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Two per cent alcoholic chlorhexidine *versus* alcoholic five per cent povidone-iodine for the prevention of perineural catheter colonisation: The CHLOVEPI randomised, controlled trial

Hakim HARKOUK^{1,2*}, Tristan THIBAUT-SOGORB¹, Alain BEAUCHET³, Florence ESPINASSE⁴,
Christine LAWRENCE⁵, Valeria MARTINEZ^{2,6} and Dominique FLETCHER^{1,2}

¹ Service d'Anesthésie-Réanimation, Hôpital Ambroise Paré, Boulogne-Billancourt, France

² Unité INSERM U987, Université Versailles Saint-Quentin, Versailles, France

³ Unité de recherche clinique, Hôpital Ambroise Paré, Boulogne-Billancourt, France

⁴ Service de microbiologie, Hôpital Ambroise Paré, Boulogne-Billancourt, France

⁵ Service de microbiologie, Hôpital Raymond Poincaré, Garches, France

⁶ Service d'anesthésie, Hôpital Raymond Poincaré, Garches, France

***Address correspondence to:** Hakim Harkouk, MD

Department of Anaesthesia, CHU Ambroise-Paré, 9 Avenue Charles De Gaulle, 92100

Boulogne-Billancourt, France

E-mail: hakim.harkouk@aphp.fr

ABSTRACT

Background: Multimodal analgesia, including a regional technique using perineural catheters (PNCs), is recommended for the treatment of moderate-to-severe acute postoperative pain. Perineural catheters are at risk of bacterial colonisation. In this study, we compared the cutaneous antiseptic efficacy of 2% alcoholic chlorhexidine and povidone-iodine-alcohol for preventing the bacterial colonisation of PNCs in orthopaedic surgery.

METHODS: We performed a randomised, controlled trial, comparing two cutaneous antiseptics strategies, one based on 2% alcoholic chlorhexidine and the other on povidone-iodine-5% alcohol, for placed PNCs before orthopaedic surgery. The primary endpoint was the incidence of catheter bacterial colonisation (threshold > 1000 colony-forming units/ml). The secondary endpoints were the incidence of catheter-related infections and the adverse effects of the antiseptic solutions.

Results: From November 2016 to May 2018, we included 113 patients in this study. The use of alcoholic chlorhexidine was associated with a lower incidence of catheter colonisation (15.5% (n = 9) *versus* 32.7% (n = 18); OR: 0.28 [0.09-0.77], $p = 0.01$). No catheter-related infections or adverse effects of antiseptic solutions were observed in either group. The risk factors associated with colonisation were a duration of catheter use ≥ 3 days ($p = 0.04$) and obesity ($p = 0.005$). The most frequently identified bacterium was *Staphylococcus epidermidis*.

CONCLUSION: Skin disinfection with 2% alcoholic chlorhexidine decreases bacterial colonisation rates for placed perineural catheters.

Keywords: chlorhexidine, perineural catheter colonisation, povidone-iodine-alcohol and skin antiseptics.

INTRODUCTION

Acute postoperative pain is managed with multimodal analgesic strategies including peripheral nerve blocks, which seem to be particularly effective at decreasing opioid prescription on the day of surgery [1].

Published perineural catheter (PNC) colonisation rates ranged from 6.2 to 57%, whereas the rates of less frequent catheter-related infections range from 0 to 3.2% [2–7]. These large variations can be explained by the heterogeneous design of published studies (different antiseptics, multiple insertion sites, various colonisation thresholds, different culture and quantification methods, antiseptic before catheter ablation, tunnelling etc.). Various techniques for reducing the infection risk, such as antiseptic-bearing dressings, catheter tunnelling, and antibacterial filters, have been proposed, but their efficacy has not yet been formally demonstrated [8].

Antiseptic solutions have recently been studied for other indications of placed catheters [9–13]. The most recent study concerned cutaneous antisepsis for intravascular central catheters placement, and highlighted the superiority of 2% alcoholic chlorhexidine [14]. Indeed, the use of 2% alcoholic chlorhexidine has been reported to decrease the risk of catheter-related bacterial infection by a factor of 6 (RR: 0.15, 95% CI [0.05-0.41]) and that of catheter colonisation by a factor of 5 (RR: 0.18, 95% CI [0.13-0.24]) relative to povidone-iodine-5% alcohol. However, no randomised controlled trial comparing the impact of cutaneous asepsis with 2% alcoholic chlorhexidine on the bacterial colonisation of PNCs for orthopaedic surgery with that of povidone-iodine-5% alcohol has yet been reported.

We hypothesised that the use of 2% alcoholic chlorhexidine for cutaneous antisepsis during the placement of PNCs in orthopaedic surgery would be more effective than povidone-iodine-5% alcohol for decreasing the bacterial colonisation of PNCs.

METHODS

In accordance with the French law, ethics approval for this study was obtained from the "CPP IDF 8", and the written informed consent was obtained from all patients included [15]. This protocol has been registered with ClinicalTrial.gov (NCT02950246). Adult patients with an ASA score of I-III selected for scheduled orthopaedic surgery or emergency post-traumatic surgery and requiring a PNC for postoperative analgesia were included prospectively from November 2016 to May 2018 in this study by a single university hospital group in France (Hôpitaux Universitaires Paris Ile De France Ouest). Pregnant or breastfeeding women, and patients with contraindications for the use of iodine solution or chlorhexidine, or for perineural catheterisation were not included. The exclusion criteria were: refusal of regional anaesthesia, failed PNC placement, accidental removal of the catheter tip, need to change the dressing involving the use of a new antiseptic solution, or the catheter not being sent to the bacteriology department for analysis.

Patients were randomised to the "povidone-iodine-5% alcohol" (PIA) group or the "2% alcoholic chlorhexidine" (AC) group, in blocks of two, with a computer-generated randomisation table and R software©. In case of femoral PNC placement, preoperative cutaneous preparation with inguinal clipping was performed the day before surgery. In all cases, the patient was instructed to take a shower, using a mild soap and no antiseptic, on the morning of surgery. PNCs were implanted under aseptic conditions, before surgery. The anaesthetist performed surgical hand rubbing with mild soap, followed by surgical

disinfection of the hands with hydroalcoholic gel, and then donned surgical clothing (sterile gown, surgical mask, hat and sterile gloves). The antisepsis protocol was selected at random. For the PIA group, the area of puncture was cleaned with antiseptic soap (Betadine scrub® 4%, Meda Pharma), rinsed with 0.9% NaCl solution and allowed to dry in air, in accordance with the local protocol, and povidone-iodine-alcohol (5% Alcoholic Betadine®, Meda Pharma) was then applied. For the AC group, the puncture area was not cleaned, and 2% coloured alcoholic chlorhexidine was applied without an applicator (Bactiseptic®, Vesism Health). The rest of the procedure was similar in both groups and followed SFAR recommendations for the placement of a PNC [16]. Incision drapes, positioned after disinfection of the cutaneous zone, delimited the area of puncture (100 cm²). All catheters were positioned under ultrasound control, with a sterile protective sheath covering the ultrasound probe and its cable. A sterile single-dose gel was used with the ultrasound probe. The procedure involved no skin tunnelling to cover the catheter. Once the catheter was in position, a sterile, transparent dressing was applied (Tegaderm™) for monitoring of the puncture site. A single antibacterial filter was used for the entire duration of catheter use.

After each procedure, the ultrasound probes and cables were wiped, cleaned and disinfected by the operator, using a wipe and disinfectant cleaning spray (Surfa'Safe® ANIOS). Finally, the entire ultrasound machine was cleaned every evening at the end of the operating program [17]. It was not possible to blind the operator to the skin preparation product used, but the anaesthetist and nurse in the ward and the bacteriologist analysing the catheters were blind to the group to which the patient was allocated.

The anaesthetist and nurse monitored the PNC insertion site and checked for systemic signs of infection (fever, local inflammation and swelling) daily. If the dressing was accidentally

removed, the dressing was redone with an antiseptic solution, and the patient was then excluded from the study. The decision to remove the PNC was taken by the anaesthetist, according to standard management criteria, for reasons of catheter infection or to stop analgesia. The duration of catheter use was noted. The catheter was removed by a nurse according to a defined protocol: hand rubbing with hydroalcoholic gel and the wearing of sterile mask and cap; the skin was not disinfected; the edges of the dressing were peeled back with sterile gloves, and the catheter was then removed and the final 2 cm of the catheter was removed with sterile scissors. The catheter tip was placed in a sterile tube and sent immediately to the bacteriology department, for quantitative culture, as described by Brun-Buisson et al. [18]. All colony types were counted at 24, 48 and 72 h and identified by standard methods.

The primary outcome measure was the incidence of bacterial colonisation of the PNC, defined as positive cultures containing more than 1000 colony-forming units per millilitre (CFU/ml). If more than one bacterial population was identified, then the number of CFUs was determined separately for each type of bacterium. For the analysis, we considered only bacterial types for which > 1000 CFU/ml were present [18]. Assuming a frequency of catheter colonisation of 40% in the absence of treatment, the demonstration of a relative reduction in frequency of 80% on treatment, for a power $1 - \beta$ of 80%, an alpha risk of 5% and an anticipated 20% missing data, it would be necessary to include a total of 110 patients. This calculation is based on the incidence of 40% observed for colonisation in a pilot study we performed on 26 PNCs and the 80% (RR: 0.18 (95% CI 0.13–0.24) decrease in such colonisation reported by Mimoz et al. [19].

The secondary outcomes considered were the incidence of PNC-related infections, defined as the occurrence of an abscess or systemic infection, and the incidence of antiseptic-related local or systemic adverse events.

Quantitative data are expressed as the mean \pm standard deviation (SD) and median, and qualitative data are expressed as frequencies and percentages. Means were compared in Student's *t*-test. Frequencies were compared in Chi-squared tests and the Fisher's exact tests, as appropriate. We considered *p*-values < 0.05 to indicate statistical significance.

Risk factors with a *p*-value < 0.2 in univariate investigation were included in the multivariate analysis. Logistic regression modelling was used to compare associations between risk factors and PNC colonisation. Statistical analysis was performed with R software version 3.0.2.

RESULTS

From November 2016 to May 2018, 160 single catheters were randomised. Of these, 47 were excluded from the study due to an absence of bacteriological data (catheters not sent to the bacteriology department, accidentally removed or removed by a procedure not conforming to the standardised protocol). In total, 113 catheters were analysed (Figure 1).

The characteristics of the patients and procedures were similar between groups (Table 1). For the primary endpoint, the incidence of catheter colonisation was 15.5% ($n = 9$) in the AC group, *versus* 32.7% ($n = 18$) in the PIA group ($p = 0.03$). Regarding the secondary endpoints, no infections or adverse effects related to antiseptic products were reported in either of the groups (Table 2).

Risk factors related to colonised catheters are presented in Table 3. Multivariate analysis identified the risk factors independently associated with bacterial colonisation as a duration of catheter use ≥ 3 days (OR: 5.13 [1.23-35.85], $p = 0.04$) and obesity (OR: 4.31 [1.58-12.54], $p = 0.005$). Antisepsis with alcoholic chlorhexidine reduced the risk of bacterial colonisation of peripheral PNCs by a factor of four (OR: 0.28 [0.09-0.77], $p = 0.01$) (Table 4).

Finally, the most frequently identified bacterium was *Staphylococcus epidermidis* (Table 4). Only one PNC with a multiple germ colonisation bacterial populations was identified with: *Enterobacter aerogenes*, *Enterococcus faecalis* and *Morganella morganii*. The bacterial colonisation quantification was inferior to 1000 CFU/ml, and the patient was excluded because of accidental removal of PNC (accidental removal of the PNC at day 1 after surgery during a physiotherapy session).

DISCUSSION

We report here that 2% alcoholic chlorhexidine significantly decreases the bacterial colonisation of PNCs relative to 5% povidone-iodine-alcohol (15.5% (n = 9) *versus* 32.7% (n = 18); OR: 0.28 [0.09-0.77], $p = 0.01$). This finding is consistent with the results of many studies comparing the efficacy of chlorhexidine and iodine solution, which have provided evidence of the superiority of chlorhexidine for preoperative skin disinfection [10–14,19]. However, the methods used in these previous studies were highly heterogeneous: comparisons of aqueous and alcoholic solutions [10,13], retrospective studies [12,14], use of different sites or clinical situations to assess asepsis, but with most concerning preoperative skin disinfection. It is therefore difficult to establish a very high level of evidence in favour of the use of chlorhexidine. To our knowledge, the study providing the highest level of evidence to date is that of Mimoz et al. [19]. These authors performed a large randomised controlled trial, in which they demonstrated the superiority of 2% alcoholic chlorhexidine over povidone-iodine-alcohol for decreasing the incidence of central catheter-related infections (RR: 0.15, 95% CI [0.05-0.41]) and the bacterial colonisation (RR: 0.18, 95% CI [0.13-0.24]) of these catheters. Interesting, the effect size observed in our study is close to that reported by Mimoz et al. [19].

Our colonisation rate was 23.8% in the general population. It is difficult to compare this rate of colonisation with that in published trials on the prevention of PNC colonisation, due to considerable heterogeneity in the methodology of published studies (different antiseptics before catheter placement, different insertion sites, different definitions of the threshold for bacterial colonisation, different methods of culture and bacterial quantification, disinfection before catheter ablation [20], tunnelling [6,21], and duration of use [4]. For example, Aveline et al. [7], using an alcoholic antiseptic solution (0.5% alcoholic chlorhexidine) and the same

definition of colonisation as we used here, reported an incidence of bacterial colonisation of 10.4%. The large difference between the results of their study and ours can be explained by the longer median duration of catheter use in our study (3 days *versus* 2 days in the study by Aveline et al.). We also included a larger proportion of femoral PNCs (83% *versus* 62% in the study by Aveline et al.), this site being known to be associated with a high infectious risk [22].

In our study, 14% of the population had a diabetes mellitus which could impair tissue perfusion and wound healing [23]. Diabetes mellitus is identified as a risk factor for PNC infection [7,24] but we were unable to detect it as a risk factor for PNC colonisation in our study probably due to the small patient sample size.

Several pathophysiological pathways leading to the bacterial colonisation of PNCs and infection have been identified [9]: blood diffusion; contamination of infused drugs; pathogen penetration into the body via the catheter. This last mechanism is the most widely accepted, and is used as a justification for effective and prolonged cutaneous antiseptics [8,9]. Chlorhexidine gluconate has potent germicidal properties, with broad-spectrum antibacterial and anti-fungal activities. It acts by altering membrane permeability, causing an immediate precipitation of the membrane and intracytoplasmic components [25]. It can also adhere to the corneal layer of the epidermis, which extends its duration of action, and leads to its remaining effective in the presence of organic compounds such as those of the blood. These properties suggest that alcoholic chlorhexidine should be superior to povidone-iodine-alcohol for disinfection purposes, consistent with our results.

Our study has several limitations. Firstly, there were a large number of exclusions (n = 47, 29.3%) due to catheters not being sent to the bacteriology department after their removal.

Despite briefings on the study and the dissemination of protocols for catheter removal, there was a high turnover of nurses, many of whom were not informed of the study and removed catheters without sending them to the bacteriology department. We therefore cannot exclude the possibility of a larger number of excluded colonised catheters in the alcoholic chlorhexidine group explaining the observed difference in colonisation rates. Secondly, we chose the rate of catheter colonisation rather than the rate of infection as the primary outcome. Rates of PNC colonisation with bacteria appear to be high, but clinically relevant infections are rare [5,7,8]. In studies with an alcoholic solution, the rate of PNC infection varied from 0 to 0.1% [6,7]. There is no clear consensus definition of PNC infection in the literature, and definitive criteria for distinguishing between infection and inflammation are lacking. PNC infection may be defined as the presence of local signs of inflammation, a purulent catheter site exudate and systemic signs of infection, or simply as the presence of two of the following three symptoms: redness, swelling, and pain [26]. It is not possible to conclude from our results that the use of chlorhexidine would decrease the rate of PNC infection. Thirdly, in the absence of data on antimicrobial efficacy for chlorhexidine concentrations of 2% and 0.5%, recent guidelines have favoured using 0.5% of chlorhexidine [26]. There is evidence to suggest that 2% chlorhexidine use may be associated with ototoxicity [27], irreversible damage to the cornea following minimal splash exposure [28] and severe cutaneous allergic reactions in 3% of cases [19]. The absence of adverse effects in our report is not, therefore, a total guarantee of safety. Finally, our population was heterogeneous in terms of patient risk factors (diabetes, emergency care) and PNC sites, but we were unable to perform a subpopulation analysis due to the limited number of patients included.

Despite the very heterogeneous nature of the studies performed to date, academic societies in Britain and Ireland have already proposed recommendations for the use of alcoholic chlorhexidine in cutaneous antisepsis for central venous or neuraxial catheters [26]. We believe that our results have important implications for daily clinical practice and that anaesthetists should be aware of the superiority of chlorhexidine in this context.

In conclusion, by reporting a reduced bacterial colonisation rate, the present study supports the use of 2% alcoholic chlorhexidine for indwelling perineural catheters.

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Conflicts of Interest:

DF received honoraria from Grunenthal and Biocodex; VM received honoraria from Grunenthal, Mundipharma and Pfizer; the remaining authors have no conflict of interest to declare.

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Authors' contributions:

HH, DF: study conception and design, patient recruitment, acquisition of data, analysis and interpretation of data, drafting, redaction and revision of the article; TTS: acquisition of data, analysis of data; AB: statistical analysis, data analysis and revision of the article; FE, CL: analysis of data and substantial contribution to revising the article; VM: analysis and interpretation of data, substantial drafting and revision of the article.

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160 catheters randomised

Exclusions: $n=47$

- Catheters not sent ($n=40$)
- Catheters accidentally removed ($n=5$)
- Non-conformity of catheter removal ($n=2$)

113 catheters analysed (70.7%)

**2% alcoholic chlorhexidine:
 $n=58$ (52.4%)**

**5% alcoholic iodine:
 $n=55$ (48.6%)**

Fig. 1: Flowchart

Table 1 : Demographics

	Global	2% alcoholic chlorhexidine	5% alcoholic iodine
	<i>n</i> =113	<i>n</i> =58	<i>n</i> =55
Age (years)	67.1±14.8	68.4±13.3	65.7±16.2
Sex (M)	47(41.6)	25(43.1)	22(40)
ASA score			
1	10(8.8)	4(6.8)	6(10.9)
2	85(75.2)	42(72.4)	43(78.2)
3	18(15.9)	12(20.7)	6(10.9)
Immunodepression	1(0.9)	1(1.7)	0(0)
Diabetes mellitus	16(14.2)	10(17.2)	6(10.9)
Corticosteroid treatment	1(0.9)	1(1.7)	0(0)
Antibiotic treatment	3(2.7)	3(5.2)	0(0)
Emergency admission	7(6.2)	5(8.6)	2(3.6)
Catheter sites :	89(78.8)	45(77.6)	44(80)
- Femoral	17(15)	7(12)	10(18.2)
- Interscalene	7(6.2)	6(10.3)	1(1.8)
- Popliteal			
Prophylactic antibiotic treatment	109(96.5)	56(96.6)	53(96.3)
Duration of catheter use (days)	2-3-3	2-3-3	2-3-3
≥ 2 days	104(92)	53(91.4)	51(92.7)
≥ 3 days	80(70.8)	39(67.2)	41(74.5)

The results shown are the mean ± SD, n (%) or median (Q1-Q2-Q3).

ASA : American Society of Anesthesiology

Immunodepression: patients treated with immunosuppressors, with polynuclear neutrophil counts <500/mm³ or immunodeficiency disease

Table 2 : Primary and secondary endpoints

	Global <i>n</i> =113	2% alcoholic chlorhexidine <i>n</i> =58	5% alcoholic iodine <i>n</i> =55
Incidence of catheter colonisation	27 (23.8%)	9 (15.5%)	18 (32.7%)
Incidence of catheter infection	0	0	0
Incidence of adverse effects	0	0	0

The results are shown as *n* (%) and Chi²-test comparisons

Table. 3 : Risk factors related to colonised catheters

	Colonised catheters n=27	Uncolonised catheters n=86	<i>p</i>
Age (years)	66.9 ± 14.5	67.1 ± 15.0	0.95
Sex (M)	12 (44.4%)	35 (40.7%)	0.90
Obesity (BMI>30 kg/m ²)	15 (55.5%)	22 (25.6%)	0.005
ASA score :			
1	1 (3.7%)	9 (10.5%)	-
2	21 (77.8%)	64 (74.4%)	0.60
3	5 (18.5%)	13 (15.1%)	-
Immunodepression	0	1 (1.2%)	-
Diabetes mellitus	4 (14.9%)	12 (14%)	0.91
Corticosteroid treatment	0	1 (1.2%)	-
Antibiotic treatment	1 (3.7%)	2 (2.3%)	-
Emergency admission	2 (7.4%)	5 (5.8%)	0.67
Indwelling catheter sites :			
- Femoral	25 (92.6%)	64 (74.4%)	0.16
- Interscalene	2 (7.4%)	15 (17.4%)	
- Popliteal	0	7 (8.1%)	
Antibiotic prophylaxis	25 (92.6%)	84 (97.7%)	0.24
2% alcoholic chlorhexidine	9 (33.3%)	49 (57.0%)	0.017
Duration of catheter use (days)	2-3-3	2-3-3	-
≥ 2 days	27 (100%)	77 (89.5%)	0.11
≥ 3 days	25 (92.6%)	55 (64.0%)	0.046

The results are shown as the mean ± SD, n (%) or median (Q1-Q2-Q3).

ASA : American Society of Anesthesiology

Table 4 : Multivariate analysis of risk factors related to catheter colonisation

	<i>p</i>	OR[95% CI]
2% alcoholic chlorhexidine	0.01	0.28 [0.09-0.77]
Duration of catheter use \geq 3 days	0.04	5.13 [1.23-35.85]
Obesity (BMI>30 kg/m ²)	0.005	4.31 [1.58-12.54]
Femoral site*	0.99	-
Interscalene site*	0.99	-

* vs popliteal

Logistic regression - OR : Odds ratio - 95% CI : 95% confidence interval

Table 5 : Identification of the bacteria colonised catheters

	Colonised catheters <i>n</i> =27
<i>Staphylococcus epidermidis</i>	13
<i>Staphylococcus aureus</i>	1
<i>Staphylococcus lugdenensis</i>	3
<i>Staphylococcus capitis</i>	1
<i>Morganella morgani</i>	1
<i>Enterobacter aerogenes</i>	1
<i>Escherichia coli</i>	2
<i>Proteus mirabilis</i>	1
<i>Klebsiella oxytoca</i>	1
<i>Citrobacter Koseri</i>	1
<i>Pseudomonas aeruginosa</i>	2