Using maximal sterile barriers to prevent central venous catheter–related infection: A systematic evidence-based review

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Background: Catheter-related infections cause increased morbidity, mortality, and health care costs. Infection control experts advocate using maximal sterile barriers to reduce the incidence of these infections. Low compliance rates suggest that clinicians are not convinced or are not aware that available data support adopting this more cumbersome, time-consuming, and relatively more expensive technique. Accordingly, we conducted a systematic, evidence-based review of the medical literature to determine the value of maximal sterile barriers.

Data sources: We used multiple computerized databases, reference lists of identified articles, and queries of prominent investigators.

Study selection: We selected studies comparing infectious outcomes using maximal sterile barriers versus using less stringent sterile barrier techniques during central venous catheter insertion.

Data synthesis: We found only 3 primary research studies. Although each study suggests maximal sterile barriers may reduce infectious complications, the evidence supporting this conclusion is incomplete. The only randomized controlled trial limited enrollment to ambulatory oncology patients. These 3 studies differed notably in their patient populations, research designs, and health care settings.

Conclusion: The medical literature suggests maximal sterile barriers are advantageous in at least one setting and may be useful in others. While we believe the available evidence does support the use of maximal sterile barriers during routine insertion of central venous catheters, prospective studies and economic analyses would better clarify its value. (Am J Infect Control 2004;32:142-6.)

Central venous catheters (CVCs) are often required for providing patients in an intensive care unit (ICU) with total parenteral nutrition (TPN), certain medications, or cardiac monitoring. Ambulatory patients may also need a central line for receiving long-term intravenous medications or for frequent blood sampling.[1] Unfortunately, CVCs are commonly associated with infectious complications. Catheter-related infections include catheter colonization, local insertion site infection, and catheter-related bloodstream infection (CR-BSI). These infections contribute to increased morbidity, mortality, length of hospitalization, and health care costs.[2] The United States experiences 15 million central-line-days per year, with 5.3 CR-BSI per 1000 catheter-days in ICUs. Annually, these infectious complications are estimated to lead to between 2400 and 20 000 deaths and cost $296 million to $2.3 billion.[3-5]

Expert panels and authors of review articles recommend several interventions to reduce the number of catheter-related infections.[3,4,6] These interventions include using improved antiseptic skin preparations, antimicrobial catheters, and improved sterile technique during insertion. The sterile technique usually advocated is maximal sterile barriers (MSB), which require that the person inserting the CVC wear a head cap, facemask, sterile body gown, and sterile gloves and use a full-size sterile drape. Less stringent measures usually require only sterile gloves and a small regional sterile drape. Over a decade ago,

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Mermel[7] reported that CVCs inserted with MSB were associated with a lower risk for catheter-related infections. In subsequent years several experts and authoritative panels have recommended adopting this procedure.[3,4,6,8-11]

Although there is no precise estimate of MSB use, research studies and review articles have consistently noted compliance with MSBs in clinical practice to be relatively poor.[12-14] One study measured MSB compliance at 44%.[12] Although the cause of noncompliance is unclear, it is possible that clinicians are not convinced or are not aware that available data support adopting this more cumbersome, time-consuming, and relatively more expensive technique. We therefore conducted a systematic review of the literature to assess the efficacy of MSBs and to determine whether sufficient evidence exists to support routinely using this intervention during the insertion of CVCs.

METHODS

With the aid of a research librarian at the University of Washington, we conducted a thorough computerized search. We searched the MEDLINE database from 1966 to February 2003, limiting the results to articles in English and to human studies. The search strategy used several search sets. Search set No. 1 combined the following medical subject headings: (catheterization, central venous OR catheterization, Swan-Ganz OR catheters, indwelling) AND (asepsis OR expanded septicemia). Search set No. 2 combined the following text words: (maximal sterile OR maximal aseptic OR maximal aeseptic) AND (barrier* OR technique*) AND catheter*. Search set No. 3 combined the following text words: full barrier* AND catheter*. These 3 search statements were then combined with an OR. In addition, we searched the Cochrane Library, 2003 Issue 1, again using the medical subject headings catheterization, central venous or catheterization, Swan-Ganz or catheters, indwelling. Once the primary research studies were identified, we searched ISI Web of Science from 1975 through February 2003 for other studies that cited these headings. Finally, we contacted prominent investigators in this field and hospital infection control experts to attempt to identify any additional unpublished or ongoing studies. All identified studies comparing MSB and less stringent sterile barrier techniques were included in our analysis.

RESULTS

Our search methods identified more than 95 articles discussing the prevention of CVC-related infections. The majority of these articles were review articles or consensus statements. In their discussions regarding sterile techniques, many authors advocated using MSB during the insertion of CVCs.[3,4,6,8-11] Despite our extensive search, we found only 3 primary research studies comparing MSB with less stringent barrier techniques. We identified no additional unpublished or ongoing primary studies.

All 3 primary studies concluded that the use of MSB resulted in a reduction in catheter-related infections.[7,12,15] However, these studies differed notably in their patient populations, research designs, and health care settings (Table 1). We summarize the 3 studies below.

Mermel et al 1991[7]

This study was conducted on adult medical and surgical ICU patients in a university hospital in Wisconsin. The authors randomized 297 hospitalized patients to either a polyvinylchloride or a polyurethane pulmonary artery catheter. The primary research question was whether a difference in rate of catheter-related infections (local infection at the site of the introducer or the intravascular portion of the pulmonary artery catheter, or bacteremia) existed between these 2 types of catheters. In a secondary analysis, the authors investigated potential risk factors for these catheter-related infections by an observational design.

No difference in rates of catheter-related infection was found between the 2 catheter materials. However, by stepwise logistic regression, 4 potential risk factors for catheter-related infections were identified: (1) site colonization with $>10^2$ colony-forming units, (2) internal jugular vein placement (compared with the subclavian vein), (3) duration of catheterization of more than 3 days, and (4) insertion under less stringent barrier precautions in the operating room (eg, no gown or large drape). Catheter placement in the ICU with MSB was associated with a decreased risk for catheter-related infections compared with catheter placement in the operating room using less stringent barrier precautions (relative risk [RR] = 0.48, 95% confidence interval [CI], 0.19-0.91, P = .03). This association held even though the catheters inserted with MSB in the ICU remained in place longer, were used more frequently for TPN, and were more often placed in infected patients.

This study was primarily designed to investigate pulmonary artery catheter materials. Using MSB to prevent catheter-related infection was a secondary analysis. Consequently, considerable heterogeneity existed between the 2 cohorts. The 86 pulmonary artery catheters inserted with MSB were all placed in the ICU, while the 211 pulmonary artery catheters inserted under less stringent conditions were all placed

Table 1. Comparing MSB with less stringent techniques for central venous catheter infection

Reference	Setting	MSB study design	No. of catheters		Main results	Additional results
			MSB	Control		
Mermel et al 1991[7]	ICU and OR	Observational study*	86 (ICU)	211 (OR)	MSB was associated with a lower risk of **Catheter-related infection:** RR = 0.48 95% CI 0.19-0.91	65 of 297 (22%) had local infections (at site of introducer or pulmonary artery catheter) Only 2 catheters (0.7%) had CR-SI
Raad et al 1994[15]	Ambulatory oncology clinic	Randomized trial	176	167	**Catheter-colonization:** 12/167 in control 4/176 in MSB RR = 0.32, 95% CI 0.10-0.96, *P* = .04 **CR-BSI:** 6/167 in control 1/176 in MSB RR = 0.16, 95% CI 0.02-1.30, *P* = .06	**Colonization rates**†**:** 1/1000 in control and 0.3/1000 in MSB (*P* = .007) **CR-BSI rates**†**:** 0.5/1000 in control and 0.08/1000 in MSB (*P* = .02)
Sherertz et al 2000[12]	ICU and step-down unit	Pre- and post-educational intervention study	Pre: 2009‡ Post: 3090‡		MSB use increased 44% to 65% (*P* <.001)‡ **Catheter-related infection:** decreased from 4.51/1000 to 3.23/1000 patient-days	**Catheter-related infection:** decreased from 3.29/1000 to 2.36/1000 device-days§

MSB, Maximal sterile barriers; *ICU*, intensive care unit; *OR*, operating room; *CR-BSI*, catheter-related bloodstream infection; *RR*, relative risk; *CI*, confidence interval.
*The primary study was a randomized controlled trial of catheter materials. For MSB analysis, an observational design was used.
†Rate in catheter days.
‡Prevalence was estimated from purchasing data (numbers of central venous catheters and full-size sterile drapes provided to the units).
§Based on a 73% utilization rate for central venous catheters.

in the operating room. In addition to one group's undergoing major surgery and the other not, these 2 groups had statistically significant differences in catheter insertion site, use of TPN, number of prior CVCs in the site, duration the introducer was left in place, and the presence of other infections. Additional unmeasured confounders are probable.

Of 65 local infections at the site of the introducer or the intravascular portion of the pulmonary artery catheter, only 2 cases were bacteremia. Detailed information about and analysis of these 2 cases of CR-BSI were not provided. Finally, every CVC in this study was a pulmonary artery catheter. It is unclear if these findings can be generalized to the majority of hospitalized patients requiring central venous access, since most hospitalized patients are using a multilumen CVC rather than a pulmonary artery catheter.

Raad et al 1994[15]

This prospective trial randomized 343 ambulatory oncology patients to MSB or standard precautions (sterile gloves and small sterile drape) during central venous catheterization. The investigators followed patients for 3 months or until catheter removal. Study endpoints were catheter colonization and CR-BSI, diagnosed by quantitative catheter or blood cultures.

The 2 study groups were similar, with comparable ages, malignancy types, therapeutic interventions (bone marrow transplant, high-dose steroids, and interleukin-2), and frequency/duration of neutropenia. Catheter characteristics, such as duration of catheterization, insertion site, and number of lumens, were also similar for the MSB and control arms. The MSB group had significantly fewer episodes of both catheter colonization (RR = 0.32, 95% CI, 0.10-0.96, *P* = .04) and CR-BSI (RR = 0.16, 95% CI, 0.02-1.30, *P* = .06). In the MSB group, both the timing of the CR-BSI (occurring much later) and the pathogens (mostly gram-negative rods rather than gram-positive skin colonizers) were different from the control group's.

This is the only randomized trial comparing MSB with less stringent precautions. Unfortunately, only ambulatory oncology patients in a cancer referral center were enrolled. The vast majority of CVCs are placed in critically ill patients in hospital ICUs. Generalizing these findings to other types of patients who require a CVC should be done cautiously, because of potential differences in patient characteristics, risk factors for infection, indications for CVC placement, duration of CVC use, and health care setting.

Sherertz et al 2000[12]

Sherertz and colleagues conducted a nonrandomized, preintervention and postintervention, observational study to investigate whether or not a one-day instructional course would improve infection control practices and procedures. This course, for medical students and interns at a university hospital in North Carolina, promoted the universal practice of MSB for CVC placement. The course was provided twice during the study period. Attitudes toward MSB, frequency of MSB use, and catheter-related infections were determined before and after the training program. The investigators used hospital purchasing department records to estimate the use of MSB by comparing the number of CVCs and full-size sterile drapes supplied to the ICUs during various defined time periods. Infection surveillance programs monitored the patients for catheter-related infections.

A questionnaire seeking physicians' attitudes revealed that the instructional program was associated with an increase in the perceived need for MSB from 22% in the year before the first course to 73% 6 months after the first course ($P < .001$). The training program was also associated with an increased use of full-size sterile drapes. The estimated proportion of CVC placements utilizing MSB increased from 44% to 65% ($P < .001$). The rate of catheter-related infections decreased by 28% (baseline rate was 4.51 per 1000 patient-days; average rate after the course was 3.23 per 1000 patient-days, $P = .01$).

The focus of this study was the benefit of an educational course on infection control practices. Since the course was required, there was no control group for comparison. The intervention included discussions of many infection control principles in addition to MSB (eg, hand hygiene, skin preparation, and aseptic technique). Thus, the changes in the infection rate cannot necessarily be attributed to increases in MSB compliance. The use of MSB was estimated indirectly from hospital purchasing department data. In addition, the investigators did not follow individual patients receiving MSB or standard care to the endpoint of catheter-related infections.

DISCUSSION

Using MSB has been found to decrease nosocomial transmission of microorganisms, to delay colonization,[16,17] and to reduce the rate of nosocomial infections.[18] Our systematic review of the medical literature uncovered surprisingly few studies investigating the efficacy of MSB in preventing catheter-related infections. Although experts have recommended this procedure for almost a decade, we found only 3 primary studies evaluating this intervention. While each of these studies suggests that MSB may reduce the number of catheter-related infections, the evidence supporting this conclusion is neither complete nor robust.

Among the available studies, only that of Raad and colleagues[15] randomized patients to MSB or less stringent sterile barrier techniques. In this study, the use of MSB reduced catheter-related infection by about 65%. Since these authors enrolled only ambulatory oncology patients, it is unclear whether these results can be generalized to the majority of patients who require a CVC. Mermel and colleagues[7] observed that patients receiving MSB during pulmonary artery catheter placement had about a 50% decreased risk of developing catheter-related infection, a risk comparable to that of other methods evaluated to prevent CVC-related infections. For example, a recent meta-analysis of randomized trials found that patients given chlorhexidine gluconate for skin antisepsis had about a 50% relative decrease in CR-BSI compared with patients receiving povidone-iodine.[19] Similarly, chlorhexidine-silver sulfadiazine-impregnated CVCs reduce the risk of CR-BSI by about 40% compared with uncoated CVCs.[20]

Despite primary studies and consensus statements advocating using MSB, compliance rates have been poor. The reasons clinicians do not routinely use MSB are unclear. Since there are essentially no adverse patient effects, reluctance to use MSB is probably due to clinician preference and local practice standards. Perhaps clinicians are not convinced or are not aware that available data support adopting this more cumbersome, time-consuming, and relatively more expensive technique. It is also possible that MSB supplies are not always readily available. Studies investigating the potential causes of poor MSB compliance rates are needed.

Biological plausibility and the available evidence support using MSB during routine insertion of a CVC. Our critical evaluation of the evidence for MSB, however, reveals important gaps in supportive data. Prospective randomized trials among ICU patients would be optimal; however, since experts and consensus statements have recommended MSB for a number of years, these studies may be difficult to accomplish. Formal economic evaluation using decision-analytic modeling would be another method to evaluate the potential clinical and economic benefits of MSB.[21] A carefully designed decision tree can model a hypothetical cohort of ICU patients who require a CVC and follow the patients through their entire hospital stay. Using available data, investigators can vary likelihood and cost estimates through a wide range of plausible values. Given the lack of adverse patient reactions, the relatively low cost of MSB, and the high cost of CR-BSI, it is probable that MSB will prove to be a cost-effective or even a cost-saving intervention.

A recent study[22] evaluated the risk of colonization and infection in patients with peripheral arterial catheters randomized to MSB or standard insertion. As CVCs were not the subject of this study, it did not meet our inclusion criteria. Of note is that in this trial, patients in the MSB group had a higher risk of catheter colonization (RR = 1.34, 95% CI, 0.77-2.35, P = .32) but a lower risk of catheter-related infection (RR = 0.48, 95% CI, 0.13-1.80, P = .34).[22] Unfortunately, this trial had a drop-out rate of 27%. Also, as can be seen from the wide confidence intervals, this study was underpowered to detect a statistically significant difference between the 2 groups for catheter colonization and catheter-related infection. Nevertheless, this trial highlights the need for high-quality randomized studies in order to clarify the potential benefit of MSB use in hospitalized patients requiring various types of vascular catheters.

CVCs remain an important part of caring for patients in the ICU. Given the clinical and economic consequences of CR-BSI, prevention is paramount. While we await more definitive prospective studies and formal economic analyses, MSB can still be recommended during routine insertion of a CVC. Importantly, however, the current evidence supporting MSB is far less substantial than the data supporting other preventive measures, such as using an antimicrobial catheter[20] or using chlorhexidine solution for skin antisepsis.[19]

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References

1. Adal KA, Farr BM. Central venous catheter-related infections: a review. Nutr 1996;12:208-13.
2. Pittet D, Tarara D, Wenzel RP. Nosocomial bloodstream infection in critically ill patients: excess length of stay, extra costs, and attributable mortality. JAMA 1994;271:1598-601.
3. O'Grady NP, Alexander M, Dellinger EP, Geberding JL, Heard SO, Maki DG, et al. Guidelines for the prevention of intravascular catheter-related infections. Am J Infect Control 2002;30:476-89.
4. Mermel LA. Prevention of intravascular catheter-related infections. Ann Intern Med 2000;132:391-402.
5. National Nosocomial Infections Surveillance (NNIS) System report, data summary from October 1986-April 1998, issued June 1998. Am J Infect Control 1998;26:522-33.
6. Pearson ML. Guideline for prevention of intravascular device-related infections. Infect Control Hosp Epidemiol 1996;17:438-73.
7. Mermel LA, McCormick RD, Springman SR, Maki DG. The pathogenesis and epidemiology of catheter-related infection with pulmonary artery Swan-Ganz catheters: a prospective study utilizing molecular subtyping. Am J Med 1991;91(3B):197S-205S.
8. Farr BM. Preventing vascular catheter-related infections: current controversies. Clin Infect Dis 2001;33:1733-8.
9. Darouiche RO. Prevention of vascular catheter-related infections. Neth J Med 1999;55:92-9.
10. Raad I. Intravascular-catheter-related infections. Lancet 1998;351: 893-8.
11. Sitges-Serra A. Strategies for prevention of catheter-related bloodstream infections. Support Care Cancer 1999;7:391-5.
12. Sherertz RJ, Ely EW, Westbrook DM, Gledhill KS, Streed SA, Kiger B, et al. Education of physicians-in-training can decrease the risk for vascular catheter infection. Ann Intern Med 2000;132:641-8.
13. Pearson ML, Abrutyn E. Reducing the risk for catheter-related infections: a new strategy. Ann Intern Med 1997;127:304-6.
14. Maki DG. Yes, Virginia, aseptic technique is very important: maximal barrier precautions during insertion reduce the risk of central venous catheter-related bacteremia. Infect Control Hosp Epidemiol 1994;15(Pt 1):227-30.
15. Raad II, Hohn DC, Gilbreath BJ, Suleiman N, Hill LA, Bruso PA, et al. Prevention of central venous catheter-related infections by using maximal sterile barrier precautions during insertion. Infect Control Hosp Epidemiol 1994;15(Pt 1):231-8.
16. Leclair JM, Freeman J, Sullivan BF, Crowley CM, Goldmann DA. Prevention of nosocomial respiratory syncytial virus infections through compliance with glove and gown isolation precautions. N Engl J Med 1987;317:329-34.
17. Weinstein MP. Topics in clinical microbiology: clinical considerations in the detection of bacteremia. Infect Control 1981;2:327-8.
18. Klein NC, Schoch PE, Cunha BA. Nosocomial group B streptococcal infections. Infect Control Hosp Epidemiol 1989;10:475-9.
19. Chaiyakunapruk N, Veenstra DL, Lipsky BA, Saint S. Chlorhexidine compared with povidone-iodine solution for vascular catheter-site care: a meta-analysis. Ann Intern Med 2002;136:792-801.
20. Veenstra DL, Saint S, Saha S, Lumley T, Sullivan SD. Efficacy of antiseptic-impregnated central venous catheters in preventing catheter-related bloodstream infection: a meta-analysis. JAMA 1999;281: 261-7.
21. Saint S, Chenoweth C, Fendrick AM. The role of economic evaluation in infection control. Am J Infect Control 2001;29:338-44.
22. Rijnders BJ, Van Wijngaerden E, Wilmer A, Peetermans WE. Use of full sterile barrier precautions during insertion of arterial catheters: a randomized trial. Clin Infect Dis 2003;36:743-8.