Reviewer's report

Title: Efficacy and safety of a two-step method of skin preparation for peripheral intravenous catheter insertion - a prospective multi-centre randomised trial

Version: Date: 20 November 2006

Reviewer: Francisco Alvarez-Lerma

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Comments to the Authors

This is a prospective, multicenter, randomized study aimed to assess two methods of skin preparation prior to peripheral venous catheter insertion in 12 healthcare establishments. Local response is evaluated according to the Maddox scale in 6 grades, from local inflammatory response to purulence at the insertion site. The Maddox scale is not familiar to the reviewer and should be referenced. For each of the procedures of skin preparation, microbiological studies neither of the venous line nor of the patient have been carried out to assess the risk of local or systemic infection and/or colonization. Cost calculations are based on the assessment of times and savings of materials between both procedures.

Abstract (page 2)

1. The objective is the study is confusion. The authors should make clear whether the purpose of the study was to assess complications associated with each method, to determine whether there were differences in the level of compliance with guidelines of recommendations, or to decrease economic costs.
2. It is stated that 246 patients were randomized but in the Results (page 7) we are told that 248 peripheral venous catheters were evaluated, in Table 3 again 248 patients are repeated, and in Table 4 the number of insertions observed during the first 24 hours was 246. The number of catheters and the number of patients should be clarified (2 catheters in 1 patient?).
3. The Results section should include data, the interpretation of which supports the final Conclusions.

Introduction

1. This section is tool long and includes comments that belong to the Discussion (some points are repeated in the Introduction and in the Discussion). The second, third and fifth paragraphs should be moved to the Discussion with some modifications in reference to findings of the study.
2. In the second paragraph, it is stated that “the principal source of PVC contamination generally caused by migration of microorganisms from de surface of the skin to the interior the catheter”. Migration in this case takes place through the external surface of the catheter and may reach the catheter tip without identification of organisms in the interior of the catheter.
3. In many cases, local complications at the site of catheter insertion are related to a local inflammatory response of the host to the catheter’s material, inadequate mobilization by inappropriate fixation or administration of local irritant drugs rather than related to an infectious process. “Signs of infection” should be replaced by “precursor signs of infection”.
4. The acronym IVDs should be spelled out on first mention (page 4, line 8).

Materials and methods

1. Details of catheter brand and suppliers should be added. Criteria for the use of the different catheter should be specified.
2. Microbiological studies that would allow distinguishing colonization from infection were not included in the study protocol. No data on microbiological studies are provided, therefore, it is difficult to identify infections. The differentiation between phlebitis and thrombophlebitis should be included. The authors used incorrectly both terms indistinctively throughout the text
3. Details of randomization are lacking, e.g., randomization procedure, stratification variables for the two groups of patients (by center, central randomization procedure, telephone, closed envelopes?)
4. It is stated that this was a non-inferiority study or the purpose of which 231 patients per arm were necessary. The interruption of the study based on an interim analysis when half of the patients were recruited is not justified by the lack of differences between both procedures.
5. Data of approval by the institutional review boards are lacking.
6. Acronym AMM should be spelled out on first mention.
7. The first five lines of Analysis of data correspond to the objectives of the study and should be emphasized in the Introduction section.

Results

1. Although this is a multicenter study, no information is provided on the number of cases included in each center.
2. Page 7, paragraph 3, line 1: Signs of infection" should be replaced by "precursor signs of infection".
3. In Table 3, the duration of catheters is not included; it is mentioned the number of catheter evaluated at 24, 48, and 72 hours. It would be interesting to add the mean duration of catheters and the presence of complications in relation to the length of time of devices in place, with each catheter assessed once (at the time of withdrawal).
4. The evaluation of complications included in Table 4 is very interesting because presents the number of complications identified at 24, 48, and 72 hours. Some catheter have been assessed on a single occasion, others in two, and the remaining in three. It is unclear whether the same complication has been evaluated several times (e.g., erythema at 24 hours, 48 hours, and 72 hours?). It would be important to know catheter-related complications in respect to duration of catheter, with the assessment of each case only once, at the time of catheter withdrawal.
5. It is important to include data on the reasons for catheter removal (e.g., accidental catheter dislodgement, catheter no longer needed, infectious complications, etc.). The number of cases in which the catheter was removed because of phlebitis and/or thrombophlebitis should be added.
6. In the cost analysis, it is important to add data of duration of catheters in place and cost of treatment of catheter-related complications.

Conclusions

1. The statement of a decrease in the incidence of nosocomial bloodstream infection with the introduction of the two-step procedure should be deleted. It is not supported by present results since there were no significant differences in the rate of potentially infectious complications between both methods.
2. The sentence that the quality of skin preparation during venous catheter insertion has improved by the two-step procedure should be removed because this is not a conclusion of findings of the study.