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REPORTS OF ORIGINAL INVESTIGATIONS

Use of a chlorhexidine-impregnated patch does not decrease the incidence of bacterial colonization of femoral nerve catheters: a randomized trial

L'utilisation de tampons imprégnés de chlorexidine ne diminue pas l''incidence de la colonisation bactérienne des cathéters du nerf fémoral: un essai randomisé

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Abstract

Purpose *Femoral nerve catheter (FNC) insertion is commonly performed for postoperative analgesia following total knee arthroplasty (TKA). A wide range of rates has been reported relating to the bacterial colonization of catheters complicating FNC insertion. The BIOPATCH® is a chlorhexidine (CHG) impregnated patch designed to inhibit bacterial growth for days. The BIOPATCH has proven to be effective at decreasing bacterial colonization in epidural and vascular catheters. We hypothesized that the BIOPATCH would be effective at decreasing the rates of FNC bacterial colonization.*

Methods *Following Institutional Review Board approval and written informed consent, 100 patients scheduled for TKA were prospectively enrolled in the study. Patients at elevated risk for infection were excluded from analysis. Femoral nerve catheters were inserted and tunneled under sterile conditions using ultrasound guidance following CHG skin cleansing. Participants were then randomized either to have the BIOPATCH applied to the catheter exit site or not to have the patch applied. All patients received pre/postoperative antibiotic therapy. The FNC tip and catheter exit site were cultured for bacterial growth at the conclusion of therapy.*

Results *No differences were observed between groups in regards to catheter exit site. Catheter colonization was observed in three of 48 (6.3%) BIOPATCH patients and two of 47 (4.3%) non-BIOPATCH patients (risk ratio [RR] = 1.5; 95% confidence interval [CI] 0.3 to 8.4; P = 1.0). Colonization of the catheter exit site was observed in 12 BIOPATCH and 14 non-BIOPATCH patients (RR = 0.8; 95% CI 0.4 to 1.6; P = 0.65). Local skin inflammation (non-BIOPATCH 10.6% vs BIOPATCH 2.1%) and colonization of the FNC exit site by more than one type of bacteria trended towards increased values in the non-BIOPATCH group.*

Conclusions *The baseline rate of bacterial colonization of FNCs is quite low in the setting of short-term use, CHG skin decontamination, ultrasound guidance, subcutaneous tunneling, and perioperative antibiotic therapy. No benefit was shown by using the BIOPATCH in this patient population. (ClinicalTrials.gov number: NCT01411891).*

Résumé

Objectif *L'insertion d'un cathéter du nerf fémoral (CNF) est couramment réalisée pour l'analgésie postopératoire après arthroplastie totale de genou (ATG). Des taux très variables de colonisation bactérienne du cathéter compliquant l'insertion d'un CNF ont été décrits. Le*

Author contributions *Kristopher Schroeder, Melanie Donnelly,* and *Brooke M. Anderson* were involved in the conception of the project and in drafting the manuscript. *Kyle Gassner* was involved in the conception and design of the project and in article revision. *Robert A. Jacobs, Brooke M. Anderson,* and *Christopher Guite* were involved in the acquisition of data. *Christopher Guite* critically revised the data for important intellectual content.

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Biopatch est un tampon imprégné de chlorhexidine (CHG) qui est conçu pour inhiber la prolifération bactérienne pendant plusieurs jours. Le Biopatch s'est avéré efficace pour la réduction de la colonisation bactérienne des cathéters périduraux et vasculaires. Nous avons émis l'hypothèse que le Biopatch diminuerait efficacement les taux de colonisations des CNF.

Méthodes *Après l'approbation du comité d'éthique de la recherche de l'établissement et un consentement éclairé donné par écrit, 100 patients devant bénéficier d'une arthroplastie totale de genou ont été recrutés de façon prospective. Les patients à risque élevé d'infection ont été exclus de l'analyse. Les cathéters du nerf fémoral ont été insérés et tunnellisés dans des conditions de stérilité, sous guidage échographique, après nettoyage de la peau par du CHG. Les participants ont été randomisés pour avoir un Biopatch appliqué sur le site de sortie du cathéter, ou non. Tous les patients ont reçu une traitement antibiotique pré/postopératoire. L'extrémité du CNF et le site de sortie du cathéter ont été mis en culture à la recherche d'une croissance bactérienne à la fin du traitement.*

Résultats *Il n'y a pas eu de différence statistiquement significative au niveau du point de sortie du cathéter. Une colonisation du cathéter a été observée chez 3 des 48 (6,3 %) patients du groupe Biopatch et chez 2 des 47 (4,3%) patients du groupe sans Biopatch (rapport de risque [RR]: 1,5; intervalle de confiance [IC] à 95 %: 0,3 à 8,4; P = 1,0). La colonisation du point de sortie du cathéter a été observée chez 12 patients du groupe Biopatch et chez 14 patients du groupe sans Biopatch (RR: 0,8; IC à 95 %: 0,4 à 1,6; P = 0,65). L'inflammation locale de la peau (10,6 % contre 2,1%) et la colonisation au point de sortie du CNF par plus d'un type de bactéries tendaient vers des valeurs augmentées dans le groupe sans Biopatch.*

Conclusions *Le taux de base de colonisation bactérienne des CNF mis en place dans le cadre d'une utilisation de courte durée, avec décontamination de la peau, guidage échographique, tunnellisation sous-cutanée et traitement antibiotique périopératoire est relativement faible et nous n'avons pas été capables de mettre en évidence un avantage à l'application du Biopatch. Numéro ClinicalTrials.gov: NCT01411891.*

At many institutions, femoral nerve catheter insertion for postoperative analgesia following total knee arthroplasty is considered standard of care. Compared with standard opioid therapy, perineural femoral nerve catheters have shown improved pain control, decreased opioid-related side effects, and improved functional recovery following total knee arthroplasty.[1-4] Unfortunately, the potential for infection exists any time the integrity of the skin is disturbed. Serious case reports of psoas abscess complicating femoral nerve catheter insertion have even been reported.[5]

Various groups have investigated the incidence of bacterial colonization in patients with femoral nerve catheters, and rates as high as 57% have been reported.[6] Most studies have found the incidence of bacterial colonization of femoral nerve catheters to be more moderate (9-28.6%).[7,8] Various factors have been shown to increase the risk of bacterial colonization of peripheral nerve catheters, including extended duration of therapy, diabetes mellitus, recent trauma, site of nerve catheter insertion, postoperative care in the intensive care unit setting, and lack of extended postoperative antibiotic therapy.[7-10] Bacterial colonization of invasive devices is of great importance as it has been shown to serve as a surrogate end point for catheter-related blood stream infections.[11]

The BIOPATCH® (Ethicon Inc., Somerville, NJ, USA) is a chlorhexidine-impregnated patch that is designed to release chlorhexidine and inhibit bacterial and fungal growth for a number of days. The BIOPATCH has a low incidence of reported hypersensitivity reactions and has proven to be effective at decreasing bacterial colonization at the epidural and vascular catheter exit sites.[12-14] This study was designed to evaluate the BIOPATCH for use with peripheral nerve catheters in view of the high rate of reported bacterial colonization of peripheral nerve catheters (specifically femoral nerve catheters) and the potentially devastating consequences of a local abscess or blood stream infection seeding joint hardware. Bacterial colonization of peripheral nerve catheters and the impact of the BIOPATCH may differ from findings reported for epidural catheters as the site of peripheral nerve catheter insertion is oftentimes in an anatomical location more conducive to bacterial growth. The impact of the BIOPATCH on the rate of bacterial colonization of peripheral nerve catheters may also differ from what has been reported for vascular catheters secondary to infusions of local anesthetics through peripheral nerve catheters.

The goal of this randomized investigation was to examine the effect of BIOPATCH placement on the rate of bacterial colonization at the femoral nerve catheter tip following total knee arthroplasty. We also examined bacterial colonization at the femoral nerve catheter exit site and clinical signs of infection or inflammation. We hypothesized that the use of a BIOPATCH would significantly reduce rates of colonization at both the femoral nerve catheter tip and catheter exit site.

Methods

This study was approved by the University of Wisconsin Health Sciences Institutional Review Board in July 2011,

and all participants provided written informed consent. Adult patients scheduled for total knee arthoplasty were eligible for the study. Exclusion criteria included patients aged < 18 yr, allergy to local anesthetics, local or generalized infection or inflammation, current antibiotic therapy, compromised immune system, current chronic steroid use, neurological deficits, pregnancy, imprisonment, refusal to participate, and primary language other than English. Randomization was accomplished by inserting a sheet of paper determining patient group (50 stating "BIOPATCH" and 50 stating "Control") into an opaque envelope. The envelopes where then sealed, well shuffled, and numbered sequentially by a member of the study team (K.S.). Consent, envelope retrieval, and randomization were done by a member of the study team (staff anesthesiologist) involved in block placement.

For femoral nerve catheter placement, patients were transported to a dedicated area outside of the operating room (OR). Nerve catheters were inserted by an anesthesia resident under the supervision of a faculty anesthesiologist. A "time out" procedure was performed to ensure correct patient, correct side, and correct procedure. Following application of standard monitors, including blood pressure, electrocardiography (ECG), and pulse oximetry, the patient was sedated with intravenous midazolam and/or fentanyl. Sedation was titrated to patient comfort, and the groin was shaved with electric clippers as needed to allow for adherence of a sterile dressing following catheter placement. Chlorhexidine gluconate 2% / isopropyl alcohol 70% (ChloraPrep, CareFusion, Leawood, KS, USA) was used to decontaminate the skin in the area of needle insertion, and a sterile drape was then placed over the needle insertion site. All physicians involved in placement of femoral nerve catheters wore cap, mask, sterile gown, and gloves for catheter placement. A SonoSite M-Turbo® ultrasound system with a 13-6 MHz ultrasound probe (SonoSite, Bothel, WA, USA) was covered with a sterile probe cover (Bard Access Systems, Inc., Salt Lake City, UT, USA). Sterile ultrasound conducting gel was applied to the probe, and ultrasound guidance was utilized to identify the femoral nerve in cross section. Following skin infiltration at the needle insertion site with 1% lidocaine, a 17G Tuohy needle from an Arrow® StimuCath® Continuous Nerve Block Procedural kit (Teleflex Medical, Research Triangle Park, NC, USA) was inserted adjacent to the nerve. Current was passed through the needle, and the femoral nerve catheter was advanced through the needle when a quadriceps muscle contraction was elicited at a suitable current (variable but typically 0.5-1.5 mAmps·cm^{-2} Current was applied to the catheter as it was advanced through the Tuohy needle, and if the quadriceps muscle contraction dissipated, the catheter was pulled back to within the Tuohy and then re-advanced following needle repositioning. When catheter insertion continued to result in quadriceps muscle contraction at a current 0.5-1.5 mAmps·cm^{-2} the Tuohy needle was removed and the catheter was secured. If we were unable to obtain a quadriceps contraction via the stimulating catheter despite repositioning the needle, the needle was positioned adjacent to the femoral nerve and the catheter was threaded 5 cm beyond the needle tip and secured at that location. The femoral nerve catheter was then tunneled 1-2 cm lateral and superior to the initial needle insertion site. Dermabond^{TM} (Ethicon Inc., Somerville, NJ, USA) was applied at the femoral nerve catheter exit site and the site of tunneling.

Once the femoral nerve catheter was placed, the attending anesthesiologist opened the next envelope in the sequence to determine the treatment allocation. The BIOPATCH group had a BIOPATCH applied at the catheter exit site prior to application of a Tegaderm^{TM} (3 M Healthcare, St. Paul, MN, USA) film dressing. In the non-BIOPATCH group, a Tegaderm film was applied as the only dressing. Following completion of femoral nerve catheter dressings, the femoral catheter was initially dosed/tested with 3-5 mL of 1.5% lidocaine with 5 μg·mL^{-1} epinephrine and then dosed further with an additional 20 mL of 0.5% ropivacaine. Patients then received a perineural infusion (0.2% ropivacaine at 6 mL·hr^{-1} until 0600 hrs on postoperative day 1) via a programmable infusion pump (Hospira, Inc., Lake Forest, IL, USA) initiated in the postanesthesia care unit (PACU). The infusion was then changed to 0.1% ropivacaine at 6 mL·hr^{-1} until 0600 on postoperative day 2. Importantly, a bacterial filter is used with all perineural local anesthetic infusions at our institution. For the surgical procedure, patients received either general or neuraxial anesthesia at the discretion of the anesthesia provider and the patient. Postoperatively, all patients received additional intravenous and oral opioids as deemed appropriate by the nursing and surgical staff. Following femoral nerve catheter placement, all patients received a preoperative dose and two postoperative doses of appropriate prophylactic antibiotic therapy. Additional postoperative antibiotic doses were given to patients deemed by the orthopedic service to be at high risk of infectious complications.

Upon completion of therapy, a study team member was responsible for femoral nerve catheter removal and culture retrieval. The Tegaderm dressing and any residual Dermabond adhesive was first carefully removed. Residual Dermabond adhesive was removed with a sterile forceps. With the catheter still in place, the skin at the catheter exit site was swabbed with a sterile cotton tip applicator moistened with sterile normal saline. The swab was placed in a sterile container and sent immediately to the microbiology laboratory. Staff members in the microbiology lab

performing the bacterial cultures were blinded with regard to patient group. The swab was inoculated onto a blood agar plate/eosin-methylene blue plate/chocolate agar plate and incubated for three days aerobically, then inoculated onto an anaerobic brucella agar plate and incubated for seven days anaerobically. Bacterial growth found in the first quadrant of the inoculated plate was defined as low-grade growth; bacterial growth in the second and/or third quadrant was moderate growth, and bacterial growth in the fourth quadrant was heavy growth.

Skin around the catheter insertion site was then disinfected with sterile povidone-iodine solution and allowed to dry. The skin was then cleansed with 70% alcohol x 2 and allowed to dry between and after each application. The catheter was then removed, and 2 cm of the distal portion of the femoral nerve catheter were cut using sterile scissors. The catheter was immediately sent to the microbiology lab for culture in a sterile container. The catheter segments were rolled onto blood agar plates at 35°C under aerobic and anaerobic conditions. Bacterial growth found in the first quadrant of the inoculated plate was defined as low-grade growth; bacterial growth in the second and/or third quadrant was moderate growth, and bacterial growth in the fourth quadrant was heavy growth.

The primary outcome of the investigation was bacterial growth present on culture of the femoral nerve catheter. Secondary outcomes included bacterial colonization of the skin at the catheter insertion site and clinical signs of infection or inflammation. Since anesthesia residents would be inserting our femoral nerve catheters, we assumed that our baseline rate of bacterial colonization would approximate that reported by Cuvillon *et al*.[6] We therefore assumed that the rates of catheter colonization in the control group and treatment group would be 60% and 30%, respectively. A 50% reduction in the rate of colonization was arbitrarily chosen as representing a clinically significant reduction. Using a two-sample binomial test with a type I error of 5% (two-sided) and a power of 80%, we needed 44 subjects in each group (88 subjects in total). The planned enrolment size of 50 subjects per group (100 subjects in total) allowed for potential dropouts or losses to follow-up. Between-group comparisons for the primary and secondary outcomes were evaluated with Fisher's exact test; point estimates and confidence limits were determined for the relative risk.

Results

One hundred patients were successfully recruited and randomized from September 13, 2011 to January 26, 2012. Three patients in the non-BIOPATCH group and two patients in the BIOPATCH group were unable to be cultured secondary to premature Tegaderm or catheter dislodgement.

Table 1 Baseline patient characteristics

		No Patch ($n = 47$)	Patch ($n = 48$)
Age (yr)	Mean	65.8	60.6
	SD	9.6	8.6
Sex (%)	Male	40.4	50.0
	Female	59.6	50.0
Height (in)	Mean	67.3	68.0
	SD	4.2	3.9
Weight (kg)	Mean	90.0	96.9
	SD	17.0	15.8
BMI	Mean	30.9	32.5
	SD	5.8	4.4
ASA (%)	I	2.1	4.2
	II	76.6	81.2
	III	21.3	14.6
Catheter Duration (min), [hr]	Mean	(2,897) [48.3]	(2,900) [48.3]
	SD	(154) [2.6]	(264) [4.4]

SD = standard deviation; BMI = body mass index; ASA = American Society of Anesthesiologists

Baseline patient characteristics were generally similar between groups as documented in Table 1. Importantly, catheter duration was similar between the two groups.

We observed a slightly higher risk of catheter colonization in the BIOPATCH patients, three of 48 (6.3%) *vs* two of 47 (4.3%) control patients (risk ratio [RR] = 1.5). However, due to the small number of events, the estimation of the RR is very imprecise (95% confidence interval 0.3 to 8.4). Thus, the data are compatible with no association (RR = 1.0) (a harmful effect of BIOPATCH, RR > 1.0; and a beneficial effect of BIOPATCH, RR < 1.0). The results for the secondary outcomes (Table 2) are similarly imprecise.

Skin culture without the BIOPATCH grew coagulase-negative *Staphylococcus* (*Staphylococcus epidermidis)* in 39% of positive cultures and Gram-positive rods/bacillus *(Actinomyces, Propionibacterium*, and *Corynebacterium)* in 61% of positive cultures. Skin culture with the BIOPATCH grew coagulase-negative *Staphylococcus* (*Staphylococcus epidermidis)* in 50% of positive cultures and Gram-positive rods/bacillus *(Actinomyces, Propionibacterium*, and *Corynebacterium)* in 42% of positive cultures. Our catheter colonization rate was low (5.3% of all catheters cultured), and culture results revealed predominately coagulase-negative *Staphylococcus* (*Staphylococcus epidermidis*) present in 80% of colonized catheters.

Discussion

This randomized trial did not show either statistically or clinically significant reductions in bacterial colonization of

Table 2 Results of primary and secondary outcomes

		No patch ($n = 47$)	Patch ($n = 48$)	Relative risk	Confidence interval	P value
Primary outcome						
Catheter (any growth)	Present (%)	2 (4.3)	3 (6.3)	1.5	(0.26 to 8.40)	1
	Absent (%)	45 (95.7)	45 (93.7)			
	Total	47	48			
Secondary outcomes						
Skin inflammation	Present (%)	5 (10.6)	1 (2.1)	0.2	(0.02 to 1.61)	0.2
	Absent (%)	42 (89.4)	47 (97.9)			
	Total	47	48			
Skin (any growth)	Present (%)	14 (29.8)	12 (25.0)	0.8	(0.43 to 1.62)	0.65
	Absent (%)	33 (70.2)	36 (75.0)			
	Total	47	48			
Other outcomes						
Temperature max (°C)	Mean	37.6	37.5			
	SD	0.45	0.39			
	Total	47	48			
Preoperative white blood cell count	Mean	6.9	6.9			
	SD	1.6	2.3			
	Total	44	41			
Skin (≥ moderate growth)	Present (%)	2 (4.3)	3 (6.3)			
	Absent (%)	45 (95.7)	45 (93.7)			
	Total	47	48			
Skin (> 1 bacterial type growth)	Present (%)	3 (6.4)	0 (0.0)			
	Absent (%)	44 (93.6)	48 (100.0)			
	Total	47	48			
Catheter (≥ moderate growth)	Present (%)	0 (0.0)	0 (0.0)			
	Absent (%)	47 (100.0)	48 (100.0)			
	Total	47	48			
Catheter (> 1 bacterial type growth)	Present (%)	0 (0.0)	0 (0.0)			
	Absent (%)	47 (100.0)	48 (100.0)			
	Total	47	48			
Any growth (skin or catheter)	Present (%)	15 (31.9)	14 (29.2)	0.91	(0.50 to 1.68)	0.83
	Absent (%)	32 (59.1)	34 (70.8)			

SD = standard deviation

the femoral nerve catheter or the catheter exit site with a BIOPATCH application when the catheter is tunneled and used for only 48 hr.

Some of the results and limitations of this study warrant further discussion. Our baseline rate of catheter and exit site colonization appears to be much less than what has been reported thus far in the literature. The baseline rate of bacterial colonization was taken from another study (Cuvillon *et al.* 2001) that was 12 years old and utilized different methods of skin preparation. In addition, many of the studies evaluating bacterial colonization of peripheral nerve catheters fail to mention the conditions under which nerve catheters are removed. For example, Cuvillon *et al.* state only that "catheters were carefully removed." Without adequate skin cleansing prior to catheter removal, significant bacteria from the skin entry site could conceivably contaminate the tip upon removal.[6] As the current literature presents a range of reported peripheral nerve catheter colonization rates, it would have been more appropriate to calculate the sample size over a range of parameter values to investigate sensitivity. The most appropriate sample size calculation, given our different catheter insertion and removal conditions, would have utilized recent historical data from our own institution. A pilot study evaluating our current practice of catheter insertion presumably would have shown a much lower rate of baseline bacterial colonization and would therefore have led us to recruit a larger number of patients to this study.

Multiple factors could have led to our low rate of bacterial colonization. For example, instead of using povidone iodine for skin preparation and cleansing, we utilized chlorhexidine gluconate, which has been shown in multiple

studies to provide superior bactericidal results.[15] The application of Dermabond prior to applying the BIOPATCH may have further impacted bacterial colonization. While not antimicrobial, Dermabond application may have decreased bacterial colonization by providing a microbial barrier and decreasing bacterial migration along the length of the catheter. Our low rate of bacterial colonization may also be secondary to subcutaneous tunneling, which, in a previous study, was able to reduce the incidence of femoral nerve catheter colonization to 11.7%.[10] Patients in this study had preoperative and postoperative antibiotic therapy that was continued for at least two post-surgical doses, and this certainly may have played a role in decreasing our rate of contamination.[9] In this study, we examined only catheters left in place for two days in a hospital setting, and therefore our results may not apply to catheters in place for a longer duration or those managed in an outpatient setting. Also, in our study, we examined only one site of peripheral nerve catheter insertion, and it is possible that other sites may benefit to a greater extent from perioperative BIOPATCH placement. While the microbiology lab was blinded to patient group, those who inserted and removed the femoral nerve catheter were not blinded, which could have introduced a source of bias.

Chlorhexidine gluconate has been studied extensively in the medical literature for a variety of indications. Chlorhexidine gluconate functions by altering cell wall permeability, precipitating components of the cell membrane and cytoplasm, and rapidly killing Gram-positive and Gram-negative bacteria in addition to yeasts. Chlorhexidine has the ability to adhere to the skin's stratum corneum, thereby extending duration, and it consistently outperforms povidone iodine when used as a skin antiseptic. Reports of antibacterial resistance to chlorhexidine are rare as are serious reports of adverse reactions to chlorhexidine.[15]

The BIOPATCH protective disc is absorptive foam impregnated with chlorhexidine. The patch provides sustained presence of antibactericidal chlorhexidine at the site of catheter skin penetration. The BIOPATCH has been approved to reduce device colonization and catheter - related blood stream infections for a variety of medical devices, including intravenous catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheter drains, chest tubes, externally placed orthopedic pins, and epidural catheters.[A] The BIOPATCH has a proven record in the medial literature for decreasing device contamination. Specific to the field of regional anesthesia, use of the BIOPATCH has resulted in significant reductions in the rates of epidural catheter colonization (29 - 3.8%) and epidural catheter exit site contamination (40.1 - 3.4%).[12,13] Cost-benefit analyses have been performed and consistently show that the use of chlorhexidine dressing is highly cost-effective when used to prevent catheter-related bloodstream infections from central lines.[16,17]

There has been concern in the regional anesthesia literature regarding bacterial contamination with the use of continuous peripheral nerve blocks. Concern has been heightened by the recent increase in the number of peripheral nerve catheters inserted. Select catheters are even sent home with patients, and health care providers thus lose the ability to monitor the patient closely for physical signs of infection or inflammation. A study of 628 femoral nerve catheters showed a 0.6% incidence of local inflammation and a 0.5% incidence of local pustule formation.[18] A study evaluating 574 femoral nerve catheters showed a 4% incidence of local inflammation, a 3.3% incidence of infection, and a 1.4% incidence of infection requiring surgical drainage.[19] In contrast, a study that included 206 outpatient femoral nerve catheters did not report any problems with infection related to nerve catheter placement.[20]

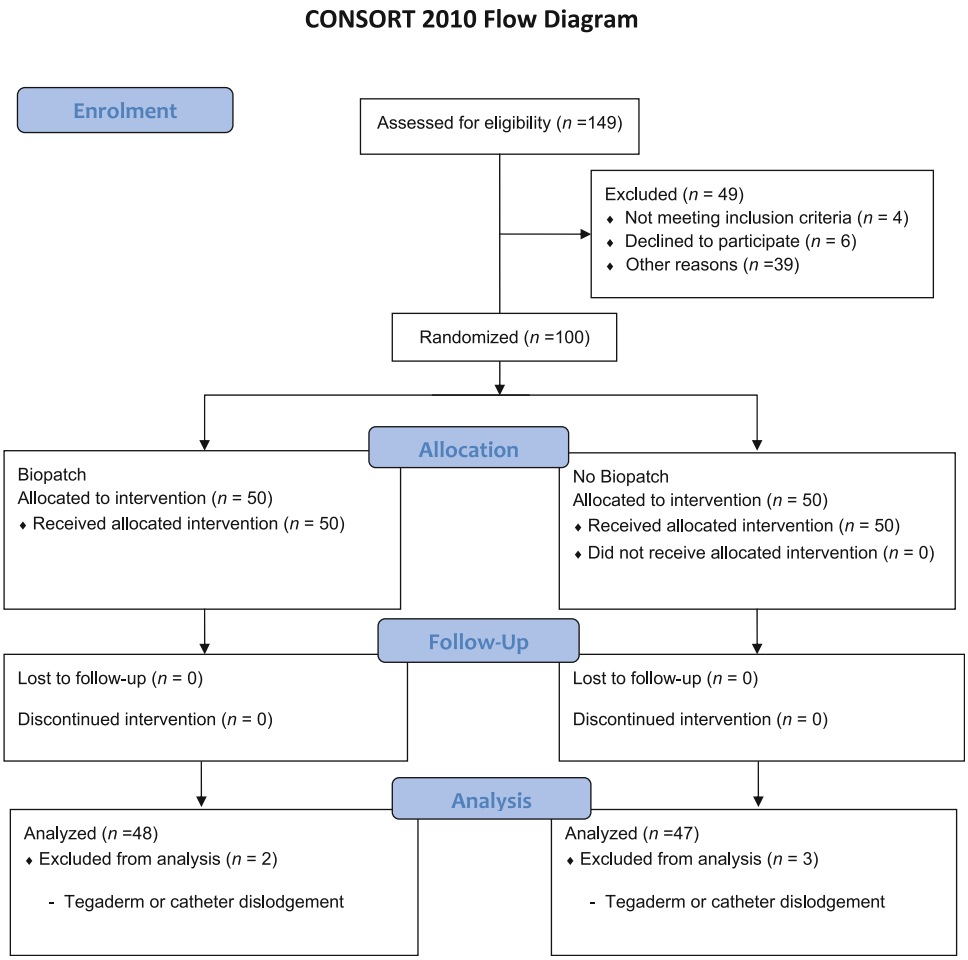
Cuvillon *et al.* have reported a high incidence (57%) of femoral nerve catheter bacterial colonization. The etiology of their increased incidence is unclear, but it may have been related to the use of iodine for skin preparation.[6] Capdevila *et al*. reported one abscess and a 28.6% incidence of femoral nerve catheter colonization in 683 femoral nerve catheters. Iodine was again used for skin preparation, and the infusion was continued for a longer duration than the previous study so the etiology for the decrease in colonization is unclear.[7] Aveline *et al.* reported a 9% incidence of bacterial colonization in femoral nerve catheters placed under ultrasound guidance with either chlorhexidine or iodine skin decontamination.[8] Compere *et al.* found that the incidence of colonization could be reduced to 11.7% with catheter tunneling and chlorhexidine skin preparation.[10]

The pathogenesis of catheter colonization and eventual infection has been well documented. Most catheter-related infections of short-term devices are thought to originate from cutaneous sources. Bacteria are thought to migrate extraluminally from the insertion site along the length of the catheter.[21] A study of epidural catheter bacterial contamination was able to show that infection/contamination of the skin surrounding the epidural catheter exit site was associated with an increased risk of catheter colonization. The authors suggested that their results showed the role of bacterial migration along the catheter and the need for strict asepsis of the catheter entry site.[22] Bacterial colonization of the catheter has been previously validated as a reasonable surrogate end-point for catheter-related bloodstream infections.[11]

The bacteria isolated in nearly all studies of bacterial colonization in percutaneous devices represent some form of normal skin flora turned pathogenic following violation of

[A] Biopatch package insert. Ethicon, Inc., Somerville, NJ, USA.

Figure CONSORT 2010 flow diagram



the skin's protective barrier. *Staphylococcus epidermidis* represents the most commonly identified pathogen in nearly all studies. Gram-negative bacilli (*Klebsiella*, *E. coli, Enterobacter*, *Citrobacter*, *Serratia*, and *Pseudomonas*), *Staphylococcus aureus*, and Gram-positive bacilli are also commonly found when perineural catheters are cultured.[6-10] This again shows the importance of strict asepsis when performing placement of peripheral nerve catheters. Handwashing, use of protective barriers (masks, gloves, gowns, and drapes), and appropriate selection of skin disinfectants are all clearly highly important with regard to prevention of catheter colonization and infection.

In summary, the baseline rate of bacterial colonization of femoral nerve catheters is quite low when placed in the setting of short-term use, chlorhexidine skin decontamination, ultrasound guidance, subcutaneous tunneling, and perioperative antibiotic therapy. This randomized trial did not show any benefit to using the BIOPATCH in this patient population. Given the very low colonization rate, much larger trials would be required to detect a difference in catheter colonization rates. Also, it should be determined if routine use of the BIOPATCH is economically responsible to prevent nerve catheter colonization in this patient population.

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Competing interests None declared.

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