GAVeCeLT
Gli Accessi Venosi Centrali a Lungo Termine

Ha ancora senso utilizzare cateteri in silicone valvolati?

Mauro Pittiruti

Cateteri in silicone valvolati?

Sì: parliamo dei **Groshong** !!!

Una famiglia di cateteri:

- Groshong PICC
- Groshong Midline
- Cateteri Groshong tunnellizzati cuffiati
- Groshong port

Cateteri Groshong

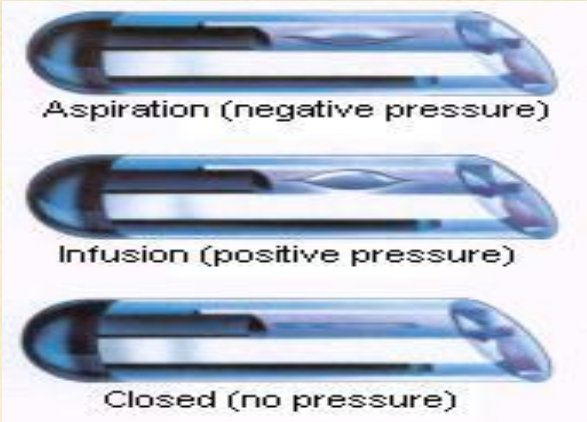
1) Prima caratteristica: silicone trasparente, non commisto a sali di bario – la radio-opacità è garantita da una striscia contenente bario + una punta contenente tungsteno

2) Seconda caratteristica: punta chiusa con valvola (valvola 'a fessura' a tre posizioni)

Brevetto del 1980: LeRoy E Groshong MD.

Dr. Groshong

- Surgical oncologist Portland Oregon USA
- Catheter Technology Corporation (1985)



Groshong distal valve

- Originally on a tunneled catheter
- Marketed as a PICC line by Davol (owned by CR Bard) in the 1990's
- First distal 3 way valve / closed tip
- Manufactured in silicone
- Dual (5F) and single lumen (4F & 5 F)

https://www.google.com/patents/US4431426

Razionale del silicone trasparente

- Maggiore biocompatibilità
- Minor rischio trombotico
- Minor rischio infettivo
- Buona resistenza
- Maggiore compatibilità con i farmaci a base alcolica

Razionale della punta valvolata

- Riduzione del rischio di ostruzione
- Miglior mantenimento della pervietà
- Non necessaria la eparinizzazione
- Minor rischio di embolia gassosa

Cosa c’è di vero?

Cosa c'è di vero?

NULLA

Il silicone non comporta minor rischio infettivo

Rischio infettivo ?

Rischio di infezione

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)

Rischio di infezione

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

(effeto del materiale o del tipo di valvola ?)

CCT valvolati vs. non valvolati

Fratino 2002

Studio prospettico su due tipi di CCT (51 Broviac vs. 41 Groshong) in pazienti pediatrici

Nessuna differenza in termini di complicanze meccaniche o di complicanze infettive

Rischio di infezione

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 CR-infections.[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

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

Rischio di infezione

ESPEN 2009

Clinical Nutrition 28 (2009) 365–377

Contents lists available at ScienceDirect

Clinical Nutrition

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

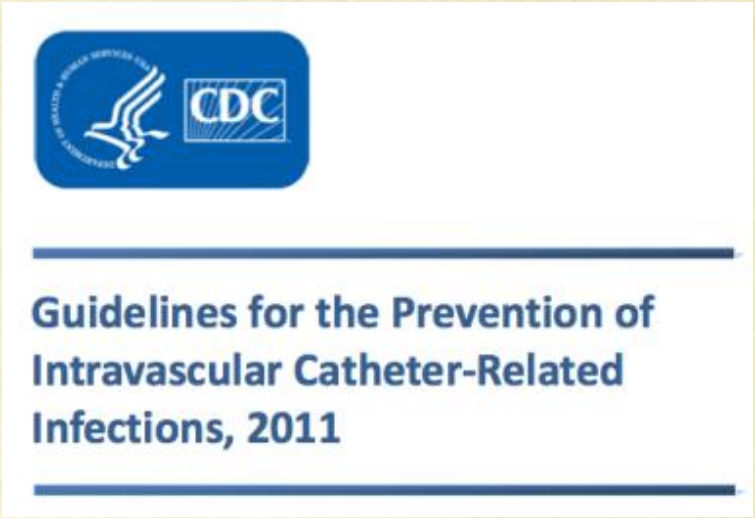
ESPEN Guidelines on Parenteral Nutrition: Central Venous Catheters (access, care, diagnosis and therapy of complications)

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

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 medium-term) or silicone (medium-term and long-term); no specific recommendation for clinical practice is made.

Rischio di infezione

CDC 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].

Rischio infezione

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

JVA
ISSN 1129-7298

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

[1] General and Thoracic Surgery Unit, Department of Surgery, Bambino Gesù Children's Hospital, IRCCS, Rome - Italy
[2] Pediatric Oncology Unit, Vito Fazzi Hospital, Lecce - Italy
[3] Department of Surgery, "Agostino Gemelli" Catholic University, Rome - Italy
[4] Pediatric Hematology and Oncology Unit, Department of Pediatrics, Azienda Ospedaliero-Universitaria di Parma, Parma - Italy
[5] Pediatric Hematology and Oncology, Pediatric Clinic, Azienda Ospedaliero-Universitaria Policlinico, Bari - Italy
[6] Thrombosis and Hemostasis Unit, Giannina Gaslini's Children Hospital, Genova - Italy
[7] Pediatric Hematology Oncology, Azienda Ospedaliera Universitaria Integrata, Verona - Italy
[8] Pediatric Surgery Unit, University Policlinic Hospital, Modena - Italy
[9] 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).

JVA
ISSN 1129-7298

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 both lines are shown.

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)

Rischio trombotico ?

Rischio di trombosi

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

Rischio di trombosi

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

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

Rischio di trombosi

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)

Rischio di trombosi

BCSH 2007

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

L. BISHOP*, L. DOUGHERTY†, A. BODENHAM‡, J. MANSI*, P. CROWE§, C. KIBBLER¶, M. SHANNON**, J. TRELEAVEN†

- 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 !)

Rischio di trombosi

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[1], M. PITTIRUTI[2], C. CAMPISI[3], ON BEHALF OF THE GAVeCeLT* COMMITTEE FOR THE CONSENSUS PAPER ON 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. Triple-lumen 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.

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[1], M. PITTIRUTI[2], C. CAMPISI[3], ON BEHALF OF THE GAVeCeLT COMMITTEE FOR THE CONSENSUS PAPER ON CATHETER-RELATED CENTRAL VENOUS THROMBOSIS*

[1]Dept. of Surgery, European Institute of Oncology, Milan - Italy
[2]Dept. of Surgery, Gemelli Hospital, Catholic University of Sacred Heart and IASI - CNR/Shock Pathophysiology Section, Rome
[3]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.

Curelaru I, Gustavsson B, Hansson AH, Linder LE, Stenqvist O, Wojciechowski J. Material thrombogenicity in central venous catheterization II: a comparison between plain silicone elastomer, and plain polyethylene, long, antebrachial catheters. Acta Anaesthesiol Scand 1983; 27: 158-64.

Linder LE, Curelaru I, Gustavsson B, Hansson HA, Stenqvist O, Wojciechowski J. Material thrombogenicity in central venous catheterization: a comparison between soft, antebrachial catheters of silicone elastomer and polyurethane. JPEN J Parenter Enteral Nutr 1984; 8: 399-406.

Borow M, Crowley JG. Evaluation of central venous catheter thrombogenicity. Acta Anaesthesiol Scand Suppl 1985; 81: 59-64.

Cervera M, Dolz M, Herraez JV, Belda R. Evaluation of the elastic behaviour of central venous PVC, polyurethane and silicone catheters. Phys Med Biol 1989; 34: 177-83.

Beenen L, van Leusen R, Deenik B, Bosch FH. The incidence of subclavian vein stenosis using silicone catheters for hemodialysis. Artif Organs 1994; 18: 289-92.

Reynolds JV, Walsh K, Ruigrok J, Hyland JM. Randomised comparison of silicone versus Teflon cannulas for peripheral intravenous nutrition. Ann R Coll Surg Engl 1995; 77 :447-9.

Rischio di trombosi

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

Nessuna raccomandazione a proposito del materiale

Clinical Nutrition 28 (2009) 365–377

Contents lists available at ScienceDirect

Clinical Nutrition

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

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

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

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

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).

Rischio di trombosi

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

Rischio di trombosi

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

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†††††††[1]
and H. BOUNAMEAUX‡‡‡‡‡‡[1]

Nessuna raccomandazione a proposito del materiale
Nessuna differenza tra valvolati vs. non valvolati

Rischio trombosi

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

JVA
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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

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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 both lines are shown.

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.

J Vasc Access 2012; 13 (3): 393-396
DOI: 10.5301/jva.5000065

Intra-cavitary ECG is an effective method for correct positioning of the tip of tunneled Groshong catheters

Giuseppe Capozzoli, Gino Accinelli, Loris Fabbro, Roberta Pedrazzoli, Franco Auricchio

Anesthesia and Intensive Care Unit, Bolzano Central Hospital - Italy

ABSTRACT

Background: **Intra-cavitary electrocardiography (ECG) is a well-known method for correct positioning of the tip of central venous catheters (CVC). A significant increase in the P wave, as registered by the intra-cavitary electrode, signals the entrance of the catheter into the right atrium.**

Methods: **In this prospective observational study, 155 consecutive oncologic patients were enrolled for cannulation of the right or left internal jugular vein for insertion of a tunneled Groshong catheter. In 150 patients the tip was positioned by means of intracavitary ECG. Five patients with atrial fibrillation (N=4) or pacemaker in place (N=1) were excluded from the study. As the P-wave amplitude began to increase, the catheter was secured in that position and the insertion depth was registered.**

Results: **Intra-cavitary ECG was always apt to detect the increase in the P wave. On the post-operative chest x-ray all Groshong catheters except two were in the correct position.**

Conclusions: **The need for chest x-ray or fluoroscopy may be virtually eliminated by using the ECG technique.**

2 casi di immediata 'tip migration' subito dopo l'impianto

In two cases, after an apparently uneventful intravascular ECG, the post-operative chest x-ray indicated that the catheter was malpositioned (tip in the left brachio-cephalic vein). No significant cardiac arrhythmias caused by catheter positioning or intravascular electrocardiographic registration were recorded.

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.

Attenzione a lavori ‘fasulli’

Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm

Jasmin D. Busch, MD, Maren Vens, PhD, Catherine Mahler, MD, Jochen Herrmann, MD, Gerhard Adam, MD, and Harald Ittrich, MD

Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm

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Apparentemente, il lavoro dimostra che il PICC-port in poliuretano ha più rischio trombotico del PICC-port in silicone.

Però:

Hanno confrontato **PICC port in silicone da 5Fr** con **PICC port in poliuretano da 6Fr**. Ovviamente l'incidenza di trombosi è lievemente più alta nel gruppo in poliuretano, visto che sono di calibro maggiore.

Per di più, il confronto è non randomizzato, anzi tutto il lavoro è **retrospettivo**.

Dal punto di vista della terminologia, è un dramma, a partire da una classificazione delle complicanze trombotiche che include anche le occlusioni da coagulo (!).

E non finisce qui...

J Vasc Int Rad 2017

Complication Rates Observed in Silicone and Polyurethane Catheters of Totally Implanted Central Venous Access Devices Implanted in the Upper Arm

Jasmin D. Busch, MD, Maren Vens, PhD, Catherine Mahler, MD, Jochen Herrmann, MD, Gerhard Adam, MD, and Harald Ittrich, MD

- *'…contrast venography-guided vein access was achieved…'* **??**
- *'…fluoroscopic confirmation of correct catheter tip positioning at the cavoatrial junction (defined as 2 vertebral bodies below the carina)…'* **??**

Il silicone 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

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

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[1], T. MICHELI[1], B. VINCENZI[2], C. CAMPISI[3]

[1] Rep. Analgesic and Palliative Therapy Unit, ASL Frosinone, Frosinone - Italy
[2] Biomedical Campus, Rome - Italy
[3] 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

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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.

JVA
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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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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 M[1].

⊕ 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.

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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 both lines are shown.

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.

J Vasc Access 2014; 15 (5): 391-395
DOI: 10.5301/jva.5000261

ORIGINAL ARTICLE

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

Paolo Balsorano[1], Giulia Galducci[1], Ilaria De Fanti[1], Samuel Kagan Evans[2], Angelo Raffaele De Gaudio[1], Cecilia Pelagatti[3]

[1] Department of Health Science, Section of Anaesthesiology, Intensive Care and Pain Medicine, AOUC Careggi, Florence - Italy
[2] Department of Pulmonary and Critical Care Medicine, Rode Island Hospital, Providence, RI - USA
[3] Department of Oncology, Section of Anesthesiology and Intensive Care, AOUC Careggi, Florence - Italy

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**

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

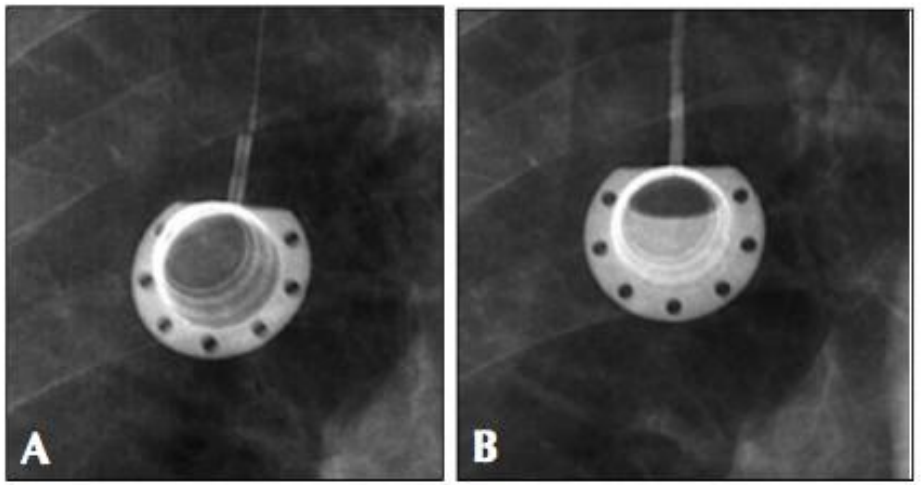

Fig. 2A - *Detail of the chest Rx at the first arrival at the emergency unit: already evident is a millimetric disconnection in the enlargement of the Dome detail.* **B** - *Chest Rx after the Port positioning some months before: Dome detail with the Groshong catheter correctly connected.*

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 G[1], 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 a 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.

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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 Kojima[1], Takao Hiraki[1], Hideo Gobara[1], Toshihiro Iguchi[1], Hiroyasu Fujiwara[1], Yusuke Matsui[1], Toshiharu Mitsuhashi[2], Susumu Kanazawa[1]

[1] Department of Radiology, Okayama University Medical School, Okayama - Japan
[2] 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

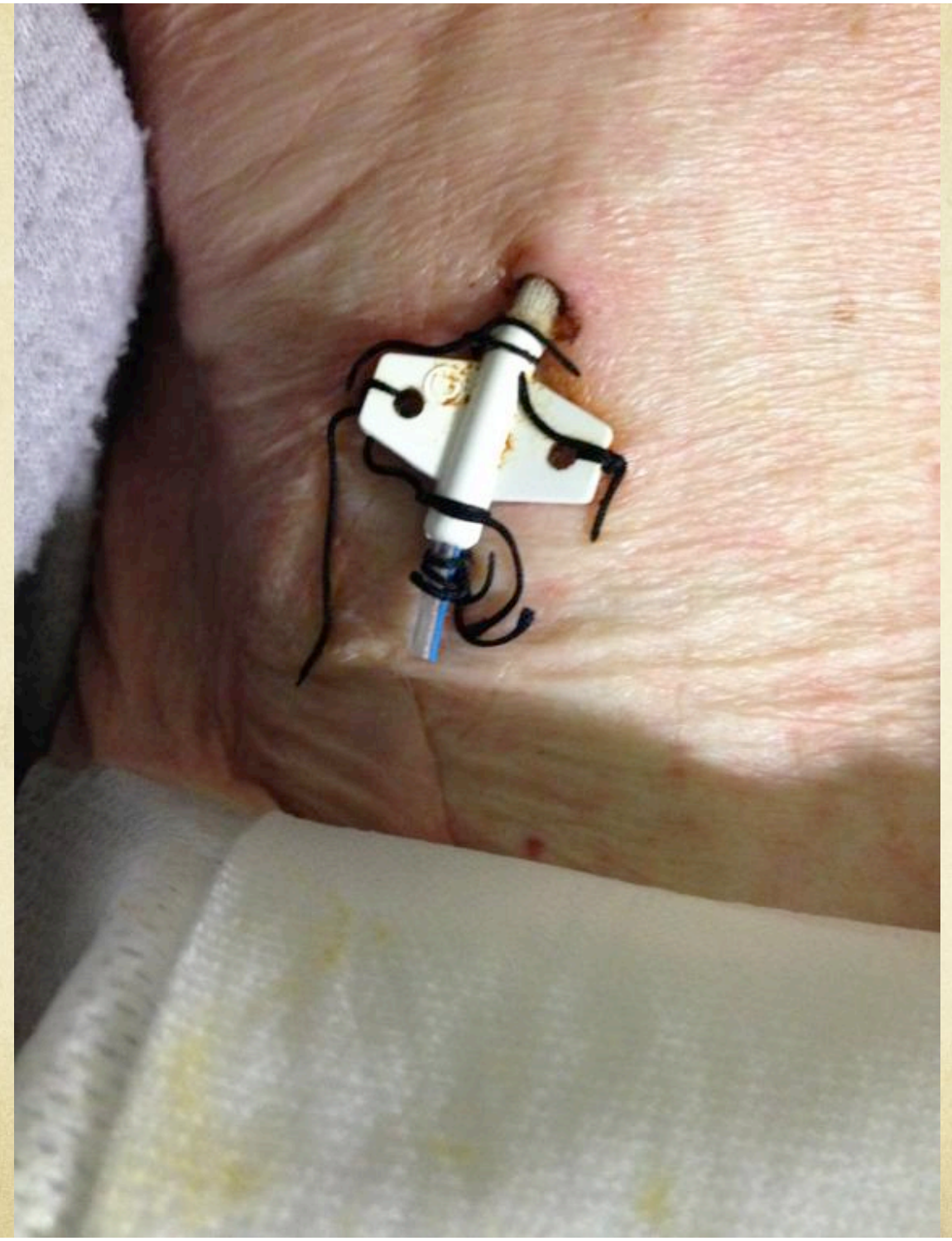
Introduction: *Establishing an effective midline program involves more than simply learning an insertion technique for a new product. Midline catheters provide a reliable vascular access option for those patients with difficult venous access who would otherwise require multiple venipunctures or the use 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 AB[1], 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.

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.

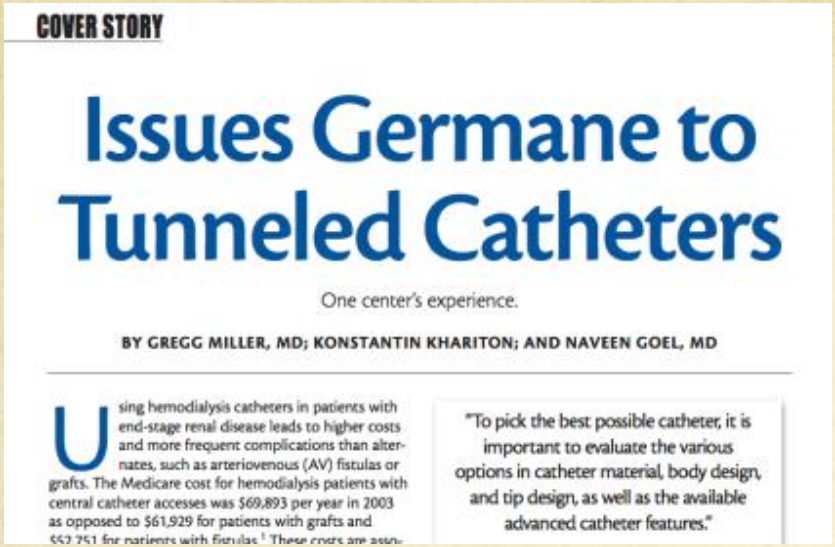
RESULTS: No significant differences between exposed and unexposed catheters were identified for any of the mechanical parameters tested except for a marginal reduction in the modulus of elasticity for both polyetherurethane and silicone catheters and minor increases in the wall area of polyetherurethane 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 prevention[8] and treatment[7] 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.



COVER STORY

Issues Germane to Tunneled Catheters

One center's experience.

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

Using 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

"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.[2] 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.[3]

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

Lecon Woo[1], *John Wesley MD*[2], *Maryellen Zibell*[2], *Christopher Gardner*[2] *and William Anderson*[2]
[1]*LWoo Associates LLC, Libertyville IL 60048*
[2] *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),

$$\eta = K\, Mw^{3.4} \qquad (1)$$

Where η 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.

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.

PICC Day Genova 2014

Conclusions

PART 2 In-vivo like condition

1) Weight variations were <2.5% after 30 days @37°C in RL/Ethanol solutions
2) Weight variations in Ethanol > Weight variations in RL
3) Pre-immersion weight was recovered in 24 h
4) 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**

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DOI: 10.5301/jva.5000452

ORIGINAL ARTICLE

A comparative study on the mechanical behavior of polyurethane PICCs

Paolo Poli[1], Antonella Scocca[1], Francesca Di Puccio[2], Giuseppe Gallone[2], Lorenza Angelini[2], Emanuele Maria Calabrò[2]

[1] Pain Therapy Unit, S. Chiara Hospital, Pisa - Italy
[2] Department of Civil and Industrial Engineering, University of Pisa, Pisa - Italy

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

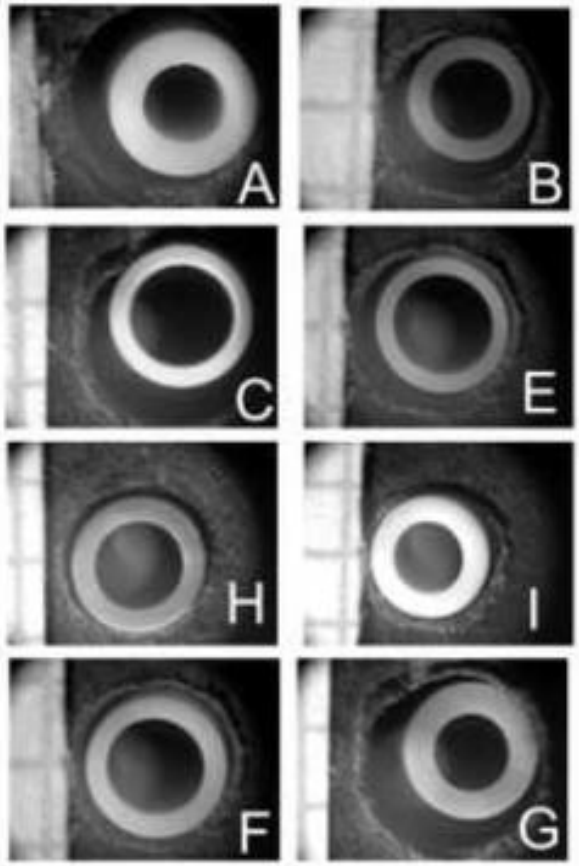
JOURNAL OF VASCULAR ACCESS

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
B	Bard	6175118 Power picc
C	Cook	G12987 TurboFlo
E	Argon	384465 L-Cath
F	Vygon	1294.115 Lifecath PICC
G	BBraun	044 39002 Celsite PICC-Cel
H	AngioDynamics	12102603
I	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…

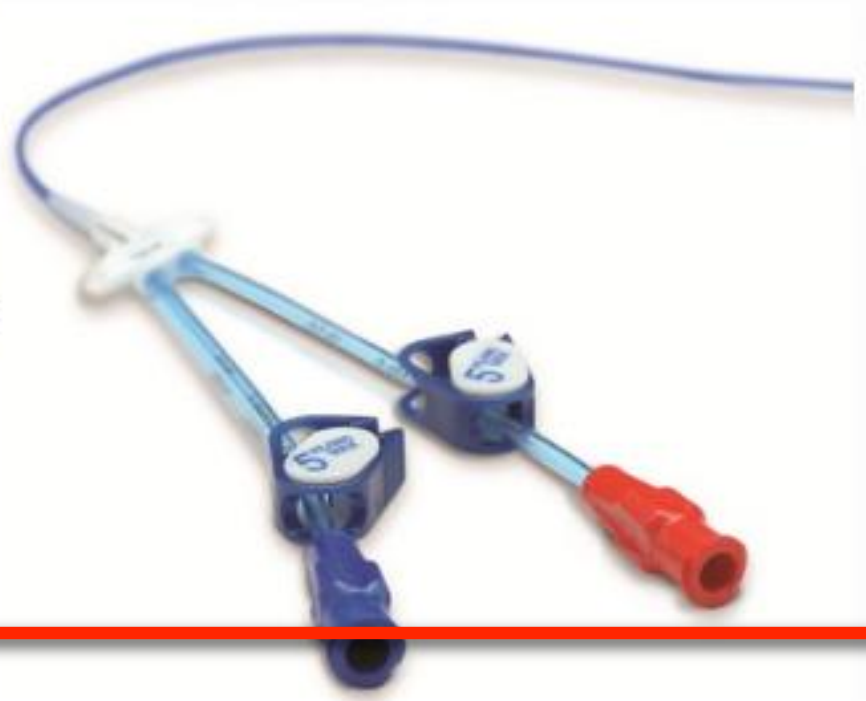
Circa l'85% dei PICC attualmente venduti in USA (circa 3 milioni/anno) sono PICC power injectable*, in poliuretano di terza generazione, e vengono usati comunemente per la infusione di chemioterapici in base alcolica.

(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.

Poly RADPICC

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

Reduced Taper
Our 3F Pro-PICC® CT combines the smallest proximal diameter and shortest taper length without compromising power injection rates.

Alcohol & iodine compatible
See our Site Care page for more information on agent compatibility.

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

tutte rotture del tratto intravascolare

tutti i cateteri erano usati con pompa

tutti e 6 l PICC erano usati con taxoli

Nessun episodio di rottura con PICC in PUR

Il 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.

La valvola distale non è utile per evitare la eparinizzazione, poiché la eparinizzazione è oramai considerata inutile

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REVIEW

Evidence-based criteria for the choice and the clinical use of the most appropriate lock solutions for central venous catheters (excluding dialysis catheters): a GAVeCeLT consensus

Mauro Pittiruti[1], Sergio Bertoglio[2], Giancarlo Scoppettuolo[1], Roberto Biffi[3], Massimo Lamperti[4], Alberto Dal Molin[5], Nicola Panocchia[1], Nicola Petrosillo[6], Mario Venditti[7], Carla Rigo[8], Enrico DeLutio[9]

[1] Fondazione Policlinico Universitario "A. Gemelli", Rome - Italy
[2] Department of Surgical Sciences, Università degli Studi, Genova - Italy
[3] Istituto Europeo di Oncologia, Milan - Italy
[4] Cleveland Clinic Hospital, Abu Dhabi - United Arab Emirates
[5] Università del Piemonte Orientale, Biella - Italy
[6] Istituto Nazionale Malattie Infettive "L. Spallanzani", Rome - Italy
[7] Università "La Sapienza", Rome - Italy
[8] Azienda Ospedaliera Universitaria "Maggiore della Carità", Novara - Italy
[9] Vascular Access Specialist, Rome - Italy

PANEL RECOMMENDATION:

- *The role of anticoagulant lock is only marginally important in the management of NDCVA, in terms of prevention of lumen occlusion.*

PANEL RECOMMENDATION :

- *Saline lock is as appropriate as anticoagulant lock in prevention of occlusion of NDCVA.*

INS 2016: Flush

- Usare flush con soluzione fisiologica in tutti i dispositivi per accesso venoso
- Il volume del flush deve essere almeno 2 volte lo spazio morto del sistema
  - 5 ml per i cateteri periferici nell'adulto
  - 10 ml per i cateteri centrali nell'adulto
  - Quantità maggiori in caso di sangue, lipidi, mdc, etc.
- Usare preferibilmente dispositivi monouso, monodose (es.: siringhe pre-riempite)

INS 2016: flush

- Usare tecniche a pressione positiva durante il flush
  - Prevenire il reflusso dopo il flush
    - Siringhe con stop a fine corsa
    - Lasciare 1 ml a fine flush
  - Appropriata sequenza di flush – clampaggio – deconnessione (secondo il tipo di NFC)
  - Tecnica push/pause (start and stop)

INS 2016: lock

- Per i cateteri non utilizzati per dialisi/feresi:
  - Non evidenza di vantaggi della soluzione eparinata rispetto alla fisiologica
  - Molte situazioni in cui la soluzione eparinata può essere controindicata in modo assoluto o relativo
- Per i cateteri per dialisi/feresi:
  - Evidenza di necessità di un lock anticoagulante (soluzione eparinata o soluzione con citrato)

INS 2016: Lock

- Lock per cateteri venosi periferici (adulto)
  - Soluzione fisiologica
- Lock per cateteri venosi periferici (neonato/bambino)
  - Soluzione fisiologica o soluzione eparinata
- Lock per cateteri venosi centrali
  - Soluzione fisiologica o soluzione eparinata
- Lock per cateteri per aferesi
  - Soluzione eparinata (100 unità/ml) o soluzione citrato 4%
- Lock per cateteri per emodialisi
  - Soluzione eparinata (1000 unità/ml) o soluzione citrato 4%

INS 2016: lock

- Volume del lock
  - Spazio morto del sistema + 20%
- Nuovo concetto: possibile utilizzo del lock NON ai fini della prevenzione delle occlusioni ma ai fini della prevenzione delle complicanze infettive
  - Soluzioni con attività antibatterica
    - Taurolidina
    - Citrato
    - Antibiotici (?)
      - Resistenze batteriche
      - Allergie

La valvola distale non previene le ostruzioni del lume

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

S. SPAZIANI[1], T. MICHELI[1], B. VINCENZI[2], C. CAMPISI[3]

[1] Rep. Analgesic and Palliative Therapy Unit, ASL Frosinone, Frosinone - Italy
[2] Biomedical Campus, Rome - Italy
[3] 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 – 20 occlusioni

Hoffer 2001

Randomizzato, 100 pazienti

PICC valvolati prossimali (PUR) vs. PICC valvolati distali (silicone)

- I PICC in silicone = più complicanze meccaniche ($p < .01$)
- Non differenze significative per % infezioni
- Non differenze significative per % occlusioni

Pittiruti 2009

Prospettico, non randomizzato, 198 pazienti

PICC valvolati distale (silicone) vs. PICC non valvolati (PUR)

- PICC in silicone = più complicanze meccaniche
- Non differenze significative per % infezioni
- Non differenze significative per % occlusioni

Di Giacomo 2009

Prospettico, non randomizzato

PICC valvolati distale (silicone) vs. PICC non valvolati (PUR) vs. PICC non valvolati (PUR power)

- Power PICC = meno complicanze meccaniche
- Power PICC = meno occlusioni

Ong 2010

Prospettico randomizzato, 326 pazienti

PICC con valvola distale (SIL) vs. PICC con valvola prossimale (PUR)

- Nessuna differenza in % occlusioni
- Nessuna differenza in complicanze meccaniche
- Maggiore incidenza di infezioni e trombosi locali nei SIL vs. PUR ($p < .001$)

Alport 2012

Randomizzato, 53 pazienti

Power PICC valvolati prossimali vs. power PICC non valvolati

- Nessuna differenza

Miyagaki 2012

Randomizzato, 26 pazienti

PICC con valvola distale (SIL) vs. non valvolati (PUR)

- Nessuna differenza in % complicanze

Johnston 2012

Randomizzato, 102 pazienti

PICC valvolati prossimali (PUR) vs. non valvolati (PUR) vs. valvolati distali (SIL)

- Nessuna differenza tra i gruppi in % occlusioni

JVasc Access 2012; 00 (00): 000-000
DOI: 10.5301/jva.5000071

ORIGINAL ARTICLE

The effect of peripherally inserted central catheter (PICC) valve technology on catheter occlusion rates - The 'ELeCTRiC' study

Andrew J. Johnston[1,2], Carmel T. Streater[1], Remy Noorani[1], Joanne L. Crofts[1], Aldwin B. Del Mundo[1], Richard A. Parker[3]

[1]Vascular Access Team, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
[2]John Farman Intensive Care Unit, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK
[3]Centre for Applied Medical Statistics, University of Cambridge

ABSTRACT:

Purpose: **Peripherally Inserted Central Catheters (PICCs) are increasingly being used to provide short to medium-term central venous access. The current study was designed to test the hypothesis that PICC valve technology does not influence PICC occlusion rates.**

Methods: **Intensive care unit (ICU) patients who required a PICC were randomized to one of three types of dual lumen PICC (open ended non-valved, Groshong valve, PASV valve). PICC occlusions were recorded and managed with a protocol that used urokinase.**

Results: **A total of 102 patients were recruited to the study. The overall risk of occlusion per catheter was 35% (95% CI 26% to 44%). The overall rate of occlusion was 76 occlusions per 1000 catheter days (95% CI 61 to 95). Presence or type of valve did not significantly influence this rate (open-ended non-valved PICC 38% of catheters, 79 occlusions per 1000 catheter days; Groshong 38% of catheters, 60 occlusions per 1000 catheter days; PASV 27% of catheters, 99 occlusions per 1000 catheter days). The dose of urokinase required to treat PICC occlusions did not significantly differ between PICC types.**

Conclusions: **Valved PICCs do not appear to influence PICC occlusion rates.**

J Vasc Access 2012; 00 (00): 000-000
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Conclusions: **Valved PICCs do not appear to influence PICC occlusion rates.**

Il nostro studio: Pittiruti 2014

J Vasc Access 2014; 00 (00): 000-000
DOI: 10.5301/jva.5000280

ORIGINAL ARTICLE

A prospective, randomized comparison of three different types of valved and non-valved peripherally inserted central catheters

Mauro Pittiruti[1], Alessandro Emoli[2], Patrizia Porta[2], Bruno Marche[2], Rosa DeAngelis[2], Giancarlo Scoppettuolo[3]

[1] Department of Surgery, Catholic University Hospital, Rome - Italy
[2] Day Hospital of Oncology, Catholic University Hospital, Rome - Italy
[3] Department of Infectious Diseases, Catholic University Hospital, Rome - Italy

JVA 2014

Progetto iniziale

Paragonare tre tipi di PICC valvolati in uso presso il nostro DH Oncologico, in termini di malfunzionamento e occlusioni:

- Groshong PICC, Bard (SIL, valvola distale)
- Power PICC Solo, Bard (P-PUR, valvola prossimale)
- PASV PICC, Navilyst (P-PUR, valvola prossimale)

…prima di iniziare lo studio…

…episodi ripetuti di rottura di cateteri Groshong :

6 rotture di Groshong PICC

2 rotture di Groshong Midline

tutte nel tratto intravascolare

tutti i cateteri erano usati con pompa

tutti e 6 I PICC erano usati con taxoli

Il DH Oncologico decide di sospendere l'uso di PICC Groshong per chemioterapia con pompa

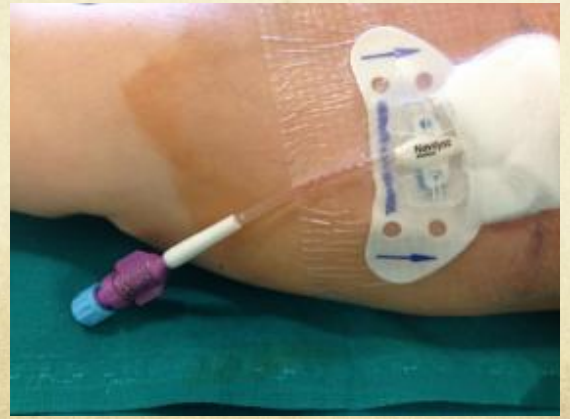
Nuovo progetto…

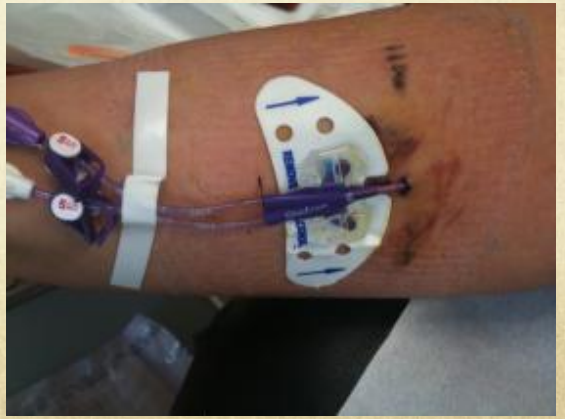
Paragonare tre tipi di PICC power injectable in uso per chemioterapia presso il nostro DH Oncologico:

100 Power Solo PICC, Bard (valvola prossimale)

100 PICC with PASV, Navilyst (valv.prossimale)

100 Pro-PICC, Medcomp (non valvolati)





Metodo

- DH Oncologia Medica, Università Cattolica, Roma
- 300 pazienti oncologici adulti
- Studio prospettico randomizzato (3 gruppi)
  - Valvola Solo vs. valvola PASV vs. non-valvolati
- PICC 4Fr monolume inseriti per chemioterapia
- Tutti i PICC inseriti secondo il protocollo SIP
- Tutti i PICC trattati con il medesimo protocollo di FLUSH/LOCK

Risultati

61 Power Solo 2 PICCs, Bard

60 PASV PICCs, Navilyst (55 Xcela + 5 BioFlo)

59 ProPICC, Medcomp

Studio interrotto a **180** pazienti (rispetto ai 300 previsti), a causa di 3 episodi di rottura di Power Solo PICCs (nel tratto intravascolare).

La Direzione ha sospeso l'uso dei Power Solo (altri 3 episodi di rottura si erano verificati in pazienti al di fuori dello studio)

Risultati –endpoint primario

	Solo Valve (n-61)	PASV (n=60)	No valve (n=59)
Occlusioni irreversibili	1	-	-
Occlusioni reversibili*	2	1	2
PWO**	1	-	1
Riduz.flusso a caduta***	19	39	-
Rimossi per occlusione	1		

- Tutte risolte con flushing di fisiologica

** entrambe irreversibili

*** difficultà con la infusione per gravità, ma non con la pompa

Risultati – endpoints secondari

	Solo Valve (n-61)	PASV (n=60)	No valve (n=59)
Infezione (CRBSI)	-	-	-
Trombosi sintomatica*	-	1	-
Trombosi asintomatica**	2	1	1
Dislocazione	-	-	-
Rottura intravascolare***	3	-	.
Rimossi per rottura	3	-	-

* Catetere (BioFlo), non rimosso; eparina bpm 100 unità/kg/12h
** Cateteri non rimossi – nessuna terapia
*** non chiara la patogenesi (probabilmente, un lotto difettoso)

Conclusioni

1) In presenza di un protocollo appropriato di Flush/ Lock e utilizzando NFC a pressione neutra, la eparinizzazione del PICC è superflua.

2) L'utilizzo di PICC in P-PUR sembra associarsi comunque, valvola o non valvola, ad un basso rischio di occlusione e ad una facile disostruzione senza il ricorso a trombolitici.

Conclusioni

3) La presenza di una valvola prossimale non sembra associarsi a vantaggi.

4) La presenza di una valvola prossimale si associa ad una possibile difficoltà alla infusione a caduta.

5) Il costo più elevato dei PICC valvolati rispetto al costo dei non valvolati non sembra giustificato da una migliore performance clinica.

Zerla 2015

Ovvero:

Il ‘colpo di grazia’ alla teoria che i PICC Groshong in silicone si associano a minori complicanze occlusive e trombotiche

Zerla

JAVA, September 2015 Volume 20, Issue 3, Pages 169–176

Open- vs Closed-Tip Valved Peripherally Inserted Central Catheters and Midlines: Findings from a Vascular Access Database

Pietro Antonio Zerla, RN, Antonio Canelli, RN
A.O. Melegnano, Milan, Italy
Giuseppe Caravella, MD, Alessandra Gilardini, MD
Hospital Pharmacy, A.O. Melegnano, Milan, Italy
Giuseppe De Luca, RN
Struttura Complessa Struttura Infermieristica Tecnica Riabilitativa Aziendale, A.O. Melegnano, Milan, Italy
Raffaella Parini, RN
Palliative Care, A.O. Melegnano, Milan, Italy
Marta Gianoli, RN
Oncology, A.O. Melegnano, Milan, Italy

Zerla 2015

Abstract

Today's patients are more complex in terms of comorbidities and other conditions requiring multiple, long-lasting therapies such as chemotherapy, total parenteral nutrition, blood transfusion or blood component infusions, and frequent blood sampling. The use of central venous catheters represents an important aspect of care for many patients. It is essential to inform health care workers of the risks associated with central venous catheters such as systemic and infectious complications, mechanical complications, and/or thrombotic complications. To maintain monitoring of our peripherally inserted central catheter team's activity, we developed and adopted a database in which all the data regarding each catheter are recorded. By doing that, we have improved catheter management, clinical efficiency, as well as achieved a cost reduction. We implanted 1416 vascular access devices in 1341 patients of both sexes (632 male and 709 female) for a total of 135,778 vascular access device-implant days between March 2010 and December 2013 for several indications. We have followed-up total complications and we correlated them with the need for catheter removal. The results were that open-tipped catheters resulted in both more complications and a greater need for removal.

Zerla 2015

	PICC open-ended	Groshong PICC	
Setting	Hospital	home	
#	173	620	
Cath-days	15819	102888	
Complications	28 (16.1%)	72 (12%)	
Occlusions	23	62	P=0.2134 n.s.
PWO	12	53	P=0.6380 n.s.
Thrombosis	5 (2.8%)	13 (2%)	P=0.5638 n.s.
Infection	5 (2.9%)	2 (0.3%)	P=0.0067
Infection/1000 cath days	0.31	0.01	

In sostanza

Nonostante i notevoli 'bias' statistici del lavoro (studio retrospettivo; i PICC a punta aperta erano tutti usati in ospedale e i PICC valvolati tutti a domicilio), alcuni dati sono incontrovertibili:

- I PICC (sia in silicone che in poliuretano) si associano ad un rischio trombotico al di sotto del 3%
- I PICC si associano (sia in ospedale che a domicilio) ad un basso rischio infettivo, al di sotto di 0.5 infezioni per 1000 giorni catetere

Confrontando PICC non valvolati in ospedale vs PICC valvolati a domicilio:

- Nessuna differenza in termini di **occlusione** del lume (benchè i PICC usati in ambito intraospedaliero in teoria avrebbero dovuto avere un rischio più elevato)
- Nessuna differenza in termini di **trombosi venosa** (confermando che non c'è differenza tra silicone e poliuretano)
- Ovvia differenza in termini di **rischio infettivo** tra uso intraospedaliero e uso a domicilio

Zerla 2015

Conclusioni

Paragonando in modo retrospettivo, non controllato, le complicanze di 173 PICC in poliuretano a punta aperta utilizzati in ambito ospedaliero vs. quelle di 620 PICC valvolati in silicone utilizzati in ambito domiciliare, non si sono evidenziate differenze significative nella incidenza di occlusioni (13,3% vs 10%, P = 0.21) o di trombosi (2.8% vs 2%, P = 0.56), sebbene i PICC utilizzati a domicilio fossero ovviamente associati ad un rischio infettivo minore (0.31 vs 0.01 infezioni/1000 gg catetere).

Quindi

- I PICC sono un dispositivo per accesso centrale particolarmente sicuro in termini di complicanze trombotiche e complicanze infettive
- Non vi sono differenze di performance clinica tra i PICC valvolati in silicone e i PICC a punta aperta in poliuretano (a parte il costo del presidio, assai maggiore per i PICC valvolati in silicone)

La valvola distale si associa a maggior rischio di malfunzionamenti

A Randomized, Prospective Trial of Central Venous Ports Connected to Standard Open-Ended or Groshong Catheters in Adult Oncology Patients

Roberto Biffi, M.D.[1]
Filippo De Braud, M.D.[2]
Franco Orsi, M.D.[3]
Simonetta Pozzi, M.D.[1]
Patrizia Arnaldi, M.D.[3]
Aron Goldhirsch, M.D.[2]
Nicole Rotmensz, M.Sc.[4]
Chris Robertson, Ph.D.[4]
Massimo Bellomi, M.D.[3]
Bruno Andreoni, M.D.[1]

[1] Division of General Surgery, European Institute of Oncology, Milan, Italy.

[2] Division of Medical Oncology, European Institute of Oncology, Milan, Italy.

[3] Division of Radiology, European Institute of Oncology, Milan, Italy.

[4] Division of Epidemiology and Biostatistics, European Institute of Oncology, Milan, Italy.

Presented in part as an oral communication at the Second National Congress of the Italian Study Group on Long-Term Vascular Accesses (GAVeCeL T), Pisa, Italia, November 18–20, 1999.

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The authors are indebted to the members of GAVeCeL (T) for their suggestions and criticism.

BACKGROUND. Implanted central venous access is practiced extensively in oncology; however, information on the relevance of using the device with a valved catheter (Groshong), compared with an open-ended catheter, is scarce. The authors investigated the two types of catheters in a randomized trial using the same type of subcutaneous port and evaluated efficacy as well as early and late complications.

METHODS. Three hundred four patients with malignant disease (solid tumors) who were eligible to receive intravenous chemotherapy were accrued during a 15-month period. After providing informed consent, the patients were assigned randomly to implantation of a titanium and silicone, rubber port (Dome Port™; Bard Inc., Salt Lake City, UT) attached either to an 8.0-F silastic Groshong™ catheter tube (experimental group) or to a 9.6-F silastic open-ended catheter tube (control group). Both catheters were manufactured by Bard Inc. Implantation, care, and follow-up followed the same protocol guidelines until removal of the device, death, or ending of the study. Power and color Doppler ultrasound examinations of internal jugular and subclavian veins were performed at 1 month and at 4 months or at anytime when a venous thrombosis was suspected.

RESULTS. Three hundred two patients (99.3%) were evaluable, 150 patients in the control group and 152 in the experimental group. The median follow-up was 237 days. There was a trend toward more early complications in the experimental group (5.9%; 95% confidence interval [95% CI], 2.7–10.9%) than in the control group (2.7%; 95% CI, 0.7–6.7%), although the difference was not statistically significant ($P = 0.26$). There was also a trend toward more late complications in the experimental group (17.1%; 95% CI, 11.5–24.1%) compared with the control group (10.7%; 95% CI, 6.2–16.7%; $P = 0.13$), although the difference, again, was not statistically significant. The most frequent late complication was the inability to draw blood samples (12.5% in the experimental group and 2% in the control group; $P < 0.001$). Sepsis was observed in 1 patient and in 3 patients and venous thrombosis was observed in 6 patients and in 11 patients in the experimental and control treatment groups, respectively (P value not significant).

CONCLUSIONS. In the tested clinical setting, the use of a Groshong catheter was not superior to a traditional, open-ended device in terms of early and late complications of the implant and its use. The theoretical justification for its superiority for more efficient use of the implantable device could not be substantiated. ***Cancer*** **2001;92:1204–12.** © *2001 American Cancer Society.*

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Groshong port = 12.5% di PWO

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Ann Vasc Surg. 2014 Feb;28(2):351-7. doi: 10.1016/j.avsg.2013.01.025. Epub 2013 Oct 3.

Comparative study of valved and nonvalved fully implantable catheters inserted via ultrasound-guided puncture for chemotherapy.

Zottele Bomfim GA[1], Wolosker N[2], Yazbek G[2], Bernardi CV[2], Valentim LA[2], De Castro TM[2], Pignataro BS[2], Benitti DA[2], Nishinari K[2].

⊕ Author information

Abstract

BACKGROUND: Fully implantable catheters are important for oncology treatments. They can be functionally categorized as valved or nonvalved. Theoretically, a valve prevents spontaneous blood reflux into the catheter, reducing the incidence of complications. We sought to compare the results from the implantation of valved and nonvalved fully implantable 8-French catheters inserted via ultrasound-guided puncture in cancer patients undergoing chemotherapy treatment.

METHODS: A retrospective analysis of 100 patients who underwent long-term catheter implantation guided by ultrasound was performed looking for early (≤30 days) or late (≥90 days) complications. They were evaluated regarding the use of valved or nonvalved catheter and assessed on univariate model.

RESULTS: The only early complication (hematoma) was identified in the valved group. Twenty-two late complications were identified (72.72% in the valved group and 27.27% in the nonvalved group; P = 0.009). Blood reflux dysfunction, which occurred in 12 patients in the valved and none in the nonvalved devices group, was the only complication with an incidence that was significantly different between the groups.

CONCLUSION: Fully implantable valved catheters with Groshong (Bard Medical Division, Covington, GA) valves have a higher rate of blood reflux dysfunction compared with nonvalved catheters, but this did not interfere with the efficacy of the treatment.

PWO = soltanto nei Groshong port

Nostra esperienza (2008-2015)

Pittiruti M, Sica S, Scoppettuolo G, Francia S et al (in press)

- 285 PICC
  - 185 auto-HSCT + 100 allo-HSCT
  - 185 PICC in silicone + 100 PICC in PUR power
- CRT 5.2%
  - No diff allo vs auto trapiantp
  - No diff silicone vs. poliuretano

Nostra esperienza (2008-2015)

Complicanze	PICC in PUR n=100	PICC in SIL n=185	Significatività Test Chi quadro
Ematoma	0	0.5%	n.s.
Malposizionamento	0	2.2%	$p < 0.05$
Malfunzionamento/occlusioni	0	6.0%	$p < 0.01$
Trombosi	5%	4.3%	n.s
Batteriemia PICC-correlata	3%	2.7%	n.s
Contaminazione PICC	4%	5.4%	n.s
Batteriemia non correlata a PICC	13%	13.5%	n.s.
Rimozione accidentale	1%	1.08%	n.s.
Rimozione per sepsi	0%	1.6%	n.s.
Rimozione per TVP	2%	2.7%	n.s.
Rimozione per malfunzionamento	0%	0.5%	n.s.

The Journal of Vascular Access 2000; 1: 36-39

BIOMATERIALS

Groshong catheters: technical aspects and clinical features

C. CAMPISI, L. CAMILLUCCI[1], A. CAMPOPIANO[1], C. FANIZZA[1], A. SARDONIO

National Research Council – Institute of Biomedical Technologies, Rome - Italy
[1] ISPESL – National Institute for Occupational Prevention and Safety - Monteporzio Catone, Rome - Italy

We examined 16 Groshong catheters, each 7 Fr. in diameter (Bard Access Systems, Salt Lake City, UT, USA), explanted from oncological patients. A new catheter (lot no. 36HF9729) was also evaluated as control.

The examined catheters were implanted in the left subclavian vein, tunnelled in subcutaneous tissue, and explanted in case of failure or running out of clinical requirements. Nine catheters were explanted when still perfectly working while six were characterized by the ball-valve dysfunction. All catheters were then classified according to time of persistence in the host organism: 3 catheters were examined six months after implant, 6 after 12 months, 3 after 18 months, 3 after 24 months and one after 36 months.

TABLE I – TIME AFTER IMPLANT, CLOSING PRESSURE, CLINICAL FAILURES AND INTRALUMINAL CLOTS IN THE 16 GROSHONG CATHETERS INCLUDED IN THE PRESENT STUDY

Catheter n.	Time before expl. (months)	Closing pressure mmHg	Ball-valve effect	Intraluminal clots
0	0	40	-	-
1	6	36	No	No
2	6	28	Yes	No
3	6	24	Yes	No
4	12	34	No	Yes
5	12	22	No	No
6	12	26	No	Yes
7	12	36	Yes	No
8	12	30	No	No
9	12	24	No	No
10	18	32	Yes	Yes
11	18	28	Yes	No
12	18	32	No	Yes
13	24	26	Yes	No
14	4	24	No	No
15	24	28	No	No
16	36	26	No	No

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4	12	34	No	Yes
5	12	22	No	No
6	12	26	No	Yes
7	12	36	Yes	No
8	12	30	No	No
9	12	24	No	No
10	18	32	Yes	Yes
11	18	28	Yes	No
12	18	32	No	Yes
13	24	26	Yes	No
14	4	24	No	No
15	24	28	No	No
16	36	26	No	No

'Closing pressure' = equivalente alla pressione di apertura della valvola in infusione.
Teorica: 40mmHg (circa .8 psi) - misurata nello studio: 22-36mmHg (circa .4-.7psi)

TABLE I – TIME AFTER IMPLANT, CLOSING PRESSURE, CLINICAL FAILURES AND INTRALUMINAL CLOTS IN THE 16 GROSHONG CATHETERS INCLUDED IN THE PRESENT STUDY

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11	18	28	Yes	No
12	18	32	No	Yes
13	24	26	Yes	No
14	4	24	No	No
15	24	28	No	No
16	36	26	No	No

'Ball-valve effect' = PWO. Riscontrato in 6 cateteri su 15 (40%)
Legato ad aumento della soglia di apertura della valvola in fase di aspirazione (pressione dichiarata 50-80mmHg ovvero 0.9-1.6psi)

TABLE I – TIME AFTER IMPLANT, CLOSING PRESSURE, CLINICAL FAILURES AND INTRALUMINAL CLOTS IN THE 16 GROSHONG CATHETERS INCLUDED IN THE PRESENT STUDY

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10	18	32	Yes	Yes
11	18	28	Yes	No
12	18	32	No	Yes
13	24	26	Yes	No
14	4	24	No	No
15	24	28	No	No
16	36	26	No	No

Coaguli nel catetere = incompetenza della valvola
Riscontrati in 4 cateteri su 15 (27%)

Conclusioni

- La pressione di apertura in infusione dovrebbe essere 0.8 psi, ma nella realtà il silicone 'cede' con l'uso e la pressione di apertura diminuisce anche del 50%
- La pressione di apertura in aspirazione dovrebbe essere 0.9-1.6 psi, ma può aumentare fino a impedire completamente la apertura in aspirazione
- In molti casi (25-30%) la valvola è incompetente e permette al sangue di entrare
- In molti altri casi (40%) la valvola non si apre in aspirazione e si associa a PWO

QUINDI: LA VALVOLA DI GROSHONG NON HA ALCUNA AFFIDABILITA'

Come dimostrato da TUTTI gli studi clinici effettuati su

- Groshong PICC
- Groshong port
- Groshong cuffiati

Infine

Il catetere in silicone con valvola distale, con tutti i suoi svantaggi, ha anche un costo più elevato !

Domanda:

Ha ancora senso utilizzare cateteri in silicone con valvola distale tipo Groshong?

Risposta:

Assolutamente no.

UNIVERSITÀ CATTOLICA del Sacro Cuore

GAVeCeLT
Gli Accessi Venosi Centrali a Lungo Termine

Grazie dell'attenzione

www.gavecelt.info

mauropittiruti@me.com