Clinical controlled trial on central venous catheter dressings*

Ensaio clínico controlado sobre o curativo de cateter venoso central

Ensayo clínico controlado sobre la cobertura de catéter venoso central

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ABSTRACT
Objective: To evaluate the effectiveness of gauze and tape as compared to transparent polyurethane film for dressing central venous catheters.

Methods: A randomized controlled clinical trial was conducted. Results: No significant difference was identified in catheter-related infection (p = 1) or the stability of the dressing (p = 0.670). There was no statistically significant difference with respect to the absorption of exudate (p <0.001). The likelihood of local reaction in the control group (gauze and tape) was different from the study group (p = 0.024). Conclusion: The type of dressing does not decrease the incidence of catheter-related infection, the binding capacity is similar, and the gauze dressing has the capacity to absorb exudate. However, the gauze dressing resulted in a higher probability of developing a local reaction. Record WHO: ACTRN12609000951257.

Keywords: Central venous catheter; Clinical trial; Infection; Bandages

RESUMO
Objetivo: Avaliar a eficácia dos curativos de gaze e fita e filme transparente de poliuretano para cobertura de cateteres venosos centrais.

Métodos: Ensaio clínico controlado randomizado. Resultados: Não foi identificada uma diferença significativa com relação à infecção relacionada ao cateter (p=1) e à fixação do curativo (p=0,670). Foi identificada diferença estatisticamente significativa com relação à absorção de exsudato (p<0,001). A probabilidade de ocorrer reação local no grupo controle é diferente do grupo estudo (p=0,024).

Conclusão: O tipo de curativo não diminui a incidência de infecção relacionada ao cateter, a capacidade de fixação é semelhante, o curativo de gaze e fita possui capacidade de absorção de exsudato, porém apresenta probabilidade maior de desenvolver reação local. Registro WHO: ACTRN12609000951257.

Descritores: Cateterismo venoso central; Ensaio clínico; Infecção; Bandagens

RESUMEN
Objetivo: Evaluar la eficacia de las curaciones de gasa y fita y película transparente de poliuretano para la cobertura de catéteres venosos centrales.

Métodos: Ensayo clínico controlado randomizado. Resultados: No se identificó una diferencia significativa con relación a la infección relacionada al catéter (p=1) y a la fijación de la curación (p=0,670). Fue identificada la diferencia estadísticamente significativa con relación a la absorción del exudado (p<0,001). La probabilidad de que ocurra reacción en el lugar en el grupo control es diferente al grupo de estudio (p=0,024).

Conclusión: El tipo de curativo no disminuye la incidencia de infección relacionada al catéter, la capacidad de fijación es semejante, la curación de gasa y cinta posee capacidad de absorción de exudado, sin embargo presenta probabilidad mayor de desarrollar reacción local. Registro WHO: ACTRN12609000951257.

Descritores: Cateterismo venoso central; Ensayo clínico; Infección; Vendajes

* Study performed in August 2008, at the General Intensive Care Unit of Hospital Universitário de Curitiba (PR), Brazil.

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INTRODUCTION

The use of central venous catheters (CVC) in the hospital environment is common, mainly in Intensive Care Units (ICU). Their use is due to the need for large solution volume and vasoactive drugs intake, parenteral nutrition administration, and the need for hemodynamic monitoring, among other indications.

Although widely used, these devices expose clients to complications, such as blood stream infection, thrombosis, pneumothorax, among others. Complications are important morbidity and mortality causes, for they exacerbate the clinical state.

Considering that CVCs are responsible for a significant rate of hospital infections, it is essential to be careful with their maintenance by: cleaning the catheter insertion area with 0.5% chlorhexidine-alcohol; applying sterile occlusive dressings; inspecting and palpating the catheter ostium; cleaning the connections with 70% alcohol; strictly controlling the solutions taken in and the connections expiration date.

Blood stream infections are responsible for 10-15% of all hospital infections. In the United States, 87% of the blood stream infections are estimated to be originated from catheters. In Brazil, the catheter-related blood stream infection rate is of 17.05/1000 invasive devices a day, considering a 95% percentile. Although this type is not the main among hospital infections, it accounts for losses to the health institution, since it increases admission and treatment time, and puts clients’ lives at risk.

The central venous access dressing is important to protect the catheter insertion site from bacteria colonization. Currently, there are different types of dressing available in the market, with the tape and gauze and the transparent polyurethane film comprising the most used type. These dressings present variations regarding durability, application, skin reaction development risk, and infection prevention capacity.

Considering the CVC dressing importance in reducing catheter-related infections, and due to the fact nurses are the professionals responsible for applying them, the present study focuses on such care practice.

The study objectives were: to assess the effectiveness of the tape and gauze dressing and the transparent polyurethane film dressing covering central venous catheters; to compare the tape and gauze and the transparent film dressings with regard to: catheter-related infection occurrence, material fixation quality, exudate absorption capacity, and the client local reaction to the dressing material; and to promote quality nursing care, based on scientific evidence.

METHODS

Ethical Aspects

This study was preceded by the approval of the Committee for Ethics and Research of a Federal University (n.ºCAAE 0048.0.091.000-07), in compliance with resolution nº196/96 of the Conselho Nacional de Saúde (National Health Department). The Informed Consent Term was also signed.

Study design, period, and location

The present is a randomized controlled clinical trial, performed in August 2008, in the Intensive Care Unit of Hospital Universitário de Curitiba-PR (Curitiba School Hospital).

Population

The sample was comprised of 21 catheters, used by clients over 18 years old, whose catheters were of the non-tunneled type, and who were included in the study within the first 24 hours of ICU admission, or within the first 8 hours after the catheter insertion. No patients presented intolerance to the dressing material, and the research protocol was not violated.

Research Protocol

A drawing was performed to allocate individuals in the control or study groups, as described below:

Control Group – The routine dressing for catheter ostia was used, with 0.5% chlorhexidine-alcohol, sterile gauze and a permeable hypoallergenic micropore, with 50mm x 10m.

Study Group – The intervention was performed with the application of 0.5% chlorhexidine-alcohol, and a transparent polyurethane film dressing (Tegaderm® IV from 3M). The dressings exchange was daily performed in the control group, and once every seven days or when exudate or displacement were presented in the study group. The dressings were applied by the researchers themselves, with rigorous aseptic techniques.

A form, validated during data collection, was used for the variables collection, observation and follow up. An educational program was offered to the unit employees regarding the research protocol, according to other studies recommendations.

The catheter ostium was daily assessed and photographed by the researchers with regard to the presence of: hyperaemia, edema, cyanosis, exudate, exudate absorption by the chosen material, dressing fixation, skin maceration, skin exfoliation, local reactions to the dressing material, and solution infiltration. Clients were assessed concerning their body temperature (if above 38°C) and the use of antimicrobials.

The catheter-related infection was characterized through two hemocultures and/or positive catheter tip culture (> 15 CFU, using the semiquantitative method), associated to one or more of the following signals and symptoms: hyperaemia, edema, purulent exudate of up.
to 2 cm of the catheter length, and body temperature above 38°C.

Clients who presented clinical signs of catheter-related infection had two samples of their blood collected for hemoculture, one peripheral sample, and one collected through the CVC. In some cases, the catheter tip was sent to the laboratory for culture. Samples were analysed through the semiquantitative method.

The absorption capacity was considered appropriate in more than 70% of the observations; the dressing material satisfactorily absorbed the exudate, preventing buildups in the catheter ostium. The dressing fixation was considered good when in more than 70% of cases the dressing kept attached to the skin for 24 hours.

The local reaction to the material was verified through skin exfoliation, maceration, and/or allergic reactions presented where the selected material was in contact with the skin. The presence of one or more of such symptoms was considered to be a reaction.

The outcome variables assessed were: 1 – Catheter-related infection; 2 – Dressing fixation to the skin; 3 – Exudate absorption by the dressing material; and 4 – Local reaction to the dressing material.

The results obtained in the study were expressed through averages and standard deviations (quantitative variables), or frequencies and percentages (qualitative variables). Fisher’s exact test was used in order to assess the association among dichotomous qualitative variables. When comparing two groups regarding quantitative variables, Student’s t-test was used for independent samples. Values of p<0.05 indicated statistical significance. Data were organized in an Excel spreadsheet and analysed through the EpiInfo v.6.0 program.

**RESULTS**

During the present study data collection, 21 central venous catheters were included, with 10 in the control group and 11 in the study group. All catheters were observed until removed and there was no lost to follow-up.

The variables “puncture location” and “catheter material” were similar for both groups and there was no significant difference for either one. According to Table 1, the lumen number and the reasons for removing the catheter presented different frequencies between the groups. With regard to permanence, there was a significant difference between groups (p=0.02), with a general average of 6.7 ± 2.6 days.

The permanence time of the transparent film ranged from one to four days, with an average of 1.9 days. The reason for anticipated exchange was related to low fixation in six cases (33%), low exudate absorption in two cases (11%), and catheter removal in 10 cases (56%).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Transparent Polyurethane Film (n=11)</th>
<th>Tape and Gauze (n=10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Material</td>
<td>11 100%</td>
<td>10 100%</td>
</tr>
<tr>
<td>Puncture Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Jugular</td>
<td>0 0%</td>
<td>1 10%</td>
</tr>
<tr>
<td>Subclavian</td>
<td>11 100%</td>
<td>9 90%</td>
</tr>
<tr>
<td>Catheter lumen number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two</td>
<td>10 91%</td>
<td>6 60%</td>
</tr>
<tr>
<td>Three</td>
<td>1 9%</td>
<td>4 40%</td>
</tr>
<tr>
<td>Catheter permanence time</td>
<td>5.4 ± 2.5 days</td>
<td>8.0 ± 2.2 days</td>
</tr>
<tr>
<td>Reason for removing the catheter</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colonization</td>
<td>3 27.2%</td>
<td>7 70%</td>
</tr>
<tr>
<td>Elective</td>
<td>4 36.4%</td>
<td>1 10%</td>
</tr>
<tr>
<td>Death</td>
<td>2 18.2%</td>
<td>2 20%</td>
</tr>
<tr>
<td>Other</td>
<td>2 18.2%</td>
<td>0 0%</td>
</tr>
</tbody>
</table>

All patients used antimicrobials concomitantly with the central venous catheter, either receiving only one type of drug (19%), or the association of two or more drugs (81%).

The global infection rate was 9.5%, namely 9% in the study group, and 10% in the control group, according to Table 2. With regard to the catheter-related infection, no significant difference was found between the two groups (p=1). A similar result was found concerning dressing fixation (p=0.670).

Microorganism growth was found in the CVC collected hemoculture, characterizing colonization, one of the main reasons for catheter removal (Table 1). The microorganisms identified were: *Staphylococcus epidermidis* (23.8%), *Enterococcus faecalis* (19%) and *Escherichia coli* (9.5%). The catheter tip cultures indicated that two devices (one from each group) contained *Acinetobacter baumannii* (9.5%).

Considering the total number of catheters, the most common signals and symptoms were: fever (62%), purulent exudate (19%) and hyperaemia (33%).

With regard to the exudate absorption variable, the tape and gauze group presented 100% absorption, and only 9% absorption was presented by the study group; the statistical difference between groups was significant (p<0.001).

Among all analysed catheters (n=21), considering their...
observation, some did not present exudate at the catheter ostium (18%), others presented bleeding exudate (32%), serous exudate (27%), bleeding and serous exudate (16%), and purulent exudate (7%).

There was a significant difference regarding local reaction between the two groups (p=0.024): the control group presented a 60% rate of local reaction, while the transparent film group presented only 9% of local reaction.

It was also possible to observe that patients with catheters for longer than seven days presented the same probability of developing catheter-related infections as patients with catheters for less than seven days (p=0.214).

**DISCUSSION**

The use of central venous catheters in Intensive Care Units is frequent, for they assist on clients’ treatment and recovery. However, such technology presents some disadvantages, because it exposes clients to complications associated to the increase of morbidity and mortality(2).

Considering the total number (n=21) of catheters used during the research, 9.5% of the subjects developed bloodstream infections as a complication. In a randomized clinical trial performed with 66 catheters, whose objective was to assess the effectiveness of tape and gauze and transparent film covering central venous catheters, a global infection rate of 10.6% was found, with 12.1% of cases in the transparent film group(11).

In the present study, the use of antimicrobials was observed in 100% of the cases, which is expected, considering the seriousness and clinical complexity of the studied population. Authors stated that the prophylactic use of antimicrobials does not determine decreased catheter infection rates(12), and the use of antimicrobials concomitantly to the CVC is a risk factor for infections(13).

Studies evidenced that the microorganism most commonly associated with catheter-related bloodstream infection is *Staphylococcus aureus*(515). In the present study, most catheters presented *Staphylococcus epidermidis* colonization.

A study performed with 37 CVCs, whose dressing used was the transparent film, along with chlorhexidine asepsis, found the hyperthermia (89.2%), the purulent exudate (27%), and the hyperaemia (18.2%) as the most prevalent signals and symptoms(11). These data confirm the present study results, which identified hyperthermia (62%) as the most common signal, followed by hyperaemia (33%), and the purulent exudate (19%).

In the control group, more triple-lumen catheters were used when compared to the study group. Studies are controversial concerning the influence of the number of lumens on catheter-related infections. The multi-lumen devices present a slightly higher rate of infection when compared to the mono-lumen catheters(19).

The reasons for catheter removal varied between the groups, but in the control group the main reason was the suspicion of catheter-related infection, which was not confirmed by laboratory exams. The higher incidence of infection signals can be related to the longer catheter use in the control group.

The Centre for Disease Control and Prevention – CDC recommends the tape and gauze use for diaphoretic clients, or for those who drain some type of exudate through the catheter ostium(3). Such recommendation was proven by this study, since the transparent dressing is not able to absorb exudate, and therefore, may facilitate clients’ blood stream infection.

The dressing fixation is important to keep it occlusive until the next exchange, and therefore, prevent catheter ostia colonization. It was possible to observe that the transparent dressing edges come off the skin easily, even when following the instructions recommended by the manufacturer, which confirms data found by other

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**Table 2 – Complications related to both patient groups in the Intensive Care Unit of Hospital Universitário de Curitiba (Curitiba School Hospital) - PR. August/2008**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Transparent Polyurethane Film (n= 11)</th>
<th>Tape and Gauze(n=10)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catherter-related infection</td>
<td>Yes 1 9</td>
<td>1 10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>No 10 91</td>
<td>9 90</td>
<td></td>
</tr>
<tr>
<td>Exudate Absorption</td>
<td>Yes 1 9</td>
<td>10 100</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>No 10 91</td>
<td>0 0</td>
<td></td>
</tr>
<tr>
<td>Dressing Fixation</td>
<td>Yes 7 64</td>
<td>5 50</td>
<td>0.670</td>
</tr>
<tr>
<td></td>
<td>No 4 36</td>
<td>5 50</td>
<td></td>
</tr>
<tr>
<td>Local Reaction</td>
<td>Yes 1 9</td>
<td>6 60</td>
<td>0.024</td>
</tr>
<tr>
<td></td>
<td>No 10 91</td>
<td>4 40</td>
<td></td>
</tr>
</tbody>
</table>

* Fisher’s exact test, p<0.05
studies on the theme\textsuperscript{16}.

Each person's skin characteristics can interfere in fixation quality, for diaphoretic clients, or clients who have oily skin present difficulties for dressing fixation in general, regardless of the material used.

The permanence of the transparent dressing was of 1.9 days, a lot less than the findings of another study, 5.1 days\textsuperscript{16}. The short permanence time found by the present study is related to the catheter removal, or to dressing problems, such as “low exudate absorption” (11%), and “low fixation” (33%).

A clinical trial performed with 101 subjects, comparing the transparent dressing with moderate permeability and permeability increased by steam, did not find differences between the two groups with regard to complications. Among the complications observed, “low exudate absorption”, with a consequent buildup between the dressing and the client's skin (11%) and “low fixation” of the dressing to the skin (19%)\textsuperscript{16}.

The tape and gauze dressing was associated to a higher probability of local reaction development, mainly where the tape was in contact with the skin. In the study group, although the incidence was lower, local reactions were observed in the region where the transparent tape adhesive part was in contact with the skin. It is relevant to highlight that both materials used were hypoallergenic. Besides the material used in the dressings, clients skin sensitivity and characteristics should be considered in order to prevent skin reactions.

Frequent dressing exchange is associated to increased skin reactions and clients’ discomfort. A multi-centered study performed with 169 non-tunneled catheters assessed the local infection development probability in two different intervals when dressings were being exchanged, every two or five days. All patients were using the transparent film. Decreasing the dressing exchange frequency reduced the skin reaction incidence without increasing the risk of infection\textsuperscript{17}, which was confirmed by another study on the theme\textsuperscript{18}.

Injuries caused by the frequent dressing exchange facilitate the microbial proliferation in the site, increasing the risk of infectious complications\textsuperscript{19}. In the present study, dressings exchanged every 24 hours (control group) presented an increased skin reaction incidence when compared to those exchanged with longer intervals (study group), which can be associated to the higher rate of local reaction in the first group.

The tape and gauze and transparent film can be used to cover CVCs, and the selection of the most appropriate material should consider the client’s clinical state, as well as his/her preference, in order to reduce catheter-related risks and complications.

Care technologies are important in order to enhance care quality and facilitate, in the majority of cases, professionals’ work. However, it is extremely important to judge each technology adequacy according to the service, as well as the professional ability to employ it. The transparent polyurethane film is a well-accepted technology in many institutions, but it should be used with caution.

The present study is limited due to its small sample size. However, differences found point to important aspects of the clinical practice, assisting in choosing the material used in the central venous catheter dressing. New randomized clinical trials should be performed in order to confirm the evidences here presented. There were no interest conflicts in the present study.

CONCLUSION

In the studied population, it was possible to confirm that the dressing type did not decrease catheter-related infection incidence, and that the material fixation capacity is similar for both materials. The gauze and tape dressing is able to absorb exudate, however, it presents a higher probability of causing local reactions.

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