



# Materiale dei PICC e rischio di complicanze: quali novità?

Mauro Pittiruti Università Cattolica, Roma

## Parte prima

## Silicone vs. poliuretano

La questione è già risolta

# Il silicone non comporta minor rischio infettivo

Uno studio assai vecchio mostrò una superiorità del SIL rispetto al PUR

McDonald 1977

(a quel tempo, i PUR di terza generazione non c'erano)

Alcuni studi di poco più recenti mostrarono una superiorità del PUR

- Linder 1984
- Rudin 1990

Altri studi successivi non hanno mostrato differenze PUR vs. PE

- Poisson 1991
- Touquet 1992

(però, studi in vitro suggerivano che il PUR fosse preferibile al PE)

Molti studi clinici di questo secolo non hanno rilevato differenze tra PUR e SIL

- Beau 1999
- Hoffer 2001
- Pittiruti 2009
- Cohen 2011
- Miyakagi 2012

Uno studio recente ha suggerito una superiorità del PUR (PICC con valvola prossimale) vs. SIL (valvola distale)

— Ong 2010 (effetto del materiale o del tipo di valvola ?)

**EPIC 2007** 

#### Catheter material

Although catheter material may be an important determinant of CR-infection, evidence available to HICPAC when developing their guidelines was inconclusive and they were unable to draw any specific conclusions about the contribution of catheter material to LK-intections 209,215

Teflon® and polyurethane catheters have been associated with fewer infections than catheters made of polyvinyl chloride or polyethylene. There is no additional evidence that demonstrates conclusively that CR-infection rates vary with different materials. 206 In England, short-term CVAD are almost always made of polyurethane and long term tunnelled catheters are usually made of silicone.

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

Clinical Nutrition 28 (2009) 365-377

Contents lists available at ScienceDirect

#### Clinical Nutrition

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



**ESPEN 2009** 

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

Mauro Pittiruti <sup>a</sup>, Helen Hamilton <sup>b</sup>, Roberto Biffi <sup>c</sup>, John MacFie <sup>d</sup>, Marek Pertkiewicz <sup>e</sup>

There is limited evidence to suggest that the catheter material is important in the etiology of catheter-related sepsis. Teflon, silicone and polyurethane (PUR) have been associated with fewer infections than polyvinyl chloride or polyethylene. Currently all available CVCs are made either of PUR (short-term and mediumterm) or silicone (medium-term and long-term); no specific recommendation for clinical practice is made.



**CDC 2011** 

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

Type of Catheter Material. Polytetrafluoroethylene (Teflon \*) or polyurethane catheters have been associated with fewer infectious complications than catheters made of polyvinyl chloride or polyethylene [36, 253, 254]. Steel needles used as an alternative to catheters for peripheral venous access have the same rate of infectious complications as do Teflon\* catheters [33, 34]. However, the use of steel needles frequently is complicated by infiltration of intravenous (IV) fluids into the subcutaneous tissues, a potentially serious complication if the infused fluid is a vesicant [34].

Maggiore per PE e PVC rispetto a PTFE, PUR e SIL



J Vasc Access 2015; 00 (00): 000-000

DOI: 10.5301/jva.5000330

REVIEW

# A comparison of silicone and polyurethane PICC lines and postinsertion complication rates: a systematic review

Tammy Seckold, Sandra Walker, Trudy Dwyer

Central Queensland University, Queensland - Australia

#### **JVA 2015**

Results: Overall the PICCs complication rates ranged from 8 to 47.9%. While both lines saw similar overall rates upon closer observation the strengths and weaknesses of

Polyurethane PICC lines were found to provide lower rates of infection, dislodgment, thrombus and rupture complications.

Mixed results were found with catheter line occlusions, overall averages showing polyurethane lines slightly higher rates than silicone. Oncology patients however saw opposite results.

#### Rischio di infezione: conclusioni

Non ci sono evidenze che la scelta tra SIL vs. PUR possa influire in modo significativo sul rischio di infezione.

Il rischio di infezione è ovviamente correlato ad altri fattori:

- educazione dello staff
- appropriata indicazione del VAD
- protocollo di inserzione
- protocollo di gestione
- etc.

Il silicone non comporta minor rischio trombotico (anzi)

Alcuni studi di quasi 30 anni or sono hanno suggerito alcune differenze tra materiali in termini di rischio trombotico

- Curelaru 1983 SIL > PE
- Curelaru 1984 PUR = PE
- Pottecher 1984 PUR e SIL > PE
- Linder 1984 PUR > SIL

Studi clinici più recenti non hanno dimostrato differenze PUR vs. SIL in termini di rischio trombotico.

- Beau 1999
- Pittiruti 2009
- Bonizzoli 2011
- Miyakagi 2012

Studi clinici recenti hanno portati dati controversi sul rischio trombotico dei PICC in P-PUR

Nichols 2008 P-PUR = basso rischio

Trerotola 2010 P-PUR = alto rischio

Pittiruti 2012 P-PUR = basso rischio

(N.B.: nello studio di Trerotola, PICC 6Fr erano inseriti in qualunque paziente, senza considerazione del diametro della vena)

**BCSH 2007** 

### Guidelines on the insertion and management of central venous access devices in adults

L. BISHOP\*, L. DOUGHERTY<sup>†</sup>, A. BODENHAM<sup>‡</sup>, J. MANSI\*, P. CROWE<sup>§</sup>, C. KIBBLER<sup>†</sup>, M. SHANNON<sup>\*\*</sup>, J. TRELEAVEN<sup>†</sup>



 Polyurethane PICC allow easier infusion of blood products as greater flow rates are achieved because the thinner walls provide a larger internal diameter of the catheter. The decision to use polyurethane catheters should be balanced against the higher risk of thrombosis with these catheters compared with silicone catheters.

La fonte citata è Galloway & Bodenham 2004, ma si tratta di una review in cui non si afferma mai la possibile superiorità del SIL rispetto al PUR in termini di rischio trombotico; invece, si suggerisce che SIL sia meno suscettibile alle infezioni (sulla base del lavoro d McDonald del 1977!)

#### **GAVeCeLT 2007**

Nutritional Therapy & Metabolism / Vol. 25 no. 4, pp. 173-182

Wichtig Editore, 2007

Review Article

Catheter-related central venous thrombosis: the development of an Italian nationwide Consensus Paper

R. BIFFI', M. PITTIRUTP, C. CAMPISP, ON BEHALF OF THE GAVeCeLT\* COMMITTEE FOR THE CONSENSUS PAPER OF CATHETER-RELATED CENTRAL VENOUS THROMBOSIS

#### 3. Role of device or material in minimizing the risks

Currently a wide variety of central venous catheters are commonly used in medicine. Major design efforts have been undertaken to develop catheters that minimize trauma to blood vessels and are less thrombogenic. Catheter types and materials have undergone major design changes and continue to evolve. Randomized trials and prospective observations indicate an inherent superiority of silicone and second-third-generation polyurethane over more rigid materials, such as polyvinyl chloride (PVC), tetrafluoroethylene, and polyethylene as well (23-29). Pure silicone-valved catheters exhibited a lower rate of thrombosis when compared with barium-added open-ended silicone ones in a randomized trial (30). The number of catheter lumens is a major predictor of catheter thrombosis. Triplelumen Hickman catheters failed at 3 times the rate of double-lumen catheters (31).

#### Conclusions of the Consensus

Silicone and second-third-generation polyurethane catheters are less thrombogenic than polyethylene or PVC ones. A lower diameter catheter and a single lumen might be protective against the risk of central venous thrombosis.

Strength B recommendation.

#### **Review Article**

# Catheter-related central venous thrombosis: the development of an Italian nationwide Consensus Paper

R. BIFFI<sup>1</sup>, M. PITTIRUTI<sup>2</sup>, C. CAMPISI<sup>3</sup>, ON BEHALF OF THE GAVeCeLT\* COMMITTEE FOR THE CONSENSUS PAPER ON CATHETER-RELATED CENTRAL VENOUS THROMBOSIS

<sup>1</sup>Dept. of Surgery, European Institute of Oncology, Milan - Italy

<sup>2</sup>Dept. of Surgery, Gemelli Hospital, Catholic University of Sacred Heart and IASI - CNR/Shock Pathophysiology Section, Rome

<sup>3</sup>Dept. of Surgery, San Pietro Hospital and Institute of Biotechnologies, CNR, Rome - Italy

\*GAVeCeLT is the Italian Study Group for Long-Term Central Venous Access

Randomized trials and prospective observations indicate an inherent superiority of silicone and second-third-generation polyurethane over more rigid materials, such as polyvinyl chloride (PVC), tetrafluoroethylene, and polyethylene as well.

**SOR 2008** 

#### review

Annals of Oncology 20: 1459–1471, 2009 doi:10.1093/annonc/mdp052 Published online 12 June 2009

#### 2008 SOR guidelines for the prevention and treatment of thrombosis associated with central venous catheters in patients with cancer: report from the working group

P. Debourdeau<sup>1\*</sup>, D. Kassab Chahmi<sup>2</sup>, G. Le Gal<sup>3</sup>, I. Kriegel<sup>4</sup>, E. Desruennes<sup>5</sup>, M.-C. Douard<sup>6</sup>, I. Elalamy<sup>7</sup>, G. Meyer<sup>8</sup>, P. Mismetti<sup>9</sup>, M. Pavic<sup>1</sup>, M.-L. Scrobohaci<sup>10</sup>, H. Lévesque<sup>11</sup>, J. M. Renaudin<sup>12</sup> & D. Farge<sup>13</sup> on behalf of the working group of the SOR

Nessuna raccomandazione a proposito del materiale



Contents lists available at ScienceDirect

#### Clinical Nutrition





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

In vitro and ex vivo data confirm that silicone, and 2nd and 3rd generation polyurethane catheters are less thrombogenic than polyethylene or PVC ones, and should be preferred for long-term use (Grade C).

a Catholic University Hospital, Roma, Italy

b John Radcliffe Infirmary, Oxford, United Kingdom

<sup>&</sup>lt;sup>c</sup> Division of Abdomino-Pelvic Surgery, European Institute of Oncology, Milano, Italy

d Scarborough Hospital, Scarborough, United Kingdom

e Medical University of Warsaw, Poland

**ACCP 2012** 



#### CHEST

Supplement

ANTITHROMBOTIC THERAPY AND PREVENTION OF THROMBOSIS, 9TH ED: ACCP GUIDELINES

#### **Executive Summary**

Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines

Gordon H. Guyatt, MD, FCCP; Elie A. Akl, MD, PhD, MPH; Mark Crowther, MD; David D. Gutterman, MD, FCCP; Holger J. Schünemann, MD, PhD, FCCP; for the American College of Chest Physicians Antithrombotic Therapy and Prevention of Thrombosis Panel\*

Nessuna raccomandazione a proposito del materiale

2013

Journal of Thrombosis and Haemostasis, 11: 71-80

DOI: 10.1111/jth.12071

#### **ORIGINAL ARTICLE**

International clinical practice guidelines for the treatment and prophylaxis of thrombosis associated with central venous catheters in patients with cancer

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P. DEBOURDEAU, *1 D. FARGE, †‡1 M. BECKERS, §¶ C. BAGLIN, §¶ R. M. BAUERSACHS, **
B. BRENNER, †† D. BRILHANTE, ‡‡ A. FALANGA, §§ G. T. GEROTZAFIAS, ¶¶ N. HAIM, ***
A. K. KAKKAR, ††† A. A. KHORANA, ‡‡‡ R. LECUMBERRI, §§§ M. MANDALA, ¶¶¶ M. MARTY, ****
M. MONREAL, ††††, ‡‡‡‡ S. A. MOUSA, §§§§ S. NOBLE, ¶¶¶¶ I. PABINGER, ***** P. PRANDONI, ††††
M. H. PRINS, ‡‡‡‡ M. H. QARI, §§§§§ M. B. STREIFF, ¶¶¶¶¶ K. SYRIGOS, ****** H. R. BÜLLER†††††
and H. BOUNAMEAUX‡‡‡‡1
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Nessuna raccomandazione a proposito del materiale Nessuna differenza tra valvolati vs. non valvolati

Maggiore per PE, PTFE e PVC rispetto a PUR e SIL



J Vasc Access 2015; 00 (00): 000-000

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Mixed results were found with catheter line occlusions, overall averages showing polyurethane lines slightly higher rates than silicone. Oncology patients however saw opposite results.

#### Rischio di trombosi - conclusioni

Non ci sono evidenze di alcuna differenza tra SIL vs. PUR in termini di trombosi. La instabilità del silicone – sia nel tratto esterno che nel tratto intravascolare potrebbe però favorire la trombosi.

Il rischio di trombosi venosa da PICC è ovviamente correlato ad altri fattori:

- puntura ecoguidata vs. 'blind'
- rapporto tra diametro della vena e calibro del catetere
- corretta posizione della punta
- uso di sistemi sutureless
- etc.



J Vasc Access 2015; 16 (2): 130-136

DOI: 10.5301/jva.5000314

ORIGINAL ARTICLE

# Central venous access devices in pediatric malignancies: a position paper of Italian Association of Pediatric Hematology and Oncology

Alessandro Crocoli<sup>1</sup>, Assunta Tornesello<sup>2</sup>, Mauro Pittiruti<sup>3</sup>, Angelica Barone<sup>4</sup>, Paola Muggeo<sup>5</sup>, Alessandro Inserra<sup>1</sup>, Angelo Claudio Molinari<sup>6</sup>, Valeria Grillenzoni<sup>7</sup>, Viviana Durante<sup>8</sup>, Maria Pia Cicalese<sup>9</sup>, Giulio Andrea Zanazzo<sup>10</sup>, Simone Cesaro<sup>7</sup>

- <sup>1</sup> General and Thoracic Surgery Unit, Department of Surgery, Bambino Gesù Children's Hospital, IRCCS, Rome Italy
- <sup>2</sup> Pediatric Oncology Unit, Vito Fazzi Hospital, Lecce Italy
- 3 Department of Surgery, "Agostino Gemelli" Catholic University, Rome Italy
- <sup>4</sup> Pediatric Hematology and Oncology Unit, Department of Pediatrics, Azienda Ospedaliero-Universitaria di Parma, Parma Italy
- <sup>5</sup> Pediatric Hematology and Oncology, Pediatric Clinic, Azienda Ospedaliero-Universitaria Policlinico, Bari Italy
- <sup>6</sup> Thrombosis and Hemostasis Unit, Giannina Gaslini's Children Hospital, Genova Italy
- <sup>7</sup> Pediatric Hematology Oncology, Azienda Ospedaliera Universitaria Integrata, Verona Italy
- 8 Pediatric Surgery Unit, University Policlinic Hospital, Modena Italy
- Pediatric Immunology and Bone Marrow Transplantation Unit, San Raffaele Telethon Institute for Gene Therapy (HSR-TIGET), "San Raffaele" Scientific Institute, Milan Italy
- 10 Institute for Maternal and Child Health, IRCCS "Burlo Garofolo", Trieste Italy

#### Choice of material

MTVAs and LTVAs are made of catheters of different materials, either silicon or polyurethane. There is no evidence of any difference between silicon and polyurethane in terms of risk of infective and thrombotic complications in the adult or in the pediatric population (13, 14). Silicon catheters have traditionally been the first choice for LTVA in pediatric patients (11, 15-18), although polyurethane catheters—and specially power injectable polyurethane catheters, which are made of third-generation polyurethanes—are as biocompatible as silicone catheters but less fragile; also, they are compatible with higher flow rates and are ideal for injection of contrast medium (19).

# Il silicone (specialmente se trasparente) è particolarmente fragile

#### Rischio di rottura

Molti studi hanno dimostrato un rischio di rottura e/o dislocazione più elevato per il SIL rispetto al PUR

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- Rudin 1990
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- Beau 1999 (p<.01)</li>
- Hoffer 2001 (p<.01)</li>
- Pittiruti 2009
- Cohen 2011 (p<.005)</li>

Uno studio prospettico non controllato ha mostrato una superiorità del P-PUR rispetto al PUR e al SIL riguardo a tutte le complicanze meccaniche

DiGiacomo 2009

# Groshong PICC and home care: an opportunity. Clinical experience after the first 200 implants

S. SPAZIANI<sup>1</sup>, T. MICHELI<sup>1</sup>, B. VINCENZI<sup>2</sup>, C. CAMPISI<sup>3</sup>

- Rep. Analgesic and Palliative Therapy Unit, ASL Frosinone, Frosinone Italy
- <sup>2</sup> Biomedical Campus, Rome Italy
- <sup>3</sup> National Research Council, Institute of Biomedical Technologies, Rome Italy

ABSTRACT: Peripherally Inserted Central Catheters (PICC) represent an alternative for critical patient care, and are safer to implant in home patients.

The authors report on their experience with the first 200 4 Fr Groshong PICC implanted during the last 18 months. The procedure can be easily applied at home (98% successful implant rate), without the need for fluoroscopic or ultrasound guidance. Moreover, the authors believe that the X-ray control after implant is not strictly necessary. After 11,570 days/catheters, only 5 devices were explanted because of complications: 4 because of sepsis and peripheral phlebitis, and the last was explanted by another medical staff for unclear reasons. The complications needing no explanation were a total of 32: for 12 of them the external portion of tube was damaged during use, while for the other 20 the internal clots were resolved with forced flushing.

The authors conclude that Groshong PICC can be considered the gold standard for home care management of critical patients, taking into account the quality of pure silicon, the presence of a valve and the specially-made closed-tip.

200 Groshong PICC: 12 rotture, 20 occlusioni da coagulo



J Vasc Access 2016; 17 (4): e79-e81 DOI: 10.5301/jva.5000551

CASE REPORT

Online Only

## Nerve damage secondary to removal of fractured PICC fragment

Qian Q. Mou, Yun X. Wang, Qiong H. Xu, Xia Liu, Ying J. Li

Division of Thoracic Oncology, Cancer Center, West China Hospital, Sichuan University, Chengdu - PR China

#### **ABSTRACT**

**Purpose:** To increase awareness of peripherally inserted central catheter (PICC) fracture and necessary nursing assessment to identify development of nerve injury after removal of the PICC fracture.

**Methods:** This is a case review of a cancer patient with fractured PICC and the postoperative symptoms leading to nerve injury.

**Results:** The reason for PICC fracture is the fragility of silicon. Secondary surgical intervention of a PICC fragment resulted in nerve damage from a hematoma placing pressure on the median nerve in the arm.

**Conclusions:** It is necessary to use power injectable polyurethane PICCs. It is vital to have a clear understanding of signs and symptoms of nerve impingement in the arm when monitoring a post-operative patient. Assessment of neurological status, circulation, swelling and patient complaints of pain are all necessary functions of the nurse in caring for this type of patient.

Keywords: Fracture, Nerve injury, Nursing implications, Peripherally inserted central catheter (PICC)

Results: The reason for PICC fracture is the fragility of silicon.



J Vasc Access 2015; 16 (1): 47-51

DOI: 10.5301/jva.5000308

ORIGINAL ARTICLE

# Percutaneous retrieval of PICC fractures via the femoral vein in six cancer patients

Qi Wang, Bin Xiong, ChuanSheng Zheng, GanSheng Feng, Ming Liang, HuiMin Liang

Department of Radiology, Union Hospital, Tongji Medical College, Huazhong University of Science and Technology, Wuhan - People's Republic of China

#### **ABSTRACT**

**Purpose:** To investigate the feasibility and safety of the interventional technique of retrieving the fractured peripherally inserted central catheter (PICC) segments within the vessels via the femoral vein.

Methods: From July 2007 to January 2012, we performed percutaneous retrieval of PICC fractures in six cancer patients who accepted chemotherapy via PICC. The fractures occurred during the traction of the catheter and were diagnosed with chest plain film radiography and/or computed tomography. The patients included four cases of ovarian cancer, one case of breast cancer and one case of cervical cancer. The fractures were retained in the vessels of the patients for 1 to 10 days. According to the location of the ends of the PICC fractures, three methods were employed using the most commonly used interventional devices in the digital subtraction angiography suite. Results: The PICC fractures were located in the subclavian vein, superior vena cava, right atrium, right ventricle or pulmonary arteries. During the procedures, a goose neck snare, pigtail catheter and stone basket catheter were used individually or in combination. The PICC fractures were removed successfully in all six patients via unilateral or bilateral femoral vein access. No major complications occurred during the operation or the follow-up period of 7 to 10 days.

**Conclusions:** Via femoral vein access, PICC fractures could be removed with common interventional instruments such as a goose snare, basket catheter and pigtail catheter. The interventional retrieval is a safe, convenient and minimally invasive method for the removal of PICC fractures.

**Keywords:** Cancer, Fracture, PICC, Retrieval

#### **Patients and Methods**

#### Patients

The patients in this study included four cases of ovarian cancer, one case of breast cancer and one case of cervical cancer. The patients received chemotherapy via PICC. The PICC catheters were silicone Groshong\* NXT PICC and Groshong\* NXT ClearVue PICC (Bard Access System, Salt Lake City, USA).

Wang, JVA 2014

#### JOURNAL OF VASCULAR ACCESS

# Use of peripherally inserted central venous catheters (PICCs) in children receiving autologous or allogeneic stem cell transplantation --Manuscript Draft--

Manuscript Number:	JVA-D-17-00122R1
Full Title:	Use of peripherally inserted central venous catheters (PICCs) in children receiving autologous or allogeneic stem cell transplantation
Short Title:	Use of PICCs in children receiving stem cell transplantation
Article Type:	Original Research Article
Section/Category:	Oncology
Keywords:	Stem cell transplantation. Children. BMT. Pediatric age. PICC. CVC. Peripherally inserted central catheters
Manuscript Region of Origin:	ITALY

in literature. So, the last 3 PICCs were implanted without tunneling. The mechanical complication rate was high (46%) and related to external rupture of the device (5 cases) and temporary obstruction (1 case). However these complications were easily resolved with additional saline flushing or lock therapy with Urokinase solution in case of catheter obstruction, and repair of the catheter in the other cases, with maintenance of the same device in all patients. So high number of external rupture of the device was due to the initial choice to use only silicone PICC; they were appreciate and easily managed from the nurses because very similar to the CICCs used before but more fragile than polyurethane devices. Probably the choice of a power injectable polyurethane PICC would have reduced the incidence of this complication.

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PICC would have reduced the incidence of this complication.

#### **JOURNAL OF VASCULAR ACCESS**

# In vitro study on the use of a two-component cyanoacrylate glue as sealant at the exit site of peripherally inserted central catheters --Manuscript Draft--

Manuscript Number:	
Full Title:	In vitro study on the use of a two-component cyanoacrylate glue as sealant at the exit site of peripherally inserted central catheters
Short Title:	Use of two-component cyanoacrylate glue on PICCs
Article Type:	Original Research Article
Section/Category:	Nursing
Keywords:	Peripherally inserted central catheters; cyanoacrylate glue; mechanical properties; material degradation; polyurethane; silicon.
Corresponding Author:	Francesca Di Puccio, Ph.D. Universita di Pisa Pisa, ITALY
Corresponding Author's Institution:	Universita di Pisa
First Author:	Francesca Di Puccio, Ph.D.
Order of Authors:	Francesca Di Puccio, Ph.D.
	Daniela Giacomarro
	Lorenza Mattei
	Mauro Pittiruti
	Giancarlo Scoppettuolo

To investigate possible degradation after several weeks of contact with glue, distinct pads were prepared and conserved in an egg incubator at 34°C and relative humidity of 60% so to reproduce in vivo like conditions (Fig.1 d). Once the desired duration was reached, the due pad was taken out from the incubator and each sample carefully removed from the skin support (Fig.1e). This step was critical but necessary to observe the PICC surface underneath the glue. In all polyurethane catheters, when detaching the sample from the pad, the glue remained upon the artificial skin, thus exposing the catheter surface to be analyzed (Fig.1 e). The silicon catheter (Groshong, Bard) could not be tested: it was weaker than the glue so it broke during the attempt to remove it from the skin pad.

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Br J Nurs. 2009 Jan 8-21;18(1):8-16.

#### Comparison of three peripherally-inserted central catheters: pilot study.

Di Giacomo M1.

Author information

#### Retraction in

Retraction. [Br J Nurs. 2014]

#### Abstract

Peripherally-inserted central catheters (PICCS) are non-tunnelled, central catheters inserted through a peripheral vein of the arm. They are 50-60 cm long and are usually made of either silicone or second-third generation polyurethane. PICCs can be used for prolonged, continuous or intermittent infusion therapies (up to 3 months) both in hospitalized patients and in patients treated as outpatients, in a hospice, or at home. When establishing a vascular service it is key to select a PICC that meets the requirements of safety, cost-effectiveness, high resistance (ability to take increasing fluid volumes with high pressure devices) and durability, and low complications rate. The complications and dwell times of three different PICCs were studied: coated polyurethane, valved silicone and power-injectable. The study was conducted at the chemotherapy suite at the author's hospital with the aim of selecting the right PICC based on low incidence of complications, resistance and enhanced dwell time. Results show a low incidence of complications and long dwell time among patients with the power-injectable PICC. Furthermore, this study demonstrated a reduction on the rate of occlusion and rupture with power-injectable PICCs, which makes them safer to use for administration of chemotherapy and other vesicant agents, as well as for the management of patients in critical care.



J Vasc Access 2015; 00 (00): 000-000

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REVIEW

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Mixed results were found with catheter line occlusions, overall averages showing polyurethane lines slightly higher rates than silicone. Oncology patients however saw opposite results.

ORIGINAL ARTICLE

DOI: 10.5301/jva.5000261

### Fractures of totally implantable central venous ports: more than fortuity. A three-year single center experience

Paolo Balsorano<sup>1</sup>, Giulia Galducci<sup>1</sup>, Ilaria De Fanti<sup>1</sup>, Samuel Kagan Evans<sup>2</sup>, Angelo Raffaele De Gaudio<sup>1</sup>, Cecilia Pelagatti<sup>3</sup>

#### ABSTRACT

Purpose: Totally implantable venous access devices (Ports) represent the mainstay for infusion therapy in patients undergoing chemotherapy, total parenteral nutrition and/or long-term antibiotic treatment. Amongst mechanical complications, lesions of the catheter wall represent a rare but potentially severe condition. We report our experience with the accidental detection of catheter ruptures in a series of ports removed for complication or for end of use.

Methods: All ports removed from January 2011 to June 2013 were considered. All removed ports had been inserted according to a standardized protocol including ultrasound-guided percutaneous venipuncture (out-of-plane or in-plane approaches) and electrocardiogram-guided positioning of the tip. Once removed, each catheter was checked by inspection and saline instillation in order to evaluate the integrity of the device itself and rule out possible ruptures.

Results: In over 338 removed ports, 12 Groshong catheters out of 65 (18.5%) had evidence of partial rupture of the catheter wall. Amongst considered variables, "out-of-plane" approach and type of port (silicon, closed tip with Groshong valve) were the only ones significantly associated with catheter ruptures (p=0.0003 and 0.0008, respectively). We could detect no evidence of rupture in any silicon open-ended catheter (Celsite ports) or in any catheter inserted by "in-plane" approach to the vein.

Conclusions: The actual advantage of using port connected with Groshong silicon catheters should be questioned, since apparently they are more fragile than standard catheters. Furthermore, ultrasound-guided "out-of-plane" puncture of the internal jugular vein should be discouraged.

Key words: Catheter fractures, Catheter ruptures, Groshong catheters, Port mechanical complications, Totally implantable access devices, Vascular access mechanical complications

<sup>&</sup>lt;sup>1</sup>Department of Health Science, Section of Anaesthesiology, Intensive Care and Pain Medicine, AOUC Careggi, Florence - Italy

<sup>&</sup>lt;sup>2</sup> Department of Pulmonary and Critical Care Medicine, Rode Island Hospital, Providence, RI - USA

<sup>3</sup> Department of Oncology, Section of Anesthesiology and Intensive Care, AOUC Careggi, Florence - Italy

Twelve Groshong catheters out of 65 (18.5%) had evidence of partial rupture of the catheter wall. Seven out of 12 ruptured devices were normally functioning at the time of removal: 6 had been removed due to end of use, while 1 had been removed due to catheter-related bloodstream infection. The other five cases of rupture were associated either with catheter occlusion (three cases) or with extravasation (two cases). Patients' demo-

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J Vasc Access 2011; 12 (3): 270

DOI: 10.5301/JVA.2011.6277

# Dislocation of a Groshong catheter from a titanium Dome® Port after thoracic trauma caused by airbag activation

Editor,

A 77-year-old oncological patient who underwent the implantation of a Port titanium Dome system with a Groshong 8F Bard® catheter for chemotherapy treatment after a Billroth II gastrectomy was rushed to hospital because of a closed thoracic trauma due to the airbag activating on the driver's side after a car accident.

On his arrival at the emergency unit, the patient presented backward-looking amnesia, but he remembered the strong impact as the airbag opened on his chest. He only

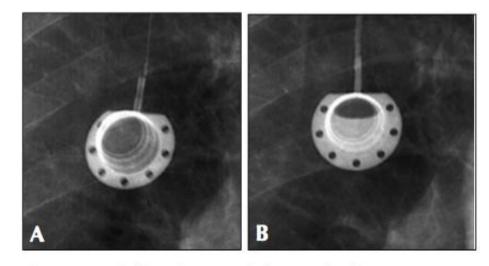


Fig. 2A - Detail of the chest Rx at the first arrival at the emergency unit: already evident is a millimetric disconnection in the enlargement of the Dome detail. B - Chest Rx after the Port positioning some months before: Dome detail with the Groshong catheter correctly connected.

J Vasc Access. 2015 Sep-Oct;16(5):431-3. doi: 10.5301/jva.5000430. Epub 2015 Jun 20.

### Retained embolized fragment of totally implantable central venous catheter in right ventricle: it is really necessary to remove?

Tazzioli G1, Gargaglia E, Vecchioni I, Papi S, Di Blasio P, Rossi R.

#### Author information

#### Abstract

**INTRODUCTION:** Central venous catheters are often required in oncologic patients for long-term safe administration of chemotherapeutic agents, antibiotics, and parenteral nutrition. Rupture of these devices and intracardiac migration is a rare complication.

METHODS: We report one spontaneous rupture and embolization of a totally implantable vascular access device (TIVAD) in an asymptomatic patient.

RESULTS: A 50-year-old woman received. TIVAD silicone catheter 8 FR for adjuvant chemotherapy. After 3 years of port time in situ, during a follow-up control, a catheter malfunction was found and radiologic investigations showed a rupture and migration of the catheter to the right ventricle. The attempt to remove the fragment under fluoroscopic control using the femoral route was unsuccessful. We did not try a surgical approach because of the complete absence of symptomatology and hemodynamic impairment.

**CONCLUSIONS:** The catheter rupture and intracardiac embolization is a rare complication associated with totally implantable or tunneled central venous catheters. When such an event happens, the patient should be managed by expert hemodynamists or interventional radiologists making an effort to remove the fragment without surgical measures. When the intravascular percutaneous route fails, the possibility to leave the fragmented catheter in heart chambers should be evaluated, being surgery questionable in asymptomatic patients.



J Vasc Access 2016; 17 (6): 535-541

DOI: 10.5301/jva.5000606

ORIGINAL RESEARCH ARTICLE

# Fracture of totally implanted central venous access devices: a propensity-score-matched comparison of risks for Groshong silicone versus polyurethane catheters

Soichi Kojima¹, Takao Hiraki¹, Hideo Gobara¹, Toshihiro Iguchi¹, Hiroyasu Fujiwara¹, Yusuke Matsui¹, Toshiharu Mitsuhashi², Susumu Kanazawa¹

<sup>&</sup>lt;sup>1</sup>Department of Radiology, Okayama University Medical School, Okayama - Japan

<sup>&</sup>lt;sup>2</sup> Department of Epidemiology, Okayama University Medical School, Okayama - Japan

#### ABSTRACT

**Purpose:** To evaluate retrospectively the fracture risk of totally implanted venous access devices connected to Groshong silicone (SC) versus polyurethane (PU) catheters, inserted via the internal jugular vein.

Materials and methods: The study population comprised 384 SC and 221 PU central venous catheters implanted via the internal jugular vein. The presence of catheter fracture was evaluated. Variables possibly related to catheter fracture were evaluated. First, in order to determine the factors associated with fracture, fracture rates were compared with the log-rank test between the two groups divided by each of the variables. Then, in order to adjust for potential confounders, propensity-score matching of the variables was employed in the two catheter groups. Finally, the rates of fracture were compared between the two propensity-score-matched catheter groups. Results: There were 16 cases of catheter fracture, for an overall fracture percentage of 2.6% (16/605). All 16 cases of fracture occurred in the SC catheter group. Smaller patient body mass index (p = 0.039), deeper catheter tip position (p = 0.022), and SC catheters (p = 0.019) were significantly associated with fracture. With the propensity-score-matching method, 180 cases were selected in each catheter group. Comparison of the two propensity-score-matched groups showed that fracture rates for SC catheters remained significantly (p = 0.018) higher than those for PU catheters.

**Conclusions:** Ports connected to Groshong SC catheters – when implanted via the internal jugular vein – posed a higher risk of fracture than did ports connected to PU catheters.

Keywords: Breakage, Central venous catheter, Fracture, Polyurethane, Risk, Silicone

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# Totally implantable ports connected to valved catheters for chemotherapy: experience from 350 Groshong devices

Kenji Nishinari, Nelson Wolosker, Christiano Vinicius Bernardi, Guilherme Yazbek

Department of Vascular Surgery, Hospital A.C. Camargo, São Paulo - Brazil

ABSTRACT: Purpose: There are few studies regarding the use of totally implantable valved ports for chemotherapy. The objective of this study was to analyze the results obtained from consecutive implantation of 350 devices.

Methods: Adult patients submitted to port insertion in veins of the superior vena cava system over a 17-month period (July 2006 to December 2007) were considered. The device used was composed of a titanium and silicone rubber port (Dome Port™; Bard Inc, Salt Lake City, UT) connected to an 8.0 Fr silastic Groshong™ catheter tube. Follow-up was conducted on outpatient data and during clinical readmissions, until the device was removed or the patient died.

Results: Three hundred and fifty devices, total of 74,691 days in situ, were inserted, with a median follow-up of 176 days. There were 11 early complications (3.1%) and 49 late complications (14%), 21 of these (6%) were considered major ones. Early complications comprised four instances of phlebitis of the external jugular, three of pocket infection, two of technical failure and two of ecchymosis. Late complications comprised 33 instances of withdrawal difficulty, 12 of port-related bacteremia, two of deep venous thrombosis, one of occlusion and one of catheter fracture. Out of the 350 catheters implanted, 258 (73.5%) were still being used, 73 (21%) remained in use until the patient died, five (1.5%) were removed at the end of the treatment and 14 (4%) were removed because of complications.

Conclusions: There was a low rate of major complications associated with this valved system justifying its use. (J Vasc Access 2010; 11: 17-22)

There were two types of mechanical complications among this sample of patients, which did not occur in our previous study (16): excessive angulation (two patients) in the subcutaneous pathway of the catheter, leading to malfunctioning (early complication) and one case of catheter fracture associated with embolization (15, 24, 25) (late complication). For these patients, a new device had to be implanted and, in the case of catheter fracture, endovascular intervention was necessary, thereby causing additional costs. These complications resulted mainly from technical failure and could have been avoided, although there was an association with the characteristics of the catheter (thin and malleable). Classical technical precautions should be respected while inserting this type of catheter: construction of gentle curves along its subcutaneous pathway and avoidance of a very medial puncture when undertaking the infraclavicular access to the subclavian vein.

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### Midline Groshong

Nessun vantaggio mai comprovato in letteratura rispetto ai Midline in poliuretano

Cfr. Moureau 2015: shift da midline in silicone a midline in poliuretano, per ridurre le complicanze meccaniche (rotture)

# How to Establish an Effective Midline Program: A Case Study of 2 Hospitals



Nancy Moureau, BSN, RN, CRNI®, CPUI, VA-BC™

PICC Excellence Inc, Greenville Memorial Medical Campus, Greenville, SC, and Griffith University, Brisbane, Australia

Gordon Sigl, MSN, RN

Advocate Illinois Masonic Medical Center, Chicago, IL

Margaret Hill, RN

Piedmont Henry Hospital, Stockbridge, GA

#### Abstract

Introduction: Establishing an effective midline program involves more than simply learning an insertion technique for a new product. Midline catheters provide a reliable vascular access option for those patients with difficult venous access who would otherwise require multiple venipunctures or the use of higher-risk central lines to maintain access. An effective midline program establishes a protocol for device selection and includes standing orders to facilitate speed to placement. Methods: Our retrospective descriptive review evaluated the successful integration of midline programs into existing vascular access bedside insertion programs in 2 acute care hospitals. The investigator reviewed a convenience sample of hospital patients. Participants in the study included vascular access team managers and team members from the sample sites. Results: The results of this 2-hospital study demonstrate successful integration of a midline program into a bedside insertion program with 0 midline-related infections since initiation. Documentation of overall central line-associated bloodstream infection rates for hospital 1 changed from 1.7/1000 catheter-days to 0.2/1000 catheter-days, reflecting a 78% reduction in infections and a projected cost avoidance of \$531,570 annually. Both hospitals demonstrated reduced rates of infection following implementation of a midline program.

Conclusions: Midlines have a history of lower risk for both infection and thrombosis compared with central venous devices. Although more research is needed on the more recently developed midline catheters, available evidence suggests that midlines provide a safe and reliable form of vascular access, reducing costs and the risk of infection associated with central venous catheters, especially those placed solely for patients with difficult venous access.

Keywords: infusion, intravenous, catheter, indwelling, catheterization, peripheral/method



J Vasc Interv Radiol. 2011 May;22(5):638-41. doi: 10.1016/j.jvir.2011.01.433.

#### Silicone and polyurethane tunneled infusion catheters: a comparison of durability and breakage rates.

Cohen AB1, Dagli M, Stavropoulos SW Jr, Mondschein JI, Soulen MC, Shlansky-Goldberg RD, Solomon JA, Chittams JL, Trerotola SO.

#### Author information

#### Abstract

**PURPOSE:** To examine the overall durability and breakage rates of dual-lumen silicone catheters in comparison with power-injectable dual-lumen polyurethane catheters.

MATERIALS AND METHODS: Patients who received a 10-F dual-lumen silicone catheter or 9.5-F dual-lumen polyurethane catheter between January 2002 and July 2009 were identified through a quality assurance database. Medical records were reviewed retrospectively. A total of 117 silicone and 94 polyurethane catheters were identified in 192 patients. Reasons for catheter placement and removal were recorded, as were cases of breakage and repairs. Catheter durability was compared; survival analysis was also performed.

RESULTS: Breakage occurred in nine of 117 silicone catheters (8%) and none of 94 polyurethane catheters (P = .005). Most catheters were placed for malignancy (162 of 211; 77%); nonmalignant indications such as total parenteral nutrition accounted for 49 out of 211 catheters (23%). The mean silicone catheter dwell time was 99 days (11,612 total catheter-days), and the mean polyurethane catheter dwell time was 78 days (7,362 total catheter-days). There was no significant difference in overall duration of function (ie, survival) between silicone and polyurethane catheters (P = .12). The infection rates were 3.6 per 1,000 catheter-days for silicone catheters and 3.5 per 1,000 catheter-days for polyurethane catheters (P value not significant).

**CONCLUSIONS:** There were fewer catheter fractures with the polyurethane catheter compared with the silicone catheter, although there was no difference in the total access site service interval for the two catheter types.

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### Rischio di rottura - conclusioni

Le evidenze dimostrano che il SIL è più soggetto a complicanze meccaniche (rotture, dislocazioni) rispetto al PUR

E' anche plausibile che il P-PUR possa dimostrarsi ancora più vantaggioso a tale riguardo Il silicone non è indispensabile per i farmaci in base alcolica

Viene spesso riferito che l'uso di chemioterapici in base alcoolica (taxani) sarebbe una indicazione all'uso di cateteri in silicone.

COSA C'E' DI VERO ?

### Prima considerazione

Se è vero che teoricamente i poliuretani sono più sensibili del silicone all'effetto dell'alcool, effettivi danni ai cateteri non sono mai stati dimostrati, nè *in vivo* nè in studi ben condotti *in vitro*.

# THE EFFECTS OF PROLONGED ETHANOL EXPOSURE ON THE MECHANICAL PROPERTIES OF POLYURETHANE AND SILICONE CATHETERS USED FOR INTRAVASCULAR ACCESS

Christopher J. Crnich; Jeremy A. Halfmann; Wendy C. Crone; Dennis G. Maki

#### ABSTRACT:

BACKGROUND: Products containing alcohol are commonly used with intravascular devices at insertion, to remove lipids from occluded intravascular devices used during parenteral nutrition, and increasingly for the prevention and treatment of intravascular device-related bloodstream infection. The effects of alcohol on the integrity of intravascular devices remain unknown.

METHODS: Two types of widely used commercial peripherally inserted central catheters, one made of polyetherurethane and one made of silicone, were exposed to a 70% ethanol lock solution for up to 10 weeks. Mechanical testing was performed to identify force-at-break, stress, strain, modulus of elasticity, modulus of toughness, and wall area of ethanol-exposed and control catheters.

RESULTS: No significant differences between exposed and unexposed catheters were identified for any of the mechanical parameters tested except for a marginal reduction in the modulus of elasticity for both polyetherurethane and silicone catheters and minor increases in the wall area of polyetherurethane catheters.

CONCLUSIONS: These data indicate that exposure to a 70% ethanol lock solution does not appreciably alter the integrity of selected commercial polyetherurethane and silicone catheters. Given the greatly expanded use of alcoholic solutions with intravascular devices of all types, we believe that manufacturers would be well advised to subject their catheters and other intravascular devices to formal testing of the type employed in this study (Infect Control Hosp Epidemiol 2005;26:000-000).

This was the first study to systematically evaluate the effect of ethanol on the integrity of two types of vascular catheters commonly used in clinical practice. The findings suggest that a 70% ethanol lock solution has a negligible impact on the mechanical properties of polyetherurethane and silicone catheters, despite continuous exposure times as long as 10 weeks. These findings should allay fears about the use of alcohol-containing antiseptic solutions with vascular catheters made of silicone and aromatic polyetherurethanes and should prompt further study of ethanol as an anti-infective lock solution for the prevention8 and treatment7 of intravascular device-related BSI in clinical practice.

### Seconda considerazione

I poliuretani di terza generazione (es. Carbothane), ovvero quelli utilizzati per i PICC power injectable, sono resistenti all'alcool.

# Issues Germane to Tunneled Catheters

One center's experience

BY GREGG MILLER, MD; KONSTANTIN KHARITON; AND NAVEEN GOEL, MD

sing hemodialysis catheters in patients with end-stage renal disease leads to higher costs and more frequent complications than alternates, such as arteriovenous (AV) fistulas or grafts. The Medicare cost for hemodialysis patients with central catheter accesses was \$69,893 per year in 2003 as opposed to \$61,929 for patients with grafts and \$52,751 for patients with fistulas 1 These costs are some

"To pick the best possible catheter, it is important to evaluate the various options in catheter material, body design, and tip design, as well as the available advanced catheter features."

Traditionally, hemodialysis catheters were made of one of two materials: silicone or polyurethane. However, each of these materials presented a serious problem with catheter care. Silicone is greatly weakened by iodine; polyurethane is resistant to iodine but significantly structurally degraded by alcohol. In the past, when using catheters of these materials, caregivers had to be careful not to expose the given catheter to its respective nemesis. Over time, structural degradation has led to torn catheter tips, which

may break free and travel into the pulmonary artery.<sup>2</sup> The newest advance in catheter material is carbothane, which has all the advantages of its predecessors but is resistant to both iodine and alcohol. It is stronger than polyurethane, allowing it to have thinner walls and retain the same physical properties as polyurethane catheters. Most catheters on the market today are made of carbothane and have proven enhanced biocompatibility.<sup>3</sup>

#### LONG TERM POLYURETHANE CATHETER ALCOHOL COMPATIBILITY I, PHYSICAL AND RHEOLOGICAL STUDIES

Lecon Woo<sup>1</sup>, John Wesley MD<sup>2</sup>, Maryellen Zibell<sup>2</sup>, Christopher Gardner<sup>2</sup> and William Anderson<sup>2</sup>

<sup>1</sup>LWoo Associates LLC, Libertyville IL 60048

<sup>2</sup> Excelsior Medical, Neptune, NJ

#### Abstract

Thermoplastic urethanes (TPU) offer broad property range, processing flexibility, and biocompatibility for medical applications. Alcohol based disinfectants have a long history of effective and safe use. Expanding on earlier rheology molecular weight data indicating minimal reduction, we conducted a long term compatibility study covering all known urethane types in a hemo-dialysis setting with a simulated clinical exposure protocol for 90 days. After 90 days exposure, minor changes in physical properties on the catheter body and components were detected, often similar to the saline control. Most importantly, resultant properties far exceeded ISO requirements for catheters.

#### Introduction

TPU catheters are prominent in device applications and increasingly, they are subjected to longer duration use, and exposed to a wide variety of chemically active agents. Alcohol based disinfectants are the most widely used for its long history of safety and effectiveness. To understand the compatibility of polyurethane devices and alcohol exposure, we conducted both fundamental material response and device performance studies. For example, it was pointed out in our earlier studies (1,2), that due to TPU's complex annealing behavior, vastly different properties can result from thermal history and could at least in part account

components and connections exposed to the alcoholic disinfectant were studied.

#### Experimental

Continuing our previous studies where more detailed procedures are fully described, we evaluated hydrolytic molecular weight degradation upon exposure to alcoholic disinfectants with melt rheology with the well established relationship for linear polymers (4-5),

$$\eta$$
 = K Mw  $^{3.4}$  (1)  
Where  $\eta$  is the steady shear limiting viscosity  
Mw is the weight average molecular weight

Five TPU based hemo-dialysis long term indwelling catheters chosen to cover all known commercial polyurethane types were studied. They included (A) Tecoflex®, (B) Tecothane®, (C) Carbothane®, (D) Pellethane®, and (E) Chronoflex® (6-10). Sample A uses an aliphatic polyurethane with ether soft segments. Samples B and E are ether soft segment aromatic polyurethanes, Sample C contains a polycarbonate soft segment and Sample E's soft segment is also polycarbonate based but differs from C. These catheters range in size from 10 Fr to 14.5 Fr and from 24 to 55 cm in length. Figure 1 describes a locations indicated.

typical catheter and all exposed area a locations indicated.

#### Abstract

Thermoplastic urethanes (TPU) offer broad processing flexibility, property range, biocompatibility for medical applications. Alcohol based disinfectants have a long history of effective and safe use. Expanding on earlier rheology weight data indicating minimal molecular reduction, we conducted a long term compatibility study covering all known urethane types in a hemo-dialysis setting with a simulated clinical exposure protocol for 90 days. After 90 days exposure, minor changes in physical properties on the catheter body and components were detected, often similar to the saline control. Most importantly, resultant properties far exceeded ISO requirements for catheters.

### PICC Day Genova 2014



### Conclusions

#### PART 2 In-vivo like condition

- Weight variations were <2.5% after 30 days @37°C in RL/Ethanol solutions</li>
- 2) Weight variations in Ethanol > Weight variations in RL
- 3) Pre-immersion weight was recovered in 24 h
- Relaxation behavior after rapid stretching appears to correlate well with weight variations
- 5) The post-immersion mechanical response varied lightly
- 6) Its likely that no chemical reactions happened between catheter and fluids -> Apparently, Ethanol does not damage polyurethane



J Vasc Access 2016; 17 (2): 175-181

DOI: 10.5301/jva.5000452

ORIGINAL ARTICLE

## A comparative study on the mechanical behavior of polyurethane PICCs

Paolo Poli<sup>1</sup>, Antonella Scocca<sup>1</sup>, Francesca Di Puccio<sup>2</sup>, Giuseppe Gallone<sup>2</sup>, Lorenza Angelini<sup>2</sup>, Emanuele Maria Calabrò<sup>2</sup>

#### ABSTRACT

**Purpose:** This study describes a comparative analysis of eight commercial polyurethane, single-lumen peripherally inserted central venous catheters (PICCs) from different vendors. The aim was to investigate the mechanical response of the catheters providing objective and quantitative data to support a comparison among them. Such data could help nurses and physicians to select a central venous catheter (CVC) not only on the basis of the expected dwell duration or of the assessment of the vessels at the desired insertion site but also of the chemical and mechanical properties of the CVC and of the projected response of the body to these properties.

Methods: An experimental procedure was defined and tests were performed to assess some main characteristics of the PICC lines, including macro and microgeometric features, chemical and physical properties, and mechanical response. Preliminary measurements were performed to accurately define all geometric characteristics, including length, inner and outer diameters, and any inherent initial curvature of the catheter. Micro-geometric features were investigated using surface roughness analysis, optical microscopy, and scanning electron microscopy. Mechanical properties were studied by means of dynamic mechanical thermal analysis, simple uniaxial tensile tests, and kinking tests.

**Results:** Results are discussed in order to compare the different PICC lines. In particular, they show that polyurethane catheters can have a different mechanical behavior, which might play a role in the onset of pathologic processes and result in an increased risk and incidence of catheter-related complications.

Conclusions: This study provides useful information that can help identifying and facilitate the choice of a PICC.

Keywords: Comparative study, Mechanical properties, PICCs

<sup>&</sup>lt;sup>1</sup>Pain Therapy Unit, S. Chiara Hospital, Pisa - Italy

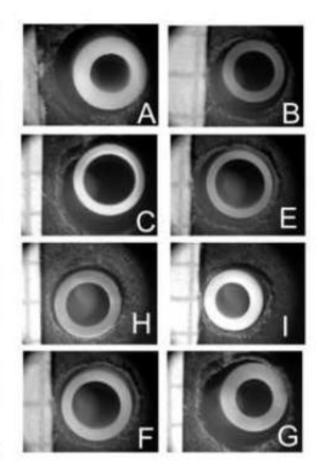
<sup>&</sup>lt;sup>2</sup> Department of Civil and Industrial Engineering, University of Pisa, Pisa - Italy

### **JOURNAL OF VASCULAR ACCESS**

# Experimental investigation on the mechanical behaviour of polyurethane PICCs after long term conservation in in vivo like conditions --Manuscript Draft--

Manuscript Number:	JVA-D-17-00083
Full Title:	Experimental investigation on the mechanical behaviour of polyurethane PICCs after long term conservation in in vivo like conditions
Short Title:	Mechanical Behaviour of PICCs in in vivo like conditions
Article Type:	Original Research Article
Section/Category:	Oncology
Keywords:	central venous catheters, indwelling catheters, polyurethane, mechanical properties, material degradation
Corresponding Author:	Francesca Di Puccio, Ph.D. Universita di Pisa Pisa, ITALY
Corresponding Author's Institution:	Universita di Pisa
First Author:	Francesca Di Puccio, Ph.D.
Order of Authors:	Francesca Di Puccio, Ph.D.
	Giuseppe Gallone
	Andrea Baù
	Emanuele Maria Calabrò
	Simona Mainardi

ID	Manufacturer	Model
A	Alfamed	MD 01 02282
В	Bard	6175118 Power picc
с	Cook	G12987 TurboFlo
E	Argon	384465 L-Cath
F	Vygon	1294.115 Lifecath PICC
G	BBraun	044 39002 Celsite PICC-Cel
н	AngioDynamics	12102603
1	HealthLine	A14H-05160



Eight 5 Fr single lumen catheters from as much different vendors were considered as samples. Several specimens were cut from each of them and kept in bath at 37°C for 1, 2, 3 and 6 months. Two fluids were used to simulate in vivo like conditions, i.e. ethanol and Ringer-Lactate solutions, the first one being chosen in order to reproduce a typical chemical environment of oncologic drugs. The test plan included swelling analyses, uniaxial tensile tests and Dynamical Mechanical Thermal Analysis.

## Results and Conclusions

Results show that all tested samples are chemically and mechanically stable in the studied conditions, in fact no significant weight variation was observed in all samples even after six months of immersion in Ethanol solution. Uniaxial tensile tests confirm such response. Curves obtained for each sample after different immersion durations in the two fluid solutions are very similar each other, particularly for strains lower than 10%.

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## Infatti...

Circa l'85% dei PICC attualmente venduti in USA (circa 3 milioni/anno) sono PICC power injectable\*, in poliuretano di terza generazione, e vengono usati comunemente per la infusione di chemioterapici in base alcolica.

(idem per i PORT power injectable con catetere in poliuretano)

\*Fonte: Bard Corp., USA

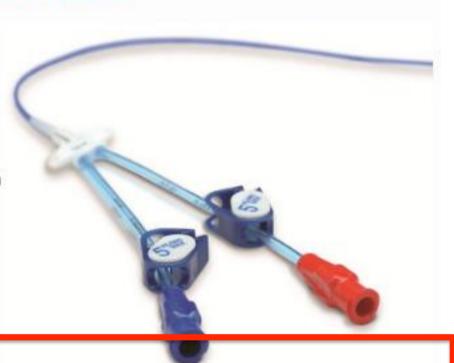
## The Morpheus Smart PICC

## Engineered for Life™

The Morpheus® SMART PICC provides clinicians with a comprehensive line of CT compatible PICC kits that offer True French size catheters with the shortest taper in the industry.

#### Best in Class Flow Rate

CT Rated and labeled for CT injection.



### All-Carbothane® catheter

The chemically resistant all-Carbothane catheter offers proven drug compatibility.

### Smart Taper™ Technology

The Smart Taper™ reverse taper technology is designed with the shortest taper in the industry.

### Highly Visible Material

Superior product visibility, complete with radiopaque markings with centimeter spacing provide increased visibility, easier catheter placement and tip confirmation.

### True French Sizing

True French size catheter means less catheter in the patient.



## **FEATURES**

## A Polyurethane PICC Designed Specifically for the Interventional Radiologist.

Poly RadPICC\* catheters combine the strength and versatility of polyurethane with high flow rates and small French sizes. A kink-resistant hub enhances catheter strength and increases patient comfort. Poly RadPICC\* catheters also feature excellent radiopacity.

### Polyurethane body

Provides strength, versatility and high flow rates in a small French size catheter

### Highly radiopaque catheter

Blend of barium and polyurethane provides high radiopacity while maintaining catheter strength

### Reverse taper hub

Gently plugs the insertion site and provides excellent kink resistance

### Longer extension legs

Promote easy application of occlusive dressing

### High durometer extension legs

Offer improved durability and greater resistance to alcohol















## products PRO-PICC® CT INJECTABLE CATHETERS

#### Pro-PICC®

Vascu-PICC®

Max Barrier Kits

Midline

Navigator® BioNavigation™ System

Pediatric Vascu-PICC®

### features & benefits

- · Catheters are approved for both CECT Injections and Infusion Therapy.
- Design allows for CT injections for diagnostic imaging at up to 5cc/sec at 300psi.
- · Thermosensitive, polyurethane material is both alcohol and iodine compatible.
- · Available in single, dual, and triple lumen configurations.
- · MRI compatible.

Features & Benefits

Ordering Info

Brochures

Product Video

**IFUs** 





## Pro-PICC® CT

Material: Polyurethane medcompnet.com/pro-picc

## Compatible Site Care Agents:

Chlorhexidine Gluconate 2% and 4%,
Betadine® Solution (10% Povidone Iodine),
70 / 30% Alcohol,
Hydrogen Peroxide,
< 0.057% Sodium Hypochlorite,
Antimicrobial Ointments and Creams (Mupirocin,
Polymyxin),
Silver Sulfadiazene Cream 1%

## Terza considerazione

Il rischio (REALE) di rottura da sollecitazioni meccaniche, legato alla fragilità del silicone, è assai più rilevante del rischio (TEORICO) di lesioni da danno chimico.

# La nostra esperienza

Nel 2012, sei episodi di rottura di Groshong PICC

tutti i cateteri erano usati con pompa
tutti e 6 I PICC erano usati con taxoli
Nessun episodio di rottura con PICC in PUR
II DH Oncologico decide di sospendere l'uso
di PICC Groshong per chemioterapia

## Quindi

Non vi è nessuna evidenza che i PICC in silicone abbiano alcun vantaggio o alcuna indicazione preferenziale rispetto ai PICC in poliuretano.

Vi sono altresì evidenze che l'utilizzo di PICC in silicone limita la performance del presidio e aumenta il rischio di complicanze meccaniche.

# Attenzione alla disinformazione interessata (travestita da 'linee guida'...)

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### GUIDELINES

# Adoption and application in Italy of the principal guidelines and international recommendations on venous access

Rosario SPINA <sup>1</sup>, Baudolino MUSSA <sup>2</sup>, Lara TOLLAPI <sup>3</sup>, Fabio CONTI <sup>4</sup>, Enrico CORTESI <sup>5</sup>, Roberto VERNA <sup>6</sup> \*

<sup>1</sup>Azienda Toscana Centro, Ospedale "San Giuseppe", Empoli, Italy; <sup>2</sup>University of Turin, Turin, Italy; <sup>3</sup>Pisa University Hospital, Pisa, Italy; <sup>4</sup>Department of Cardiology, Tor Vergata University Hospital, Rome, Italy; <sup>5</sup>Department of Radiological, Oncological, Anatomopathological Sciences, Sapienza University, Rome, Italy; <sup>6</sup>Department of Experimental Medicine, Sapienza University, Rome, Italy

\*Corresponding author: Roberto Verna, Department of Experimental Medicine, Sapienza University, Rome, Italy. E-mail: roberto.verna@uniroma1.it

# Attenzione alla disinformazione interessata (travestita da 'linee guida'...)

bloodstream and are therefore less likely to cause thrombosis. Among the new materials, the polyurethanes show advantages in terms of mechanical strength and resistance to chemical degradation, but they are still quite rigid; at the moment the softest material is silicone which has the least thrombogenic potential.<sup>8</sup>

Polyvinyl chloride (PVC) is one of the most widely used materials due to its lightness, strength and cost.9

When choosing the most appropriate device, it is also necessary to consider the potential interactions and incompatibilities between the material the device is made of and the drug to be infused: it is recommended to follow the indications stated by the drug's manufacturer. An example of this is the cancer drug cabazitaxel about which the summary of product characteristics (SPC) at point 6.2 ("Incompatibility") reads: "PVC infusion containers or polyurethane infusion sets must not be used for the preparation and administration of the infusion solution," or the alkylating antineoplastic agent busulfan which in the SPC at point 6.2-Incompatibility states: "Do not use polycarbonate syringes." As far as carmustine

that of the pacemaker (usually the left side) is recommended for CVC positioning. If you decide to place the catheter on the same side as the pacemaker, it is better to opt for a PICC. It is recommended that you evaluate the functionality partity of the pacemaker before inserting the CV

Indications

PIVs

A peripheral venous catheter should be placed with the help of visualization techniques (echography, infrared rays), especially if placement is proving difficult or repeated attempts at venipuncture have already been made.

Consider using extensions between the catheter and connector to reduce catheter manipulation.

Peripheral venous catheters should NOT be used to infuse irritant solutions, chemotherapies, continuous blister solutions, solutions for parenteral nutrition or solutions with high osmolarity (above 900 mOsm/L) or solutions

# Attenzione alla disinformazione interessata (travestita da 'linee guida'...)

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Data from the literature show that the PICC is usable in these patients for all disease stages. 86, 87 Direct puncture CVCs should be avoided due to the high risk of infection. Fully implantable devices are applicable only in patients with chronic pathology, while in acute patients they are contraindicated insofar as they are not easily removable in case of bacterial colonization.

Two-lumen devices should be preferred in order to allow simultaneous infusion of medications that are not compatible with each other. Devices with valves ensure a longer service life and are therefore to be preferred.

There are still no reliable clinical data on the usefulness of VADs with antibacterial treatment, but in patients who are candidates for treatment with high risk of aplasia, they are strongly recommended.<sup>13</sup>



sequence to reduce blood renux in the lumen; administer incompatible medications through separate catheter lumens. It is recommended to wash the catheter lumen with saline after infusing solutions for parenteral nutrition or solutions containing lipids, to prevent occlusion. The use of catheters equipped with an integrated valve that prevents endoluminal blood reflux proved to be superior in terms of complications, expressed as days of catheterization. Before use, carefully examine venous access devices and check that they are patent and working correctly.

In the case of no blood return during asnira-

192

## Parte seconda

# Ci sono evidenze per altri materiali dei PICC?

- PICC trattati con ioni argento
- PICC trattati con clorexidina
- PICC trattati con rifampicina-cloramfenicolo
- PICC trattati con endexo

## **Evolution of Surface Materials: PICC Lines**

Antimicrobial	Silicone	Polyurethane	Year
Chlorhexidine alone No Silver added unlike CICC Bonded to the catheter surface	No	Yes	2010

Antimicrobial	Silicone	Polyurethane	Year
Antimicrobial impregnated Minocycline & Rifampin First studied 1997 on CICC's	Yes	Yes	2012

	Endexo® Polymer	Year
Endexo® Polymer Part of the catheter material	Yes	2012

## PICC trattati con ioni argento

- Presenti sul mercato italiano
- Assenza di studi significativi, sia clinici che sperimentali
- Nessuna evidenza di efficacia nel ridurre il rischio infettivo o trombotico

## PICC trattati con clorexidina

- Presenti sul mercato italiano
- N.B.: tecnologia differente rispetto ai CICC trattati con CHG+Ag
- <u>Evidenze sperimentali</u> su possibile riduzione della adesività batterica e della formazione della guaina fibroblastica
- Evidenze cliniche controverse

2012

# An In Vivo Rabbit Model for the Evaluation of Antimicrobial Peripherally Inserted Central Catheter to Reduce Microbial Migration and Colonization as Compared to an Uncoated PICC

## Nicholas D. Allan, Kamna Giare-Patel, and Merle E. Olson 1,3

Sperimentale CHG-PICCs vs. uncoated

Correspondence should be addressed to Merle E. Olson, merle.olson@innovotech.ca

Received 9 January 2012; Accepted 6 May 2012

Academic Editor: Oreste Gualillo

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Infection is the leading complication associated with intravascular devices, and these infections develop when a catheter becomes colonized by microorganisms. To combat this issue, medical device manufacturers seek to provide healthcare facilities with antimicrobial medical devices to prevent or reduce the colonization. In order to adequately evaluate these devices, an *in vivo* model is required to accurately assess the performance of the antimicrobial devices in a clinical setting. The model presented herein was designed to provide a simulation of the subcutaneous tunnel environment to evaluate the ability of an antimicrobial peripherally inserted central catheter (PICC), coated with chlorhexidine based technology, to reduce microbial migration and colonization compared to an uncoated PICC. Three samples of control, uncoated PICCs and three samples of coated PICCs were surgically tunneled into the backs of female New Zealand White rabbits. The insertion sites were then challenged with *Staphylococcus aureus* at the time of implantation. Animals were evaluated out to thirty days and sacrificed. Complete *en bloc* dissection and evaluation of the catheter and surrounding tissue demonstrated that the chlorhexidine coated catheter was able to significantly reduce microbial colonization and prevent microbial migration as compared to the standard, un-treated catheter.

<sup>&</sup>lt;sup>1</sup> Innovotech Inc., Suite 101, 2011 94th Street, Edmonton, AB, Canada T6N 1H1

<sup>&</sup>lt;sup>2</sup> Research and Development Department, Teleflex Medical Incorporated, 2400 Bernville Road, Reading, PA 19605, USA

<sup>&</sup>lt;sup>3</sup> Department of Biomedical Engineering, University of Alberta, Edmonton, AB, Canada T6G 2V2



## 2015

# In Vivo Biocompatibility and In Vitro Efficacy of Antimicrobial Gendine-Coated Central Catheters

Mohamed A. Jamal, Ray Y. Hachem, Joel Rosenblatt, Mark J. McArthur, Edd Felix, Ying Jiang, Ramesh C. Tailor, Issam Raad

Department of Infectious Diseases, Infection Control and Employee Health, Department of Veterinary Medicine and Surgery, Institute for Applied Cancer Science, and Department of Radiation Physics, The University of Texas MD Anderson Cancer Center, Houston, Texas, USA

Antimicrobial peripherally inserted central catheters (PICCs) might reduce the incidence of central line-associated bloodstream infections (CLABSI). We tested the biocompatibility of a novel gendine-coated (combination of chlorhexidine [CHX] and gentian violet [GV]) PICC in a rabbit intravascular model and tested antimicrobial efficacy in comparison with commercially available minocycline/rifampin (M/R)- and CHX-treated PICCs in an in vitro biofilm colonization model. Gendine-coated and uncoated control PICCs were inserted in the jugular veins of rabbits for 4 days. Histopathological analysis was performed at the end of the 4-day period, and circulating levels of CHX and GV in the blood were measured at different time points using liquid chromatography-mass spectrometry. The antimicrobial efficacy of the PICCs was tested following simulated intravascular indwells of 24 h and 1 week against clinical isolates of methicillin-resistant Staphylococcus aureus, vancomycin-resistant enterococci, Pseudomonas aeruginosa, Escherichia coli, Acinetobacter baumannii, Enterobacter cloacae, Candida albicans, and Candida glabrata. Rabbits implanted with gendine-coated PICCs exhibited reduced levels of thrombosis and inflammation compared to those of the rabbits with uncoated controls. No GV was detected in blood samples over the entire study period, and trace concentrations of CHX were detected. The gendine-coated PICCs completely prevented the adherence of all pathogens from 24 h to 1 week ( $P \le 0.001$ ), while M/R-treated, CHX-treated, and control PICCs did not. Gendine-coated PICCs were highly effective in preventing biofilm formation of multidrug-resistant pathogenic bacteria and fungi. Gendine-coated PICCs were biocompatible in an intravascular setting. Further, the pharmacokinetic testing established that acute systemic exposures of CHX and GV from the gendine-coated catheters were well within safe levels.



## Improved Antibiotic-Impregnated Catheters with Extended-Spectrum Activity against Resistant Bacteria and Fungi

Issam Raad, Jamal A. Mohamed, Ruth A. Reitzel, Ying Jiang, Sammy Raad, Munirah Al Shuaibi, Anne-Marie Chaftari, and Ray Y. Hachem

Department of Infectious Diseases, Infection Control and Employee Health, The University of Texas M. D. Anderson Cancer Center, Houston, Texas, USA

Minocycline-rifampin-impregnated central venous catheters (M/R CVCs) have been shown to be efficacious in reducing catheter-related bloodstream infections (CRBSI) and inhibiting the biofilm adherence of resistant Gram-positive and Gramnegative pathogens, with the exception of Pseudomonas aeruginosa and Candida spp. To expand the spectrum of antimicrobial activity, a novel second-generation M/R catheter was developed by adding chlorhexidine (CHX-M/R). CVCs and peripherally inserted central catheters (PICCs) were impregnated with CHX-M/R and compared with first-generation M/R catheters, CHXsilver sulfadiazine-treated CVCs (CHX/SS-CVCs), chlorhexidine-treated PICCs, and uncoated catheters. A biofilm catheter colonization model was used to assess the efficacy of catheters against methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Enterococcus faecium (VRE), P. aeruginosa, Candida albicans, and Candida glabrata. CHX-M/Rimpregnated CVCs were the only antimicrobial catheters that completely inhibited the biofilm colonization of all resistant bacterial and fungal organisms tested at all time intervals, and they were significantly superior to uncoated catheters (all P values were ≤0.003). Furthermore, CHX-M/R-coated CVCs had a significantly more effective and prolonged (up to 3 weeks) antimicrobial activity against MRSA and P. aeruginosa than M/R, CHX/SS, and uncoated CVCs (P < 0.0001). Similarly, CHX-M/R-coated PICCs were also superior to M/R-coated and CHX-coated PICCs in preventing biofilms of MRSA, VRE, P. aeruginosa, and Candida species (P value = 0.003 for all). Our study shows that novel CHX-M/R-coated catheters have unique properties in completely inhibiting biofilm colonization of MRSA, VRE, P. aeruginosa, and fungi in a manner superior to that of M/R- and chlorhexidine-treated catheters.

Sperimentale – CHG+MR PICCs vs. CHG PICCs vs. MR PICCs vs. uncoated PICCs

# Chlorhexidine-coated peripherally inserted central catheters reduce fibroblastic sleeve formation in an in vivo ovine model

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1-7
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journals.sagepub.com/home/jva

2018

**S**SAGE

Sperimentale: CHG-PICCs vs. Endexo-PICCs vs. uncoated PICCs

Charles J Sylvia Jr<sup>1</sup>, Molly A Wagel<sup>2</sup>, Kamna Giare-Patel<sup>2</sup>, Taylor A Spangler<sup>3</sup>, Eugene M Breznock<sup>1</sup> and Nisha Gupta<sup>2</sup> Non statisticamente significativo

### Abstract

**Purpose:** This study compared an antimicrobial and anti-thrombogenic peripherally inserted central catheter treated with a chlorhexidine-based technology, a peripherally inserted central catheter with bulk distributed fluoro-oligomers, and a poly 2-methoxyethyl acrylate—based peripherally inserted central catheter to an untreated peripherally inserted central catheter (control) in an ovine model at 14 and 30 days post-implant.

Methods: One of four types of peripherally inserted central catheters was surgically implanted into the left jugular vein of each of 18 sheep for 14 or 30 days. Blood analysis consisted of complete blood counts, serum chemistries, and coagulation (fibrinogen, prothrombin time, and partial thromboplastin time) profiles. Sheep were sacrificed to examine the vein and thorax. Histological analysis was performed on serial catheter sections using standard microscopy on hematoxylin and eosin–stained tissues.

Results: All catheters developed fibroblastic sleeves at both 14 and 30 days. The chlorhexidine-peripherally inserted central catheter showed a 64% lower mean fibroblastic sleeve weight and a 66% shorter mean fibroblastic sleeve length compared to the untreated control at 14 days. By 30 days, compared to untreated control, the chlorhexidine-peripherally inserted central catheter showed 81% lower mean fibroblastic sleeve weight with 75% shorter mean fibroblastic sleeve length, the fluoro-oligomer-peripherally inserted central catheter showed 54% lower mean sheath weight with 40% shorter mean fibroblastic sleeve length, and the poly 2-methoxyethyl acrylate-peripherally inserted central catheter had 41% lower mean fibroblastic sleeve weight with 57% lower fibroblastic sleeve length.

Conclusion: Among the three anti-thrombogenic peripherally inserted central catheter technologies, the chlorhexidineperipherally inserted central catheter had the smallest fibroblastic sleeves, followed by the fluoro-oligomer-peripherally inserted central catheter, poly 2-methoxyethyl acrylate-peripherally inserted central catheter, and control peripherally inserted central catheter.



# The Influence of an Antimicrobial Peripherally Inserted Central Catheter on Central Line-Associated Bloodstream Infections in a Hospital Environment

Glenell S. Rutkoff, MSN, RN, CGRN
Chula Vista Medical Center, Chula Vista, CA



2014

Clinico Retrospettivo Riduzione CLABSI

### Abstract

Background: Federal agencies such as the Centers for Disease Control and Prevention have mandated reduction of hospitalacquired infections and recommended the use of antimicrobial catheters in clinical settings where central line-associated bloodstream infection (CLABSI) rates have remained high. The Infusion Nurses Society also recommends antimicrobial catheters for specific patient populations. At a California hospital, evidence-based infection prevention strategies for CLABSI prevention had been in effect for several years, but the CLABSI rate remained at an unacceptable level. For this reason, the effect of an antimicrobial peripherally inserted central catheter (PICC) on the incidence of CLABSI was studied.

Methods: A quasiexperimental design was used with concurrent data collection on patients in an intervention group who received an antimicrobial PICC. Retrospective data were collected for patients in a nonintervention group who received nonantimicrobial PICCs the previous year.

Results: The 257 patients in the nonintervention group experienced 8 CLABSIs with an infection rate of 4.18/1,000 line days. The 260 subjects in the intervention group experienced 1 CLABSI with an infection rate of 0.47/1,000 line days. The decrease in the number of infections per 1,000 line days for the intervention group was statistically significant.

Conclusions: The use of an antimicrobial PICC in conjunction with current infection prevention practices resulted in a statistically significant decrease in infection rate, which supports the recommendation for continued use of antimicrobial catheters. Treatment cost savings, which overcame the higher initial cost for the devices, were found to be an additional benefit of using antimicrobial catheters.

Keywords: antimicrobial catheter, central line-associated bloodstream infection, CLABSI, peripherally inserted central catheter, PICC

latantanas asharma

## Up for the Challenge: Eliminating Peripherally Inserted Central Catheter Infections in a Complex Patient Population



2014

Holly D. Tavianini, MSHSA, BSN, RN, CNRN

Vera Deacon, RN, CRNI®, VA-BC™

Judylee Negrete, RN, VA-BC™

Sharon Salapka, RN, VA-BC™

Lehigh Valley Health Network, Bethlehem, PA

Clinico
Non controllato
Riduzione CLABSI

### Abstract

Background: In response to Medicare reimbursement changes related to central line-associated blood stream infection (CLABSI) effective January 2011, a long-term acute care hospital implemented quality improvement measures to reduce these health care-associated infections. Improvements included alcohol-impregnated port protectors, chlorhexidine gluconate barrier dressings, and didactic/hands on training for care and maintenance. During 2010 the peripherally inserted central line (PICC) team at a neighboring Magnet hospital was asked to partner and develop strategies to further decrease CLABSI.

Methods: The PICC team evaluated the effects of an antimicrobial PICC device in an effort to further reduce the incidence of CLABSI. Upon initiation of the evaluation phase, a database was created to track infection/thrombus rate, insertion-related complications, dwell time, diagnosis, tip location, infusate, vein used, and catheter size. Data collection and reporting was managed by the PICC team.

Results: Across a 2-year period (July 2011-July 2013), 100 devices were inserted with a total of 1,705 line days without any reported CLABSI. The majority of patients received a 4.5F single lumen device (59%). Dwell time ranged from 1 to 57 days with an average of 17 days. To date, no CLABSIs related to this device have been reported at the long-term acute care hospital. Conclusions: Based on 100 insertions yielding no infections this new product appears to improve patient safety and quality of care. Relative to these results sole use of this product has become their institutional standard for long-term intravenous needs. Keywords: antimicrobial, bundle, CLABSI, long-term acute care hospital, peripherally inserted central catheter, vascular access



Contents lists available at ScienceDirect

## American Journal of Infection Control

journal homepage: www.ajicjournal.org

## Major article

A comparative evaluation of antimicrobial coated versus nonantimicrobial coated peripherally inserted central catheters on associated outcomes: A randomized controlled trial

Susan Storey PhD, RN <sup>a,\*</sup>, Jamie Brown MSN, RN <sup>b</sup>, Angela Foley MSN, RN <sup>b</sup>, Erica Newkirk MSN, RN <sup>c</sup>, Jan Powers PhD, RN <sup>d</sup>, Julie Barger BSN, RN <sup>b</sup>, Karen Paige MSEd, BSN, RN <sup>b</sup>

Clinico
Randomizzato
Nessun effetto

<sup>&</sup>lt;sup>a</sup> Indiana University School of Nursing, Indianapolis, IN

b Vincent Hospital, Indianapolis, IN

c Indiana University Hospital, Indianapolis, IN

d Parkview Health System, Fort Wayne, IN

## Antimicrobial versus Non-Antimicrobial PICC

- Only published RCT (2016) USA in Indiana
- Total patients = 167

Catheter	N=167 Patients	CLA-BSI Cases	VTE Cases
CHG PICC	80	2 (2.5%)	1 (1.1%)
Non-CHG PICC	87	1 (1.1%)	3 (3.4%)

"In this study, no difference was noted in CLABSI or VTE between patients who received the CHG or non-CHG PICC line. More patients with the CHG PICC line had post insertion bleeding requiring the application of a thrombogenic dressing and in some instances a pressure dressing. Additional RCTs with larger samples from multiple acute care hospitals are warranted to validate the findings of this study."

## PICC trattati con minociclina-cloramfenicolo

- Non in commercio in Italia
- Tecnologia analoga ai CICC con MR
- Sia in silicone che in poliuretano
- Evidenze cliniche promettenti

Burns. 2013 Jun;39(4):632-5. doi: 10.1016/j.burns.2012.08.017. Epub 2012 Sep 23.

## The impact of antibiotic impregnated PICC lines on the incidence of bacteremia in a regional burn center.

Armstrong SD1, Thomas W, Neaman KC, Ford RD, Paulson J.

Author information

#### **Abstract**

**INTRODUCTION:** Peripherally inserted central catheters (PICCs) have been used increasingly in burn patients who often have decreased intravascular volumes and obtaining intravascular access for resuscitative efforts can be difficult. A potentially serious complication is bloodstream infection. The purpose of our study is to examine the impact of antibiotic impregnated PICC lines on the bacteremia rate in a regional burn center.

**METHODS:** Consecutive patients admitted to the burn unit and receiving an antibiotic impregnated PICC line were included in the study. Baseline demographics and bacteremia rate was recorded. A retrospective chart review was then undertaken of the 30 consecutive patients admitted to the burn unit and receiving a PICC line prior to the study period.

**RESULTS:** Nineteen patients were enrolled over the two-year period. The bacteremia rate for the study group was 0% compared to the 50% bacteremia rate of the retrospective control group (p=<0.001).

**CONCLUSION:** Antibiotic impregnated PICC lines decrease the bacteremia rate in our burn population. This has potential benefits for both patient morbidity and mortality as well as potential cost savings for the healthcare system.

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PMID: 23010088 DOI: 10.1016/j.burns.2012.08.017

Clinico
Retrospettivo, non controllato
Riduzione CLABSI

J Vasc Interv Radiol. 2014 Mar;25(3):411-8. doi: 10.1016/j.jvir.2013.11.024.

## Long-term central venous access in pediatric patients at high risk: conventional versus antibioticimpregnated catheters.

Baskin KM<sup>1</sup>, Hunnicutt C<sup>2</sup>, Beck ME<sup>3</sup>, Cohen ED<sup>4</sup>, Crowley JJ<sup>2</sup>, Fitz CR<sup>2</sup>.

Author information

2014

#### **Abstract**

**PURPOSE:** To study selective use of antibiotic-impregnated catheters in children at increased risk of venous catheter-related infections (CRIs).

MATERIALS AND METHODS: From December 2008 to June 2009, 428 peripherally inserted central catheters (PICCs) were placed by the interventional radiology service of a large metropolitan children's hospital. This retrospective study analyzed demographic and outcome data for the 125 patients in this group at high risk for venous CRI. Patients at high risk were those with active systemic infection, previous complicated central venous access, intensive care unit (ICU) admission, intestinal failure, transplantation, complex congenital heart disease, or renal failure. Patients (age, 7.6 y  $\pm$  7.0; 73 male and 52 female) received a conventional or antibiotic-impregnated PICC, with 17 receiving more than one catheter.

**RESULTS:** Of the 146 of 428 qualifying patient encounters (34%), 53 patients received an antibiotic-impregnated PICC and 93 received a conventional PICC, representing 5,080 total catheter-days (CDs). The rates of CRIs per 1,000 CDs, including catheter exit site infections and catheter-related bloodstream infections, were 0.86 for antibiotic-impregnated PICCs and 5.5 for conventional PICCs (P = .036). A propensity-based model predicts 15-fold greater infection-free survival over the lifetime of the catheter in patients who receive an antibiotic-impregnated PICC (P < .001). Antibiotic-impregnated PICC recipients with active infection or ICU admission at the time of insertion had no catheter-associated infections, compared with 3.42 and 9.46 infections per 1,000 CDs, respectively, for patients who received conventional PICCs. Patients with intestinal failure had 1.49 and 10 infections per 1,000 CDs with antibiotic-impregnated versus conventional PICCs, respectively.

**CONCLUSIONS:** Antibiotic-impregnated long-term PICCs significantly improve infection-free catheter survival in pediatric patients at high risk.

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Clinico – pediatrico Retrospettivo Riduzione infezioni EI SEVIER

Contents lists available at ScienceDirect

## American Journal of Infection Control

journal homepage: www.ajicjournal.org



## Brief reports

The influence of using antibiotic-coated peripherally inserted central catheters on decreasing the risk of central line-associated bloodstream infections

2016

Ammar Yousif MD <sup>a</sup>, Anne-Marie Chaftari MD <sup>a</sup>, Majd Michael MD <sup>a</sup>, Mary Jordan MD <sup>a</sup>, Zainab Al Hamal MD <sup>a</sup>, Alawami Hussain MD <sup>a</sup>, Natividad Elizabeth RN <sup>b</sup>, Ying Jiang MS <sup>a</sup>, Ray Hachem MD <sup>a</sup>, Issam Raad MD <sup>a</sup>

Key Words: Central venous catheters Antimicrobial catheters Bacteremia Minocycline Rifampin The use of peripherally inserted central catheters (PICCs) has increased over the past few years due to their less serious insertion complications. The purpose of the present study was to determine whether patients receiving PICCs impregnated with minocycline and rifampin had a lower rate of CLABSI compared with a concurrent control group of patients receiving uncoated PICCs.

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## Clinico – prospettico – non randomizzato

Department of Infectious Diseases, Infection Control and Employee Health, The University of Texas MD Anderson Cancer Center, Houston, TX

<sup>&</sup>lt;sup>b</sup> Department of Infusion Therapy, The University of Texas MD Anderson Cancer Center, Houston, TX

## Antimicrobial versus Non-Antimicrobial PICC

- Prospective observation MD Anderson
- Total patients =159

Catheter	N=167 Patients	CLA-BSI Cases
Non coated	65	5 (1.7/1,000 catheter days)
Minocycline Rifampin Coated	94	0

In the present study, we demonstrated that use of conventional uncoated PICCs in cancer patients, particularly those with hematologic malignancies, was associated with a relatively high rate of CLABSI of 1.7 per 1,000 catheter-days.

Yousif A: (2016) AJIC 44: 1037-1040

## Peripherally inserted central catheter-associated bloodstream infection: Risk factors and the role of antibiotic-impregnated catheters for prevention.

Kagan E<sup>1</sup>, Salgado CD<sup>2</sup>, Banks AL<sup>2</sup>, Marculescu CE<sup>2</sup>, Cantey JR<sup>2</sup>.

Author information

2018

#### **Abstract**

**BACKGROUND:** Antimicrobial-impregnated (AIP) peripherally inserted central catheters (PICCs) may lower risk of central line-associated bloodstream infection (CLABSI) compared with nonantimicrobial-impregnated (NAIP) catheters. We sought to assess risk factors for CLABSI with a focus on the effect of AIP PICCs.

**METHODS:** CLABSI rate was determined among patients who received PICCs from July 2009 through June 2012 using a retrospective study design. A nested case-control study matched for operators (interventional radiology [IR], infectious diseases [IDs], and the nurse venous access team [VAT]) was conducted to assess risks for PICC CLABSI.

**RESULTS:** Eighty-nine PICC CLABSIs (1.66%) occurred among 5,372 PICC placements a mean of 32 days after placement. Higher infection risk (1.75) was observed for IR-placed PICCs compared with ID-placed PICCs (P=.02). In addition, higher infection risk (4.22) was observed for IR-placed PICCS compared with VAT-placed PICCs (P=.0008). IR-placed NAIP catheters, as indicated by multivariate analysis, revealed a 5.45-fold greater CLABSI risk compared with AIP catheters (P < .0005). Other risk factors included chemotherapy, placement of a tunneled catheter, leukemia, and AIDS.

**CONCLUSIONS:** PICC CLABSIs were highest among patients receiving NAIP catheters in this large study. Highest risk occurred with placement of a tunneled catheter, AIDS, leukemia, and if the indication for PICC was chemotherapy. Our study suggests that the AIP PICC should be considered in all patients receiving PICCs.

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KEYWORDS: Bloodstream infection; Central line-associated bloodstream infection; Peripherally inserted central catheter

PMID: 30180989 DOI: 10.1016/j.ajic.2018.07.006

Clinico
Retrospettivo
Riduzione CLABSI

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## Major Article

Are antimicrobial peripherally inserted central catheters associated with reduction in central line-associated bloodstream infection? A systematic review and meta-analysis



Rachel D. Kramer BS <sup>a,\*</sup>, Mary A.M. Rogers PhD <sup>b,c</sup>, Marisa Conte MLIS <sup>d</sup>, Jason Mann MSA <sup>b</sup>, Sanjay Saint MD, MPH <sup>b,c</sup>, Vineet Chopra MD, MSc <sup>b,c</sup>

<sup>&</sup>lt;sup>a</sup> University of Michigan School of Medicine, Ann Arbor, MI

b The Patient Safety Enhancement Program and Center for Clinical Management Research, VA Ann Arbor Healthcare System, Ann Arbor, MI

<sup>&</sup>lt;sup>c</sup> Division of General Internal Medicine, Department of Medicine, University of Michigan School of Medicine, Ann Arbor, MI

d Taubman Health Science Library, University of Michigan School of Medicine, Ann Arbor, MI

## Review/Meta-analisi

- 5 studi con MR-PICCs
- 3 studi con CHG-PICCs

**Table 1**General study characteristics

Author (year)	N	Study design (method)	Operator inserting PICC	Study population	Coating type
Armstrong et al (2013) <sup>18</sup>	49	Pre-post design; prospective (study) retrospective (controls)	IR	Adult burn patients (high risk)	MR
Baskin et al (2014) <sup>19</sup>	146	Nonrandomized controlled trial	IR	Pediatric patients (high risk)	MR
Kagan et al (2012/2014) <sup>20,21</sup>	5,372	Retrospective cohort study	Multiple Providers	Adult medical or surgical patients with cancer or infection (high risk)	MR
Rutkoff et al (2014) <sup>22</sup>	517	Pre-post design; prospective (study) retrospective (controls)	Nurse PICC team	Adult hospitalized patients (average risk)	CHG
Stenz et al (2013) <sup>23</sup>	6,031	Pre-post design; retrospective (study and controls)	NR	Adult hospitalized patients (average risk)	MR
Storey et al (2016) <sup>24</sup>	167	Randomized controlled trial	PICC team	Adult cardiothoracic, ICU, and oncology (high risk)	CHG
Tavianini et al (2014) <sup>25</sup>	100	Pre-Post design; Prospective (study) Retrospective (controls)	Nurse PICC Team	Adult long-term acute care hospital (high risk)	CHG
Yousif et al (2016) <sup>26</sup>	159	Nonrandomized controlled trial	NR	Adult cancer patients (high risk)	MR

## N.B. unico randomizzato è Storey (studio negativo)

**Background:** Antimicrobial peripherally inserted central catheters (PICCs) may reduce the risk of central line-associated bloodstream infection (CLABSI). However, data regarding efficacy are limited. We aimed to evaluate whether antimicrobial PICCs are associated with CLABSI reduction.

**Methods:** MEDLINE, EMBASE, CINHAL, and Web of Science were searched from inception to July 2016; conference proceedings were searched to identify additional studies. Study selection and data extraction were performed independently by 2 authors.

**Results:** Of 597 citations identified, 8 studies involving 12,879 patients met eligibility criteria. Studies included adult and pediatric patients from intensive care, long-term care, and general ward settings. The incidence of CLABSI in patients with antimicrobial PICCs was 0.2% (95% confidence interval [CI], 0.0%-0.5%), and the incidence among nonantimicrobial catheters was 5.3% (95% CI, 2.6%-8.8%). Compared with noncoated PICCs, antimicrobial PICCs were associated with a significant reduction in CLABSI (relative risk [RR], 0.29; 95% CI, 0.10-0.78). Statistical heterogeneity ( $I^2$ , 71.6%; T2 = 1.07) was resolved by publication type, with peer-reviewed articles showing greater reduction in CLABSI (RR, 0.21; 95% CI, 0.06-0.74). Twenty-six patients (95% CI, 21-75) need to be treated with antimicrobial PICCs to prevent 1 CLABSI. Studies of adults at greater baseline risk of CLABSI experienced greater reduction in CLABSI (RR, 0.20; P = .003).

**Conclusions:** Available evidence suggests that antimicrobial PICCs may reduce CLABSI, especially in high-risk subgroups. Randomized trials are needed to assess efficacy across patient populations.

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'....antimicrobial PICCs may reduce CLABSI...'
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"...RCTs are needed..."

## PICC trattati con endexo

- Tecnologia nuova
- Evidenze sperimentali sulla ridotta adesività di piastrine e materiale ematico
- Molti abstracts, ma soltanto due studi clinici
- Evidenze cliniche promettenti in termini di efficacia
- Dubbi sulla costo-efficacia

#### THE BIOFLO TECHNOLOGY

The BioFlo technology's thromboresistant character is achieved by intimately combining the Endexo polymer with the base Carbothane polymer via thermoplastic extrusion processes. Unlike coatings that are superficial and impregnated agents that are transient, the BioFlo technology is an integral, non-eluting polymer technology that imparts thromboresistant properties to the indwelling catheter (Figure 2).

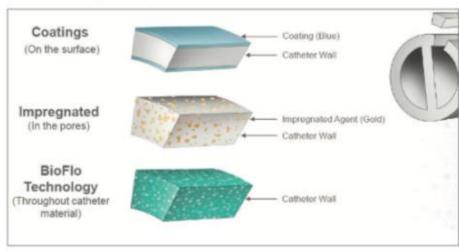


Figure 2. Comparison of BioFlo to Other Technologies

'...resistant to the accumulation of blood components...'

'....less thrombus accumulation on its surface...'



# FEATURES BioFlo Endexo Technology



#### **BENEFITS**

- Provides a catheter material that is more resistant to the accumulation of blood components. In-vitro studies show an 87% reduction in thrombus accumulation on catheter surfaces, when compared to other commonlyused PICCs, reducing the risk of thrombosis and Occlusion.
- Unlike other technologies that are superficial and/or transient, like coatings and or impregnations, the BioFlo material is designed to be both integral and non-eluting.

## **Abstracts**

- 1) Kednapa Thavorn (Ottawa Hospital) "A cost effectiveness analysis of BioFlo compared to Power PICC Solo peripherally inserted central catheters: The Ottawa Hospital Evaluation" Abstract 0-23
  - Independent retrospective study demonstrating that Power PICC Solo was 51% more likely to become occluded and 67% more likely to require cathflo than BioFlo with PASV technology
  - The average cost per picc based on management of occlusions was \$40.07 more for Power PICC Solo as compared to BioFlo
  - · Independent oral abstract presentation by Sheryl McDiarmid
  - · Publication pending- date TBD
- 2) Sheryl McDiarmid (Ottawa Hospital) "Venous Thrombotic Events Associated with Implanted Vascular Access Devices in Oncology Patients: A prospective cohort study" Abstract P 134
  - Prospective investigator-initiated study (supported partially by Angio)
  - · Catheter-related DVT rate of 1.29%
  - · Improved catheter-related DVT rate from previous, similar study with BardPort
  - High patient satisfaction
  - · Poster presentation
  - · Publication in progress

## **Abstracts**

- 3) Jane Pain (Royal Free London) "Reducing peripherally inserted central catheter related upper extremity deep vein thrombosis (UEDVT) and occlusions a retrospective case controlled study" Abstract P 140
  - Independent retrospective audit demonstrating a reduction in thrombolytic usage of 95% and a reduction of UEDVT of 66.7% with BioFlo with PASV technology compared to clamped, polyurethane PICC
  - Independent poster presentation and commercial symposium podium presentation
  - Additional economic analysis presented in commercial event demonstrating a cost savings in management of complications with BioFlo with PASV technology
  - · Independent publication anticipated
- 4) Liz Simcock (University College London) "Reduced Incidence of Clinically Evident PICC-Related DVT in Sarcoma Patients" Abstract P 151
  - · Independent retrospective audit comparing UEDVT rates with BioFlo with PASV technology vs. Xcela PICC
  - · Reduction of UEDVT rates from 13% to 6% in this patient population
  - · Other changes in practice were cited as potential variables in improvement
  - · Independent poster presentation and commercial symposium presentation
  - Publication plans TBD

# Outcomes in a nurse-led peripherally inserted central catheter program: a retrospective cohort study

2017

Sheryl McDiarmid RN MBA, Nicholas Scrivens BSc, Marc Carrier MD, Elham Sabri MSc, Baldwin Toye MD, Lothar Huebsch MD, Dean Fergusson PhD

#### **Abstract**

#### Clinico – retrospettivo – non controllato

**Background:** Peripherally inserted central catheters (PICCs) provide enormous benefit to patients. However, recent publications have highlighted relatively high PICC-associated complication rates. We report on patient and device outcomes from a nurse-led program.

**Methods:** We performed a retrospective analysis of a prospective cohort of consecutive patients undergoing PICC insertion at The Ottawa Hospital between Jan. 1, 2013 and Dec. 31, 2014. Of the 8314 BioFlo PASV PICCs inserted, we randomly selected a sample of 700 and obtained a complete data set for 656. We measured the cumulative incidence of major complications (catheter-related bloodstream infections and deep vein thrombosis) and use of a thrombolytic to alleviate occlusions.

**Results:** The total number of catheter days was 58 486, and the median dwell time 45 days. We observed 4 cases of catheter-related bloodstream infection (0.6% [95% CI 0.17%–1.55%]) (0.07/1000 catheter days). Ten patients (1.5% [95% CI 0.83%–2.78%]) (0.17/1000 catheter days) had catheter-related deep venous thrombosis. At least 1 dose of thrombolytic was required in 75 catheters (11.4% [95% CI 8.61%–13.39]), 31 (7.1%) of the 436 single-lumen catheters and 113 (25.7%) of the 440 lumina of dual-lumen catheters (p < 0.001).

Interpretation: We attribute our low rates of major complications to a nurse-led expert insertion team, standardized care and maintenance protocols, high insertion volumes, novel catheter material and continuous quality-improvement initiatives that are implemented and evaluated regularly. We conclude that the considerable benefits PICCs provide to patients are attained with a low risk of major complications.

#### How Does Your PICCOMPARE? A Pilot Randomized Controlled Trial Comparing Various PICC Materials in Pediatrics.

Kleidon T<sup>1,2</sup>, Ullman AJ<sup>2,3</sup>, Zhang L<sup>2</sup>, Mihala G<sup>2,4,5</sup>, Chaseling B<sup>6,7</sup>, Schoutrop J<sup>6,7</sup>, Rickard CM<sup>2,3</sup>.

Author information

2018

#### **Abstract**

BACKGROUND: Despite the popularity of peripherally inserted central catheters (PICCs), recent literature highlights their potential injurious complications. Innovative PICC materials have been developed to prevent thrombosis and infection formation (Endexo®) and antireflux valves to prevent occlusion (pressure-activated safety valve®). No large randomized controlled trial has assessed these technologies. Our primary aim was to evaluate the feasibility of a large randomized controlled efficacy trial of PICC materials and design to reduce PICC complication in pediatrics.

METHODS: A randomized controlled feasibility trial was undertaken at the Lady Cilento Children's Hospital in South Brisbane, Australia, between March 2016 and November 2016. Consecutive recruitment of 150 pediatric participants were randomly assigned to receive either (1) polyurethane PICC with a clamp or (2) BioFlo® PICC (AngioDynamics Inc, Queensbury, NY). Primary outcomes were trial feasibility, including PICC failure (thrombosis, occlusion, infection, breakage, or dislodgement). Secondary outcomes were PICC complications during use.

**RESULTS:** Protocol feasibility was established, including staff and patient acceptability, timely recruitment, no missing primary outcome data, and 0% attrition. PICC failure was 22% (16 of 74, standard care) and 11% (8 of 72, BioFlo®) corresponding to 12.6 and 7.3 failures per 1000 hours (risk ratio 0.58; 95% confidence interval, 0.21-1.43; P = .172). PICC failures were primarily due to thrombosis (standard care 7% versus BioFlo® 3%) and complete occlusion (standard care 7% versus BioFlo® 1%). No blood stream infections occurred. Significantly fewer patients with BioFlo® had PICC complications during use (15% vs 34%; P = .009).

**CONCLUSIONS:** BioFlo® PICCs appear potentially safer for pediatrics than traditional standard care PICCs with a clamp. Further research is required to definitively identify clinical, cost-effective methods to prevent PICC failure and improve reliability.

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Clinico – randomizzato

Effetto su occlusione e su trombosi

# A Cost Effectiveness Analysis of Bioflo Compared to PowerPICC Solo Peripherally Inserted Central Catheters: The Ottawa Hospital Evaluation

K Thavorn<sup>1,2</sup>, S Van Katwyk<sup>1,2</sup>, M Carrier <sup>1,2,3</sup> S McDiarmid, <sup>1,2</sup>



<sup>1</sup>Ottawa Hospital Research Institute, <sup>2</sup>The Ottawa Hospital, <sup>3</sup>University of Ottawa

#### Results: unadjusted costs and # of complications



	Variable	BioFP (N=656)	PPS (N=2,504)	Mean difference (95% CI)
Total hospital costs, mean (SD)		\$237 (\$238)	\$281 (\$305)	\$43.66 (\$18.52, \$68.80)
-	PICC unit cost, mean (SD)	\$176 (\$12)	\$176 (\$5)	\$0.04 (-\$0.67, \$0.59)
_	PICC insertion and management cost, mean (SD)	\$28 (\$85)	\$52 (\$145)	\$24.05 (\$12.31, \$35.79)
-	DVT cost per case, mean (SD)	\$33 (\$211)	\$53 (\$264)	\$19.61 (\$2.21, \$41.43)
Number of Pts. experiencing any complications, mean (SD)		0.42 (1.20)	0.71 (1.78)	0.28 (0.13, 0.43)
-	Number of Pts. experiencing occlusions, mean (SD)	0.40 (1.17)	0.67 (1.86)	0.27 (0.12, 0.42)
_	Number of Pts. experiencing DVT, mean (SD)	0.02 (0.15)	0.04 (0.19)	0.01 (0.00, 0.03)



Anomalia: confronto tra due PICC entrambi egualmente molto costosi (power PICC Solo e BioFlo)

## PICC con Endexo

- Probabile efficacia
- Considerando l'elevato costo del dispositivo, la costo-efficacia è ancora dubbia
- N.B.: la mortalità da occlusione del PICC e da trombosi venosa da PICC è praticamente ZERO
  - Entrambe le complicanze sono 'low cost' se paragonate alle CRBSI

# Conclusioni

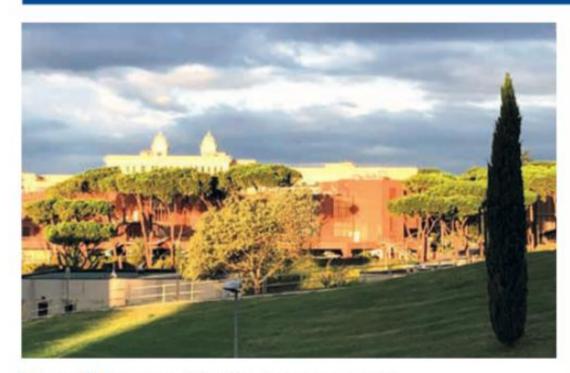
- Unica certezza: non utilizzare PICC in silicone, per minimizzare le complicanze meccaniche
- Possibilità di ridurre le <u>infezioni</u>: probabilmente legata più alla gestione che al materiale
- Possibilità di ridurre le <u>trombosi</u>: probabilmente legata più alla tecnica di impianto che al materiale
- Riduzione guaina fibroblastica: è utile?
- N.B.: Efficacia non significa costo-efficacia....



#### PRIMO CONVEGNO NAZIONALE

# **GAVePed**

Roma, 1 - 2 marzo 2019



Venerdì 1 marzo Corsi precongressuali Sabato 2 marzo Primo Convegno Nazionale GAVePed







# Grazie dell'attenzione

www.gavecelt.info

mauropittiruti@me.com

