saline method – can be used by connecting the Sapiens™ TLS Electrical Adaptor to the Arrow-Johans Adaptor, by connecting the Arrow-Johans Adaptor to any central venous catheter and by injecting saline solution into the catheter lumen through the Arrow-Johans Adaptor, thus establishing electrical conductivity to the distal tip of the catheter. When the central venous catheter or its associated stylet or guidewire is connected to Sapiens™ TLS, the Sapiens™ TLS laptop screen displays skin ECG signals and endovascular electrograms acquired at the location of the distal tip of the catheter. The waveforms provided by Sapiens™ TLS can be used for guiding and positioning of the central venous catheter. These ECG waveforms can be printed using an optional label printer to document the catheter tip location for the patient's file.

Indications for Use: The Sapiens™ Tip Location System (TLS) is indicated for guidance and positioning of central venous catheters such as PICCs, CVCs, implantable ports, and hemodialysis catheters. The Sapiens™ TLS provides real-time catheter tip location information by using the patient's cardiac electrical activity. Sapiens™ TLS is indicated for use as an alternative method to chest X-ray and fluoroscopy for central venous catheter tip placement confirmation in adult patients.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm, and in central venous catheterization procedures performed through femoral or saphaneous vein access which change the presentation of the P wave. In such patients, who are easily identifiable prior to central venous catheter insertion, the use of an additional method is required to confirm catheter tip location.

SAPIENS / NAUTILUS Tip Location System (TLS)



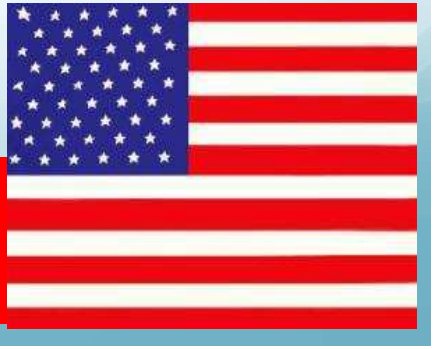
FDA 2010

5.0 Traditional 510(k) Summary

Submitter Information	
Name	VasoNova, Incorporated
Address	155 Jefferson Drive, Suite 100 Menlo Park, CA 94025
Phone number	(650) 388-5605
Fax number	(650) 388-5611
Establishment Registration Number	3006795936
Name of contact person	Kim Tompkins, RN, MBA
Date prepared	October 29, 2010
Name of device	
Trade or proprietary name	Vascular Positioning System™ (VPS™ System) Console
Common or usual name	Catheter, Ultrasound, Intravascular
Classification name	Diagnostic intravascular catheter, Class II
Classification panel	Cardiovascular
Regulation	21 CFR §870.1200
Product Code(s)	OBJ
Legally marketed device(s) to which equivalence is claimed	FlowPICC Console (K081626) Sapiens™ Tip Location System (TLS) (K093775)
Reason for 510(k) submission	Expanded labeling
Device description	The VPS System consists of a VPS Console and VPS Stylet. The VPS Console consists of two key integrated software-driven components: a data acquisition module; and a PC with processing and display capabilities. The data acquisition module of the console transmits and receives ultrasound data while receiving electrical signals from the heart through sensors mounted at the tip of the VPS Stylet. Using signals gathered by the data acquisition module, the graphical user interface of the PC provides the user with guidance for tip positioning. The VPS Stylet is a polyimide tube containing a Doppler sensor on a coax cable and an intravascular electrocardiogram (ivECG) signal sensing stainless steel wire. The Doppler sensor and the exposed portion of the ivECG are located at the distal end of the stylet and are used to detect and transmit physiological information to the VPS Console for analysis. The proximal end contains a connector to the VPS Console or to an extension cable that in turn connects to the VPS Console. The stylet can be inserted and removed from any catheter with a luminal diameter of at least 0.021 inches.

VASONOVA
Vascular Positioning System
(VPS)

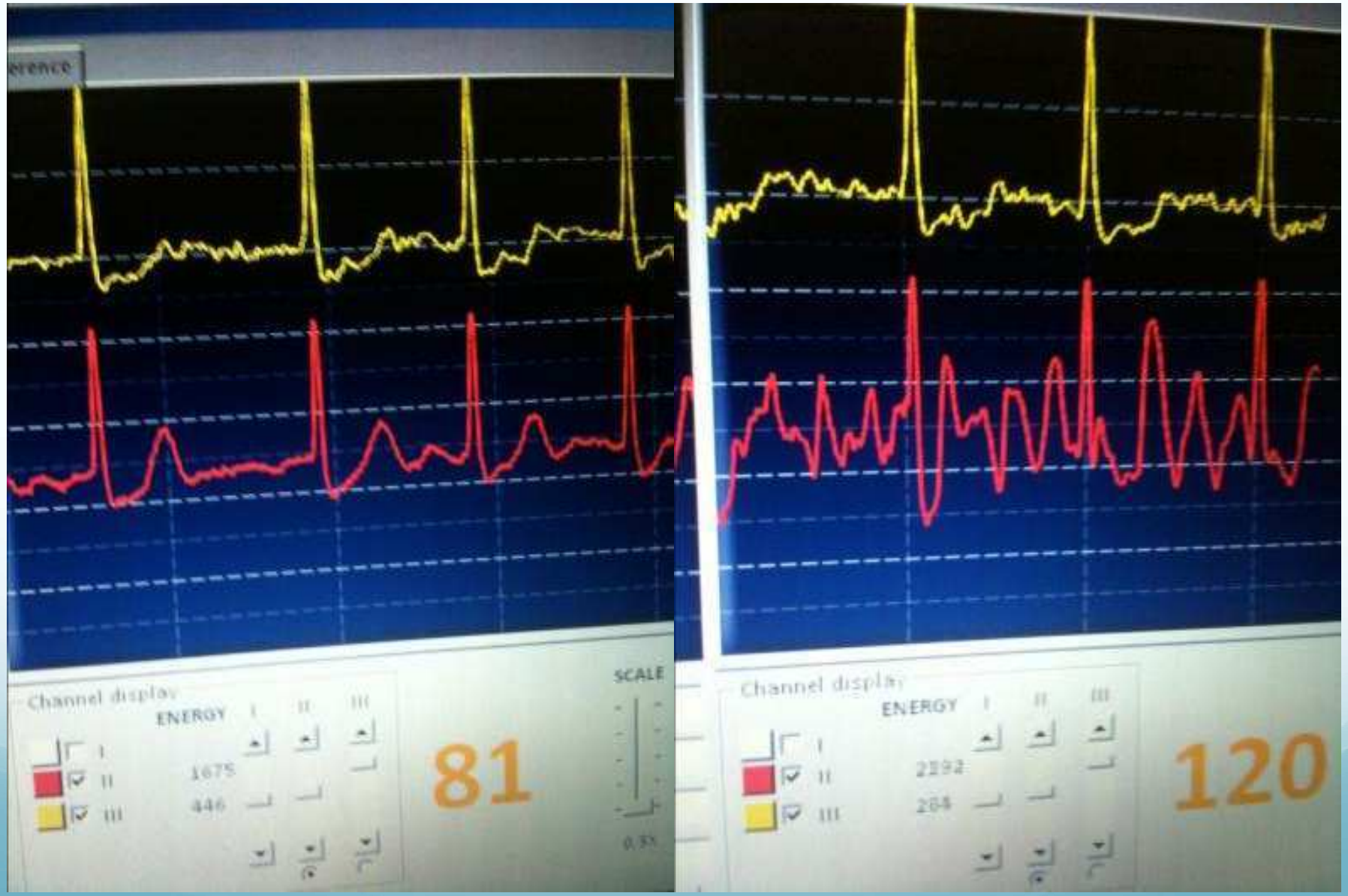
FDA 2011



ECG: IL FUTURO …

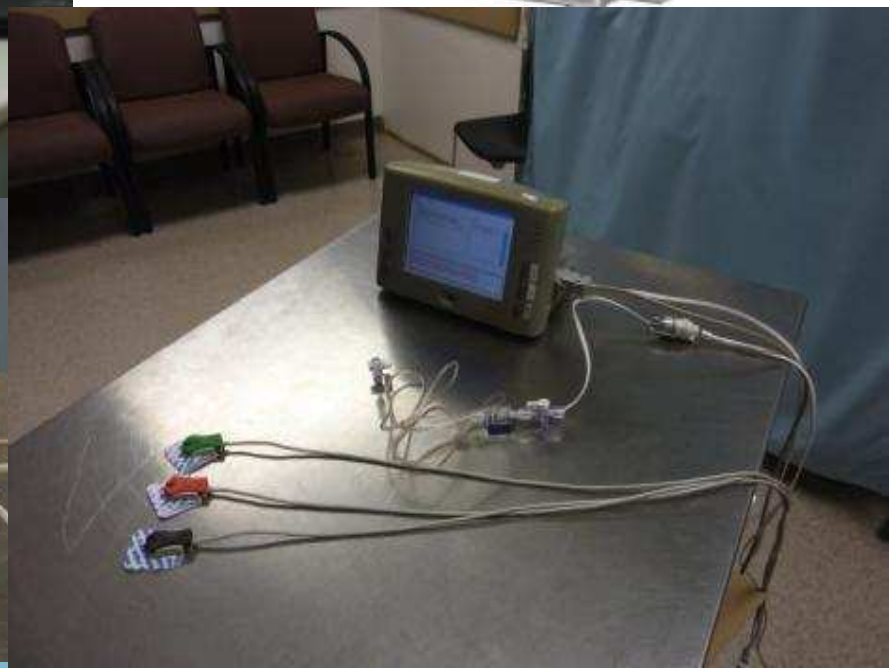
- Estensione del metodo a pazienti SENZA ONDA P (tachiaritmie atriali, FA, pace maker)
- ECG “integrato” con metodi di navigazione

FIBRILLAZIONE ATRIALE

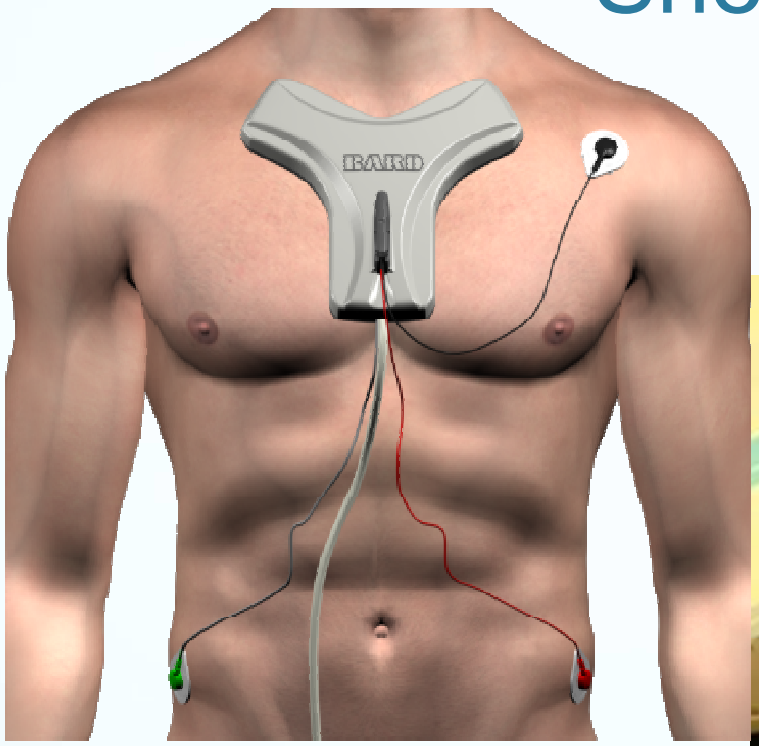


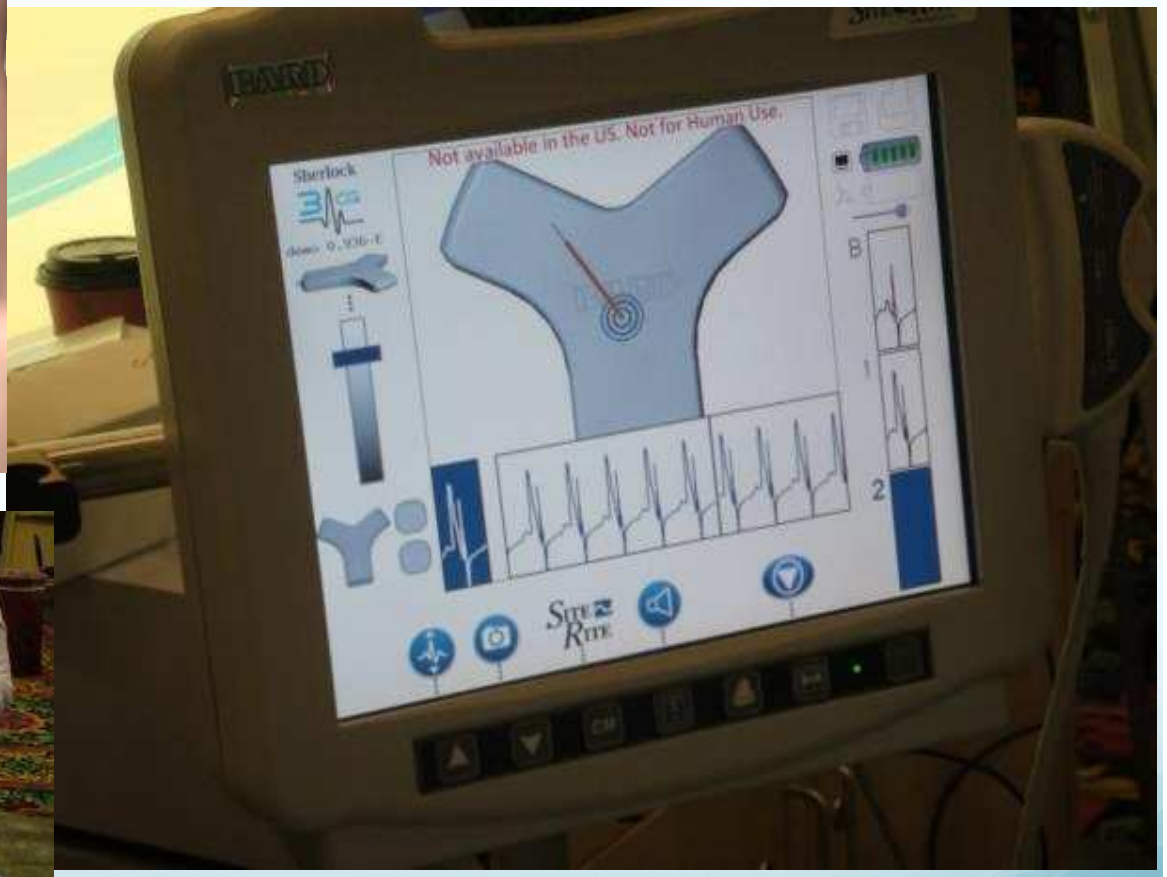
VPS, Vasonova: EKG + Doppler
(Teleflex)

Catfinder, Elcam:
EKG + pressure/acoustic measurements



Sherlock (Bard) + Sapiens (Romedex)
(Electromagnetic tracking + EKG)





3.
NOVITA' "TECNOLOGICHE"

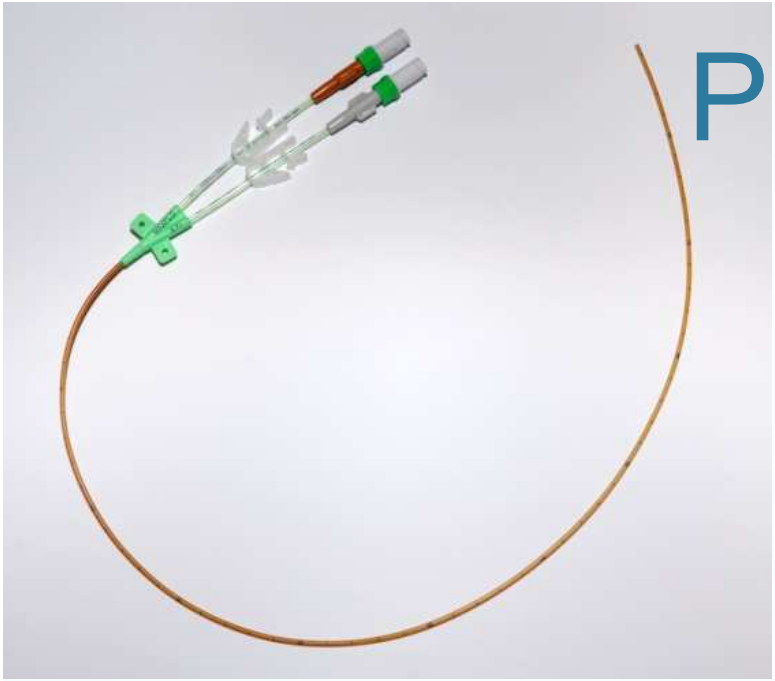
PICC IN AFERESI

PICC: la novità del secolo?

- Estensione delle indicazioni dei VAD
  - Sicurezza, costo efficacia, efficienza aziendale
  - Inserzione infermieristica (USA, Canada, Australia, UK, Italia, Spagna, Paesi Bassi, Scandinavia…)
  - Ecoguida = posizionamento nel 100% dei pazienti
- ‘Sorpasso’ in USA: PICC > CVC (2009)
- Crescita esponenziale in Italia e in tutta Europa
- Nuove tecnologie per PICC sempre più versatili e affidabili

I PICC oggi

- Riduzione dei Midline a favore dei PICC
- Introduzione dei PICC = riduzione dei tunnellizzati
- Progressivo abbandono del silicone per il poliuretano e in particolare per il poliuretano ‘ultra-resistente’ (power injectable)
- Progressivo abbandono della punta chiusa (valvola distale) per la punta aperta (no valvola opp. valvola prossimale)
- Crescente utilizzo di PICC a 2 vie e 3 vie



PICC power injectable

- Alti flussi (fino a 200-300 ml/min con pompa)
- Misurazione pressione venosa centrale
- Due, tre lumi

- Basso rischio di ostruzione, facile disostruzione
- Potenziali nuove applicazioni (Emaferesi? Dialisi? Ultrafiltrazione?)

Uso per feresi/ultrafiltrazione

- Future applicazioni dei PICC power doppio lume: procedure di feresi e di ultrafiltrazione
  - la feresi in età pediatrica e la ultrafiltrazione nell'adulto richiedono bassi flussi (10 - 40 ml/min)
  - punta in atrio destro (non deve andare a parete)
  - cateteri 'corti' (inserzione centrale)
  - problemi tecnici legati al setting della macchina per emaferesi
  - metodica ancora in studio

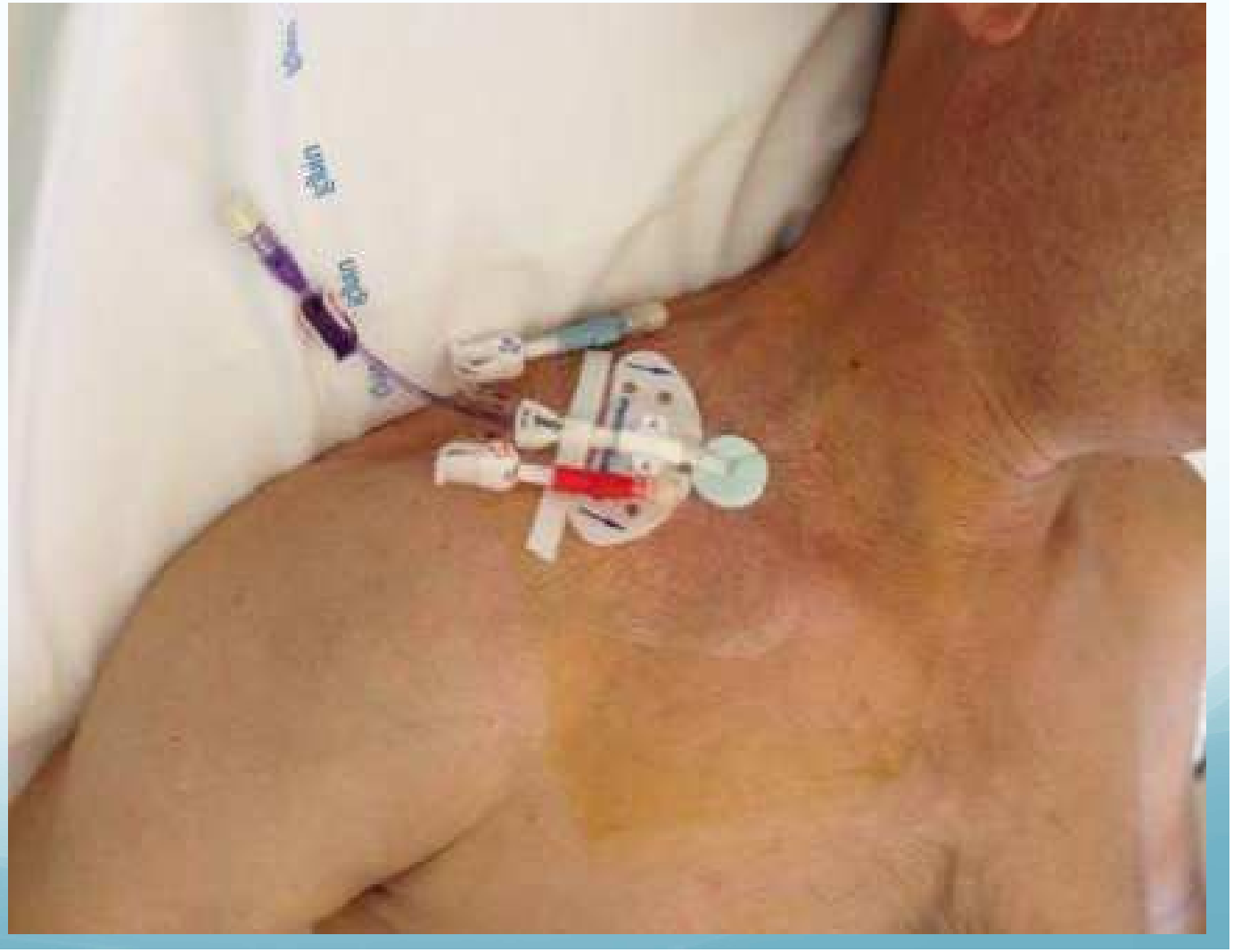
Uso per feresi

- Doppio lume power PICC 5 Fr inserito in v.anonima e tunnellizzato (bambina di 5 anni con GVH)
- utilizzato per feresi (28-30 ml/min)

Uso per feresi

- Doppio lume power PICC 5 Fr inserito in v.anonima e tunnellizzato (bambina di 6 anni)
- usato per feresi (28-30 ml/min)
- importante: punta in atrio dex

Uso “off label” in v. giug. interna di PICC per feresi in adulto (BMT)



ULTRAFILTRAZIONE

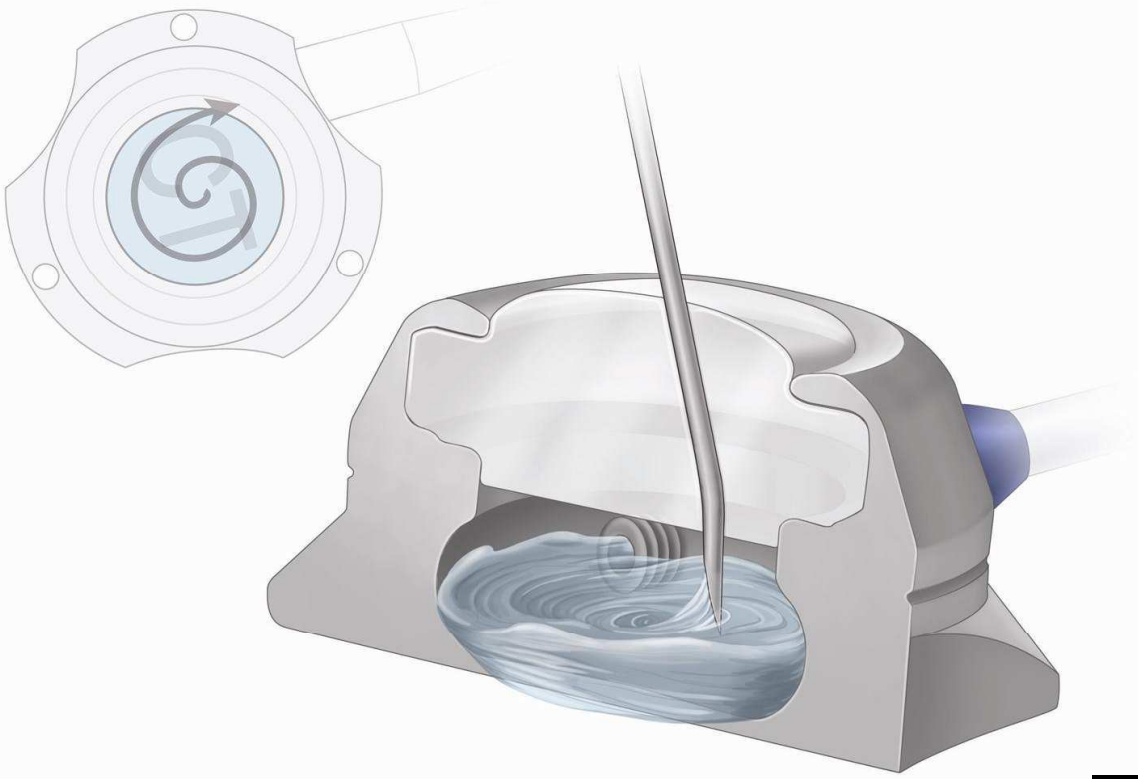
PICC power injectable 5Fr bilume in paziente con scompenso cardiaco

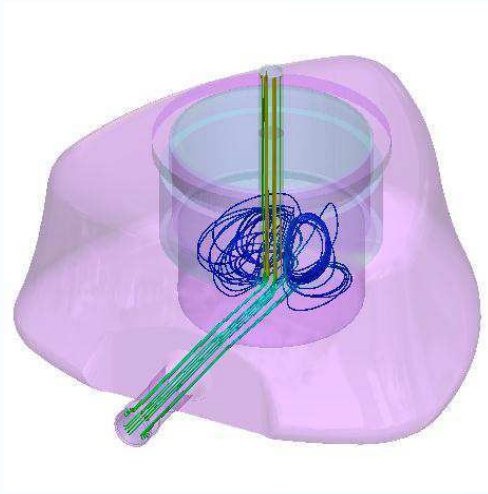
Uso per ultrafiltrazione/feresi

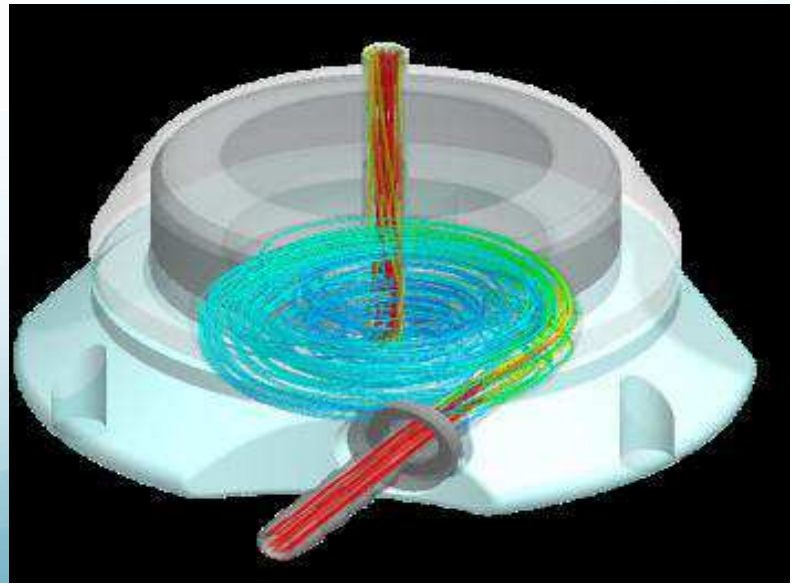
PICC 5Fr bilume power injectable inserito in bambino di due mesi

PORT IN AFERESI

- Sickle Cell Disease
- Myasthenia gravis
- LDL hyperlipidemia
- T-Cell Lymphoma
- GVHD (photopheresis)
- Solid Organ Transplant

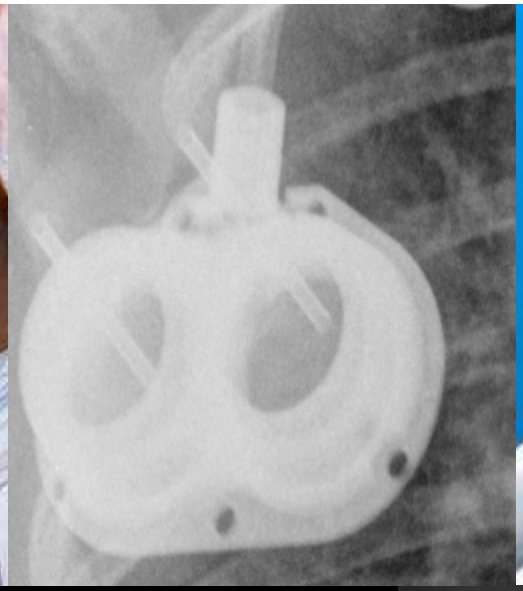


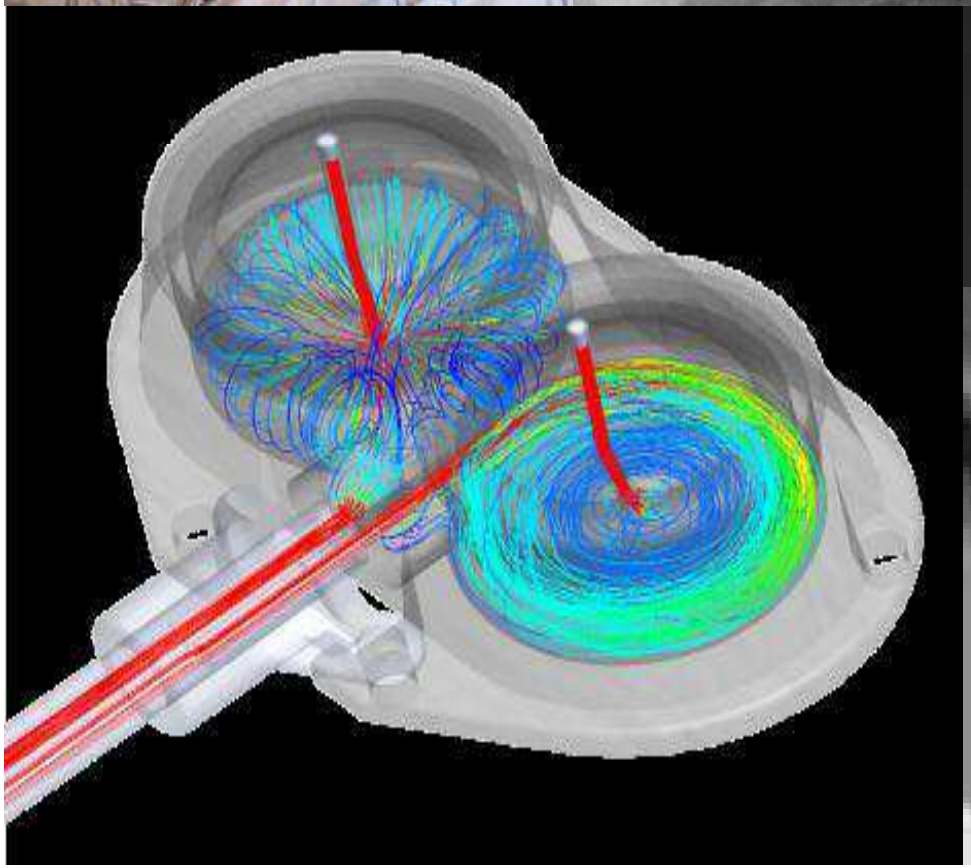
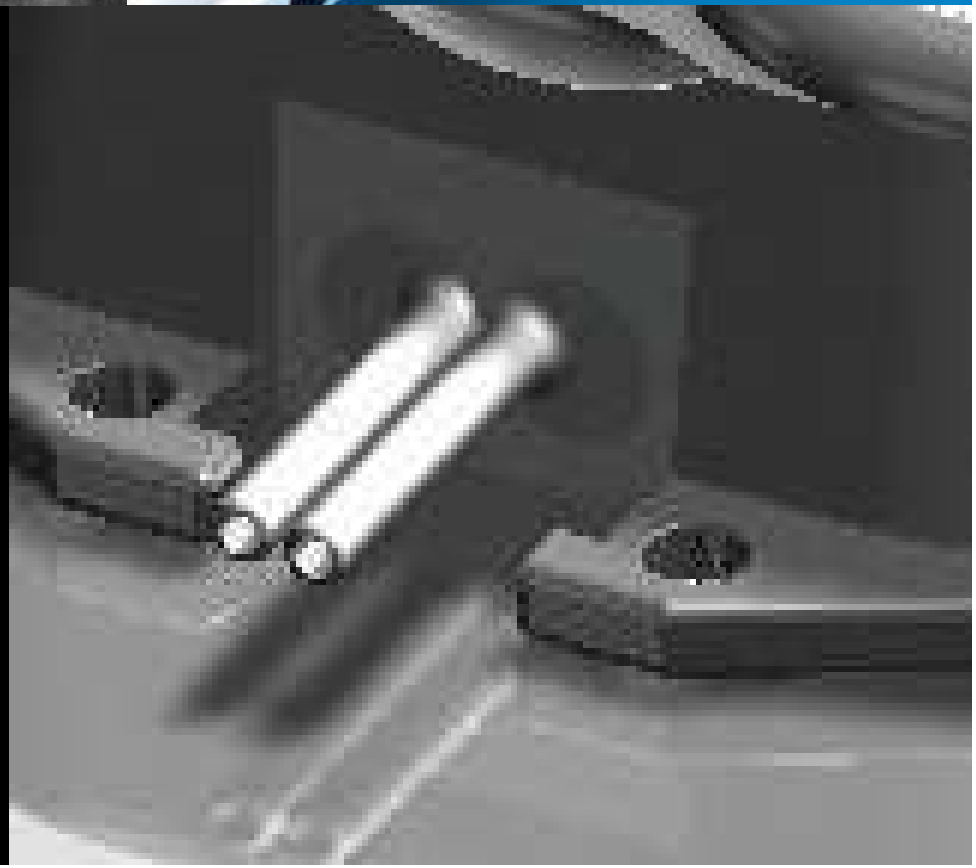




Tecnologia Vortex:
-Alto flusso
-Basso rischio di ostruzione

Tecnologia “power”

Literature

- Photopheresis in Solid Organ Transplant Rejection (JCA 2006)

  Marques, M., Tuncer, H.

  - Positive experience with Vortex® Port

- In vitro comparison of access flow rates among permanent subcutaneous port catheters of different diameters (JCA 2004)

  Tuncer HH, Marques MB, Harrison KD, Huang ST.

  - Access flow rates correlated with larger sizes of silicone catheters. The size of the ports had no effect on the flow rates.

Literature

- Efficacy of Dual Lumen Implantable Vortex® Ports During Isovolemic Hemodilution/Red Blood Cell Exchange in Sickle Cell Disease Patients (JCA 2009)

  Cleveland-Noriega, D. DO, Matevosyan, K. MD, Burner, J. MD, Refaai, M. MD, Sarode, R. MD

  - No re-circulation of red blood cells during IHD/RBCX procedures with Vortex® dual-lumen ports

Literature

- A Single-Center Experience with Double and Single Lumen Vortex® Ports for Chronic Erythrocytapheresis in Pediatric Patients With Sickle Cell Anemia (JCA 2006)

  Van Kirk, R. MD, Koncsol, J. RN, Gutin, H. RN, Villella, A. MD, Downes, K. MD

  - Vortex® ports are effective alternative for vascular access for RBCX in Pediatric SCD patients with 100% completion rate.

Literature

- Ten-year Experience With a Dual-Lumen Port for Chronic Erythrocytapheresis (RBCX) for Individuals with Sickle Cell Disease: A Single Center Experience

  Billington, C., McAfee, J., Nuss, R., Hassell, K.

  - Dual Lumen Vortex® port supported approximately 60 procedures over a 5yr period

Literature

- First Successful Use of the Vortex® Port For Plasma Exchange in a Small Child with Hyperlipidemia (JCA 2011)

  Di Mola, M., Tomlin, K., Connolly, B., Licht, C.

  - Vortex port successfully used to treat 12.3kg child with hyperlipidemia

CATETERI TRATTATI

CATETERI TRATTATI

Modificazione strutturale del catetere per conferirgli proprietà antibatteriche intrinseche

1. Aggiunta di sostanze ad azione antibatterica poi rilasciate dal catetere

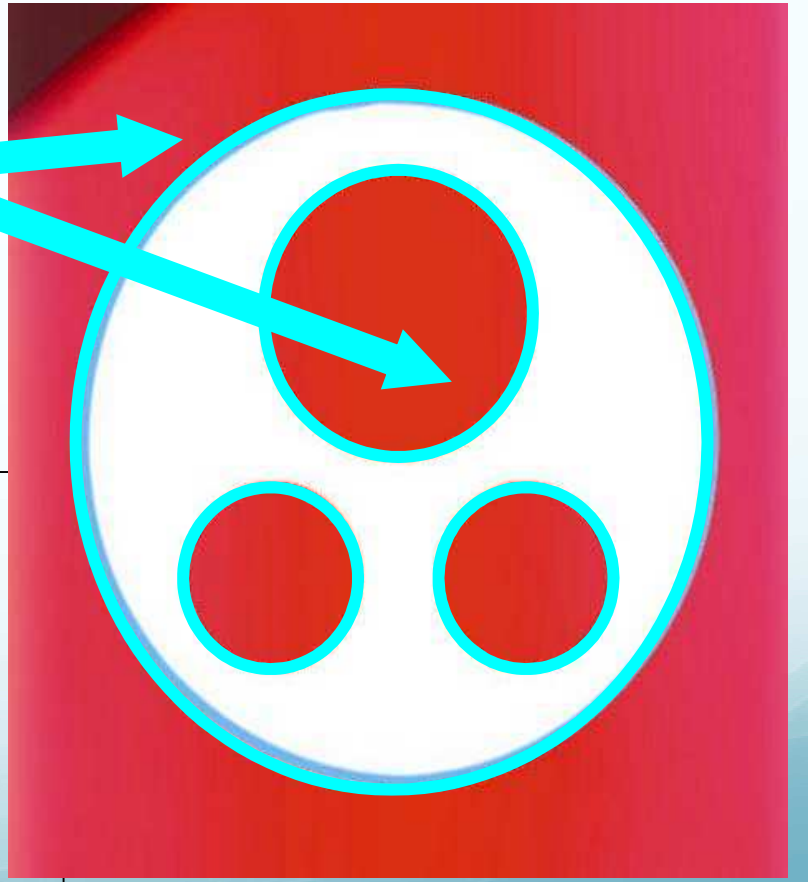
1. Coating con antisettici (clorex.-sulfadiaz. argentica)
2. Coating con antibiotici (minociclina-rifampicina)
3. Impregnazione con ioni argento
4. Impregnazione con antibiotici (rifampicina-miconazolo)

2. Modificazione delle proprietà chimico-fisiche di superficie del dispositivo (no rilascio)

1. Coniugazione con radicali ionizzati (idrofilicità, batteriolisi)
2. Coniugazione con eparina non rilasciabile (antitrombogenica., anti-adesione batterica)

… RICOPERTI …

RIVESTIMENTO ESTERNO + INTRALUMINALE con sostanze a lento rilascio:



ANTISETTICI
Clorexidina + sulfadiazina argentica

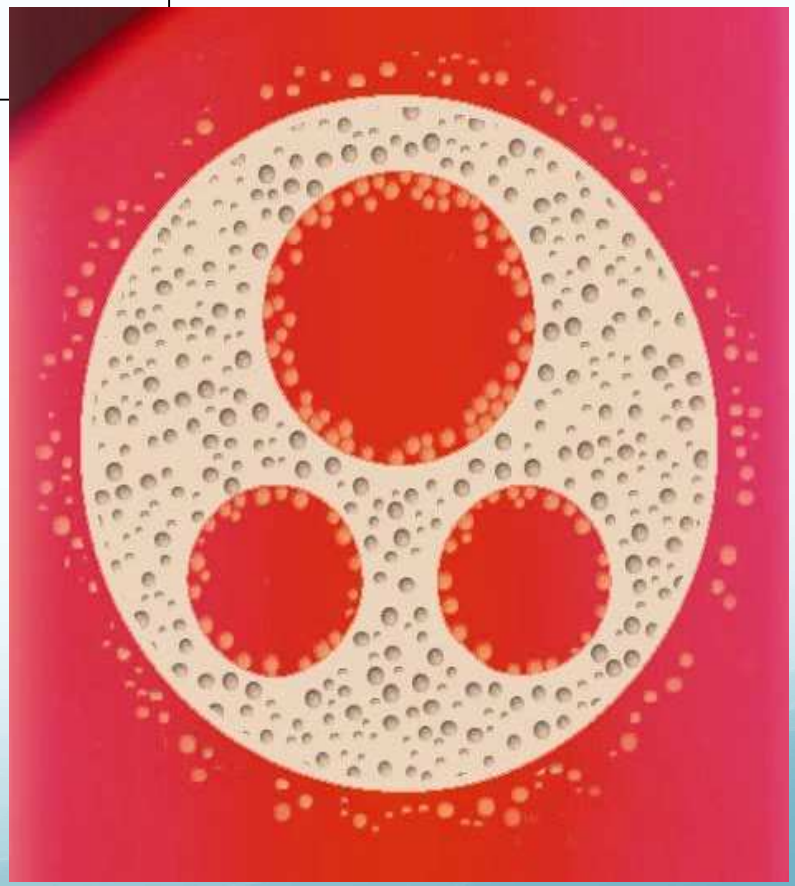
ANTIBIOTICI
Minociclina + rifampicina

… O IMPREGNATI …

INCORPORAZIONE nella struttura del materiale (POLIURETANO) del catetere di sostanze a lento rilascio:

IONI antisettici
- **ARGENTO, BISMUTO**

ANTIBIOTICI
- **RIFAMPICINA + MICONAZOLO**



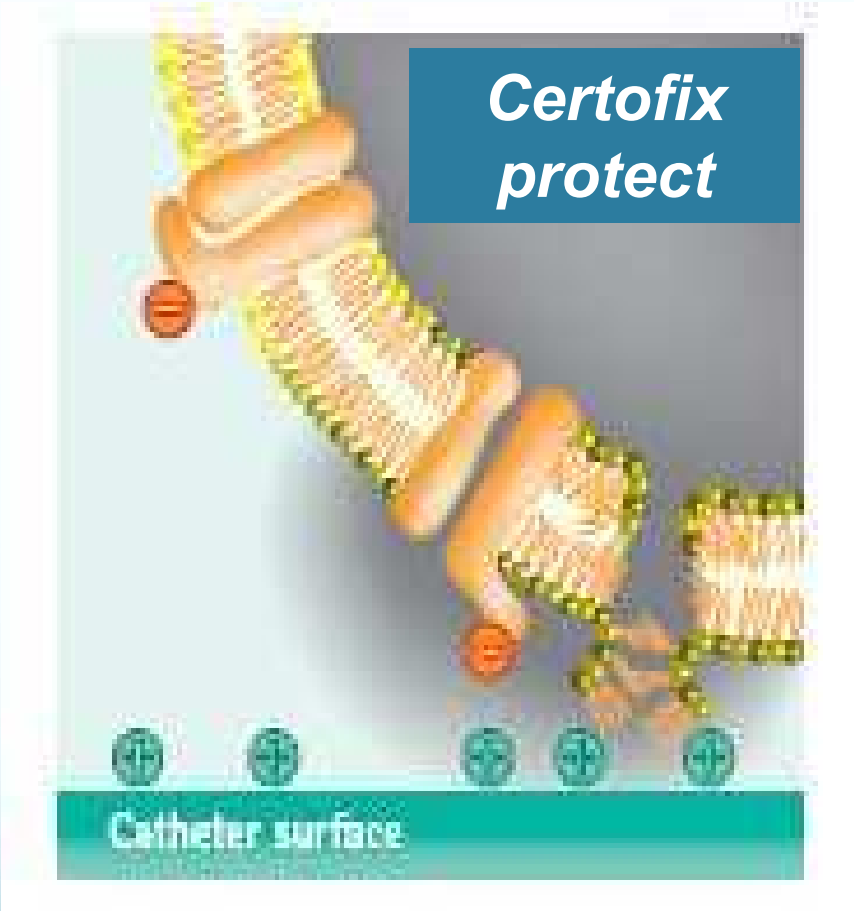
… O CONIUGATI

Superficie trattata con poliexanide metacrilato – gruppi biguanidici – superficie idrofilica (elettricamente carica)

Destabilizzazione membrana batterica - lisi

Nessun rilascio di sostanze farmacologicamente attive (meccanismo fisico)

Idrofilia = possibile attività anti-trombotica (e anti-biofilm ?)



“Heparin-bonded central venous lines reduce thrombotic and infective complications in critically ill children”

Pierce C.M., Intens Care Med, 26:967-72, 2000

COOK

Cateteri trattati: indicazioni

Studi settoriali in ambienti ad alto rischio (ICU – breve termine)

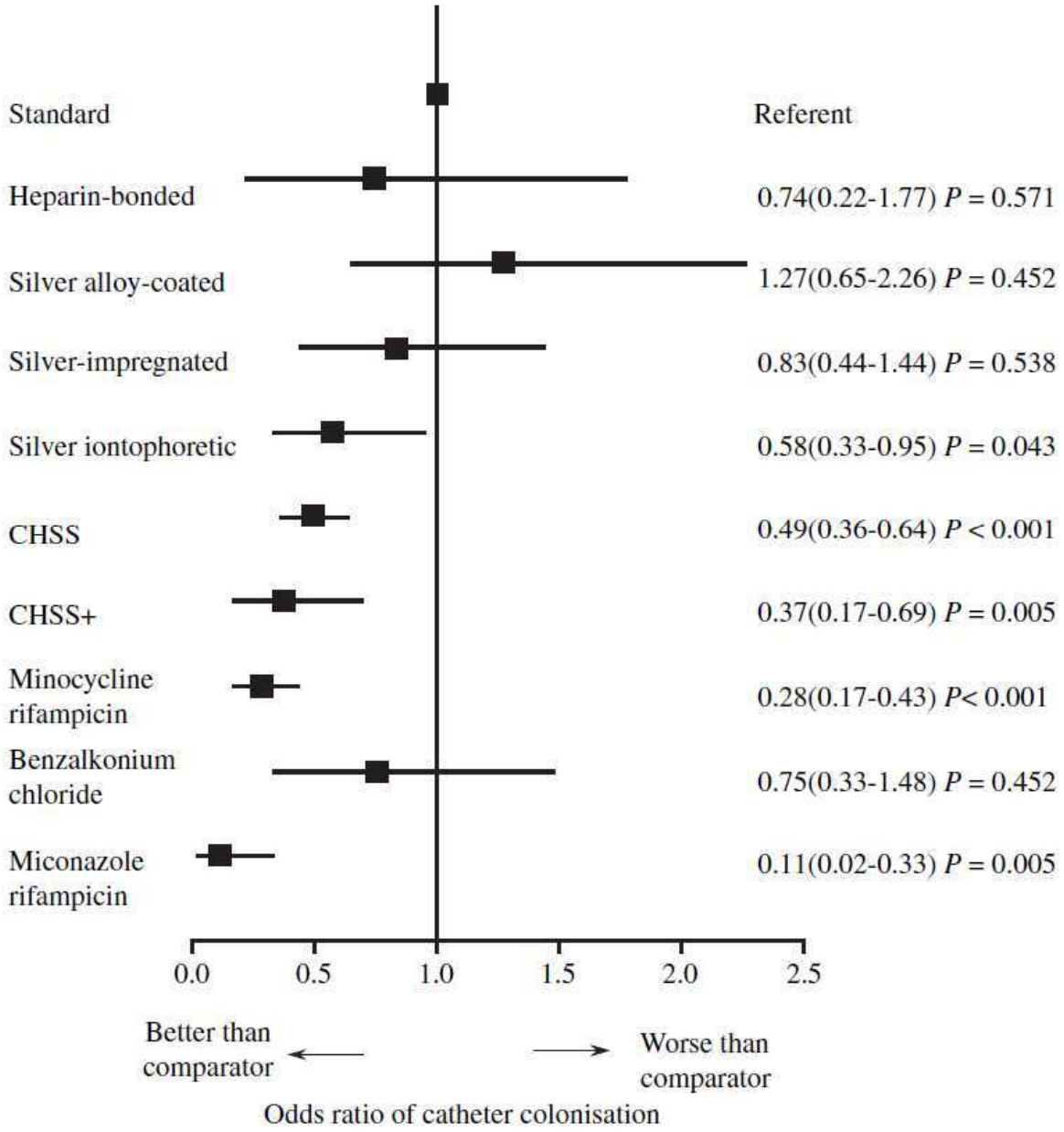
The Risk of Bloodstream Infection in Adults With Different Intravascular Devices: A Systematic Review of 200 Published Prospective Studies

Mayo Clin Proc. • *September 2006;81(9):1159-1171*

DENNIS G. MAKI, MD; DANIEL M. KLUGER, MD; AND CHRISTOPHER J. CRNICH, MD

TABLE 3. **Rates of Intravascular Device–Related Bloodstream Infection Caused by Various Types of Devices Used for Vascular Access***

Device	No. of studies	No. of catheters	No. of IVD (d)	No. of BSIs	Rates of IVD-related bloodstream infection: Per 100 devices, Pooled mean	Per 100 devices, 95% CI	Per 1000 IVD-days, Pooled mean	Per 1000 IVD-days, 95% CI
Short-term noncuffed central venous catheters								
Nonmedicated								
Nontunneled	79	20,226	322,283	883	4.4	4.1-4.6	2.7	2.6-2.9
Tunneled	9	741	20,065	35	4.7	3.2-6.2	1.7	1.2-2.3
Medicated								
Chlorhexidine-silver-sulfadiazine	18	3367	54,054	89	2.6	2.1-3.2	1.6	1.3-2.0
Minocycline-rifampin	3	690	5797	7	1.0	0.3-1.8	1.2	0.3-2.1
Silver impregnated	2	154	1689	8	5.2	1.7-8.7	4.7	1.5-8.0
Silver iontophoretic	2	396	4796	16	4.0	2.1-6.0	3.3	1.7-5.0
Benzalkonium chloride	1	277	2493	12	4.3	1.9-6.7	4.8	2.1-7.5


Standard
Referent
Heparin-bonded
0.74(0.22-1.77) P = 0.571
Silver alloy-coated
1.27(0.65-2.26) P = 0.452
Silver-impregnated
0.83(0.44-1.44) P = 0.538
Silver iontophoretic
0.58(0.33-0.95) P = 0.043
CHSS
0.49(0.36-0.64) P < 0.001
CHSS+
0.37(0.17-0.69) P = 0.005
Minocycline rifampicin
0.28(0.17-0.43) P< 0.001
Benzalkonium chloride
0.75(0.33-1.48) P = 0.452
Miconazole rifampicin
0.11(0.02-0.33) P = 0.005
0.0
0.5
1.0
1.5
2.0
2.5
Better than comparator
Worse than comparator
Odds ratio of catheter colonisation

Cateteri trattati: indicazioni

- sicuramente efficaci per uso a breve termine
- efficacia dimostrata per
  - -“coating” con clorexidina/sulfadiazina
  - -“coating” con rifampicina/minociclina,
  - -“impregnation” con miconazolo/rifampicina
  - -“bonding” con eparina
- uso consigliato in ambienti ad alto rischio (tasso CR-BSI > 3.3 episodi /1000 giorni catetere) dopo fallimento delle altre strategie preventive - CDC Atlanta 2002-2011
- Fallimento del trattamento con i derivati dell’argento
- Non vi sono ancora dati certi per:
  - cateteri A MEDIO E LUNGO TERMINE
  - cateteri a SUPERFICIE MODIFICATA MULTIFUNZIONE per natura costruttiva destinati a evolvere in dispositivi a medio-lungo termine

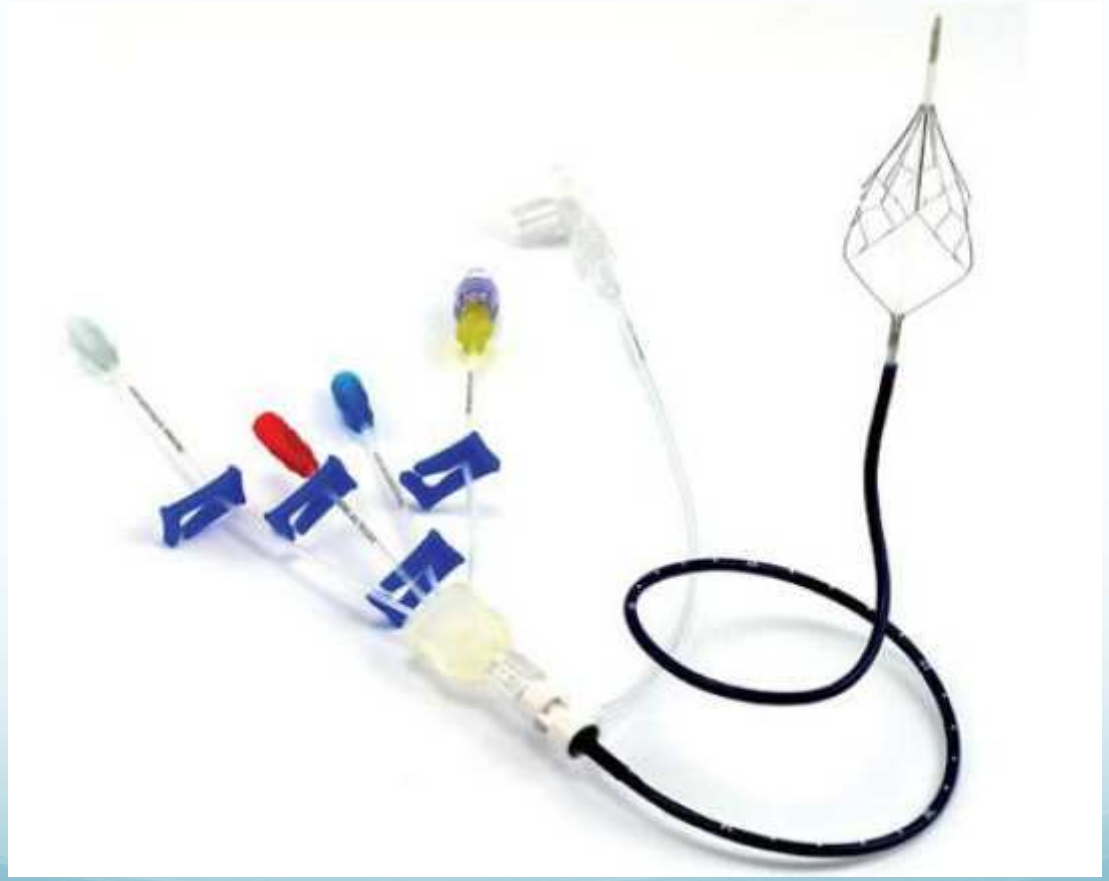
NUOVO UTILIZZO CATETERI "TRATTATI"

- Pazienti con sepsi batteriemiche da germi multiresistenti e/o fungine in corso o dopo plurimi episodi di CR-BSI
- Indipendentemente dalla fonte della batteriemia
  - Catetere vascolare vs altre fonti
- Con necessità imprescindibile di accesso vascolare stabile

E' possibile bypassare le convenzionali norme di gestione "vascolare" del paziente settico ?

- Rimozione del catetere vascolare
- Nuovo accesso invasivo
  - Dopo 48 ore di terapia antibiotica se germi non resistenti
  - Dopo 5 giorni di terapia se germi multiresistenti
  - Dopo negativizzazione delle emocolture in caso di candida

CATETERI CON FILTRO ANTI-EMBOLICO



Gestione

1° novità

CLOREXIDINA 2% in alcool isopropilico 70%

- Antisettico di riferimento per la inserzione e per la medicazione di qualunque VAD
- Sicuramente superiore allo iodo-povidone
- Da utilizzare SEMPRE (tranne che in caso di allergia specifica alla CHG)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Chloraprep

2° novità

Medicazioni trasparenti semipermeabili

- Da utilizzare ogni qualvolta è possibile
- Sicuramente superiori alle medicazioni garzate
- Riduzione delle infezioni
- Riduzione delle tromboflebiti
- Riduzione delle dislocazioni

epic2: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England

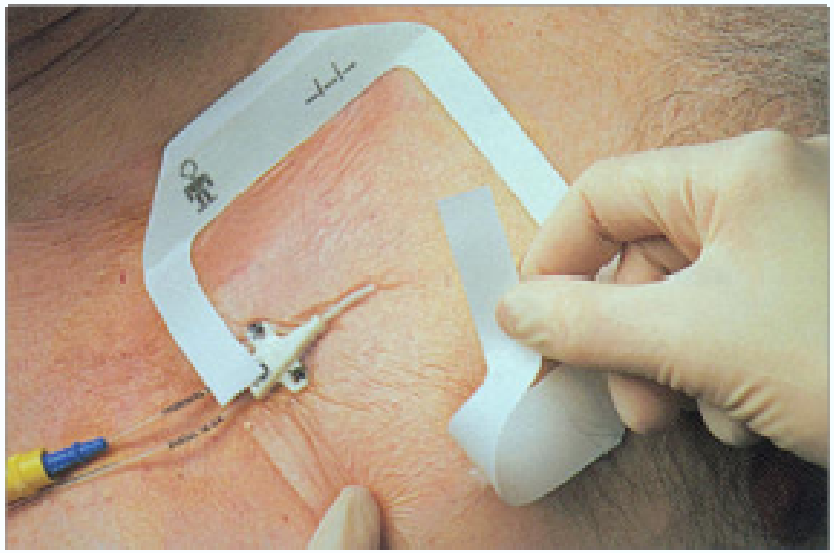
R.J. Pratt[a*], C.M. Pellowe[a], J.A. Wilson[a,b], H.P. Loveday[a], P.J. Harper[a], S.R.L.J. Jones[a], C. McDougall[b], M.H. Wilcox[c]

Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011

Supplement to
January/February 2011
Volume 34, Number 1S
ISSN 1533-1458
www.journalofinfusionnursing.com

Journal of Infusion Nursing
The Official Publication of the Infusion Nurses Society

Infusion Nursing Standards of Practice



3° novità

- I sutureless device (Statlock e Griplok) al posto dei punti di sutura
  - Da utilizzare ogni qualvolta è possibile
  - Riduzione delle infezioni
  - Riduzione delle tromboflebiti
  - Riduzione delle dislocazioni

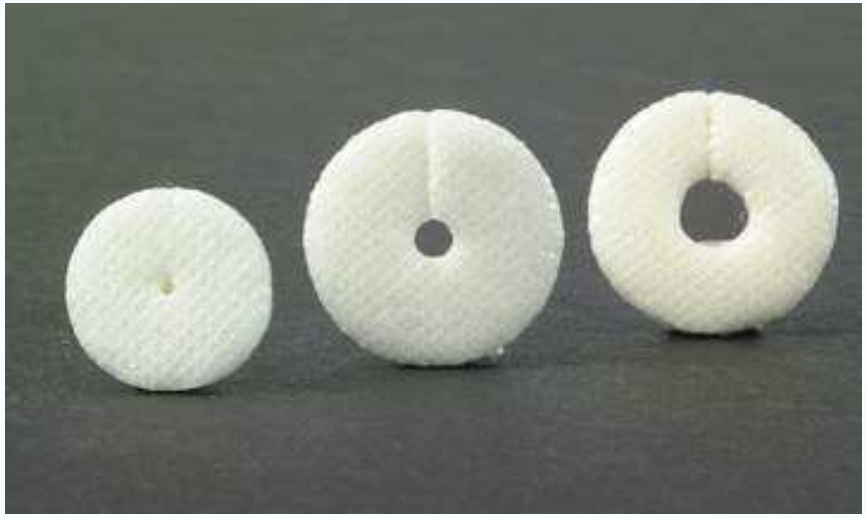
Il rischio delle suture…

4° novità

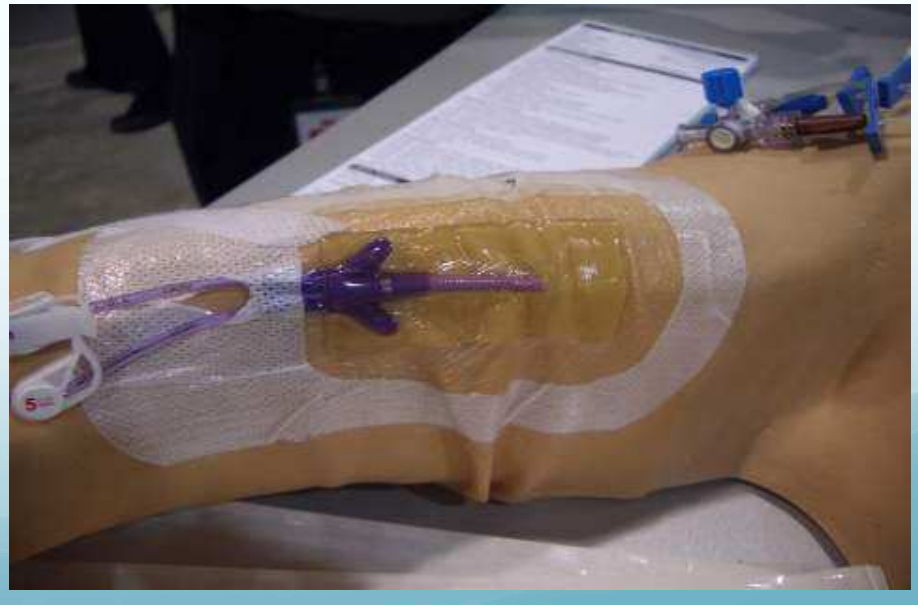
- Medicazioni con rilascio di clorexidina
- Da utilizzare nei pazienti ad alto rischio, portatori di VAD non tunnellizzati
  - Biopatch (già validato EB e raccomandato dalle linee guida)
  - Tegaderm CHG (studi in corso)

Presidi a rilascio continuo di clorexidina

BIOPATCH



TEGADERM
CHG



Conclusioni

- Numerose novità tecnologiche in ausilio all'impianto e alla gestione dei cateteri
- Ruolo decisivo dei protocolli standardardizzati per impianto e gestione nella prevenzione delle complicanze e nella performance globale dei pazienti
- Filosofia dei team medico-infermieristici dedicati