Effect of Subcutaneous Tunneling on Internal Jugular Catheter–Related Sepsis in Critically Ill Patients

A Prospective Randomized Multicenter Study

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Objective.—To evaluate the effect of catheter tunneling on internal jugular catheter–related sepsis in critically ill patients.

Design.—A prospective randomized controlled study involving 3 intensive care units (ICUs), stratified by number of catheter lumina (1 or 2) and center.

Setting.—The 10-bed medical-surgical and 10-bed surgical ICUs at Saint Joseph Hospital and 8-bed surgical ICU at Clinique de la Défense, Paris, France.

Patients.—Every patient older than 18 years admitted to the ICUs between March 1, 1993, and July 17, 1996, who required a jugular venous catheter for more than 48 hours.

Intervention.—Random allocation to tunneled or nontunneled catheters.

Measurements.—Times to occurrence of systemic catheter-related sepsis, catheter-related septicemia, or a quantitative catheter-tip culture with a cutoff of 103 colony-forming units per milliliter.

Results.—A total of 241 patients were randomized. Ten patients in whom jugular puncture was not achieved were subsequently excluded. The proportion of patients receiving mechanical ventilation (87%) and mean±SD age (65±4 years), Simplified Acute Physiologic Score (13.3±4.9), Organ System Failure score (1.5±1.0), and duration of catheterization (8.7±5.0 days) were similar in both groups. Taking into account the first 231 catheters (114 nontunneled [control], 117 tunneled), we found that tunnelization decreased catheter-related sepsis (odds ratio [OR], 0.33; 95% confidence interval [CI], 0.13-0.83; P=.02), catheter-related septicemia (OR, 0.23; 95% CI, 0.07-0.81; P=.02), and, though not statistically significant, positive quantitative tip-culture rate (OR, 0.62; 95% CI, 0.35-1.10; P=.10). These results were slightly modified after adjustment on parameters either imbalanced between both groups (duration of catheter placement and cancer at admission) or prognostic (insertion by a resident, use of antibiotics at catheter insertion, cancer, and sex).

Conclusion.—The incidence of internal jugular catheter–related infections in critically ill patients can be reduced by using subcutaneous tunnelization.

JAMA. 1996;276:1416-1420

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INTERNAL jugular catheterization is less hazardous than subclavian access but seems to increase the risk of catheter-related sepsis,[1-3] probably because of 3 factors favoring skin colonization: the proximity of oropharyngeal secretion, the higher skin temperature, and the difficulties in immobilizing the catheter and maintaining occlusive dressings.[4] Since the infection originates mainly from the skin-catheter junction,[5] especially for short-term catheters,[6-8] it has been suggested that burying the catheter in a subcutaneous tunnel could reduce pathogen transfer by increasing the distance between the skin-catheter junction and vein. Moreover, tunnelization in the homolateral shoulder might allow a better occlusion of the adhesive dressings.

The purpose of our study was to assess the efficacy of tunnelization of internal jugular catheters in decreasing catheter-related sepsis in intensive care unit (ICU) patients.

DESIGN

Setting

This multicenter prospective randomized clinical trial was carried out in 3 ICUs in Paris, France: the 10-bed medical-surgical ICU and 10-bed surgical ICU at Saint Joseph Hospital and the 8-bed surgical ICU at Clinique de la Défense.

Subjects

Inclusion Criteria.—All patients older than 18 years who were consecutively admitted to the participating ICU from March 1, 1993, to July 17, 1994, and were expected to need catheterization for at least 48 hours were eligible for this trial, providing the patient's Simplified Acute Physiologic Score (SAPS)[9] was higher than 5. Catheters introduced by guide-wire exchange were not included in the study. Patients who needed a trilumen catheter and patients who

Concepts in Emergency and Critical Care section editor: Roger C. Bone, MD, Consulting Editor, *JAMA*.

had undergone tracheostomy were excluded from the study, as were patients in whom tunnelization was unfeasible because of surgery of the neck or the infraclavicular region.

The protocol was approved by the ethics committee of Hôpital Cochin (Paris). Informed consent was obtained from the patients or closest relatives.

Randomization.—Patients were stratified by center and according to the number of lumina of the catheter (1 or 2). We used randomization lists, using opaque, sealed envelopes containing the name of the extant catheter on a card; the envelopes were opened immediately before catheter placement. Patients were randomly allocated to receive either tunneled or nontunneled (control group) catheters each time they needed a catheter during the ICU course after we checked the inclusion criteria.

Material

Polyurethane monolumen or bilumen tunneled catheters were introduced by the Seldinger method (Hasselcath 6-F 14-gauge channel [monolumen] or Seldiflex 7-F [bilumen with 2 16-gauge channels], Plastimed Company, Saint Leu, France). The 20-cm polyurethane catheters of the control group had the same internal and external diameters (Seldiflex, Plastimed, Saint Leu). All catheters were inserted at the bedside in the ICU under strict aseptic conditions. Physicians were required to wear a cap, mask, and sterile gloves and gown. The insertion site was prepared with povidone-iodine and draped with sterile towels. The subcutaneous tunnel was fashioned by retrograde passage of the catheter through the cannula to the point of exit at a preselected site in the homolateral infraclavicular region. The distance separating the cutaneous puncture site from the venous entry site had to be more than 8 cm.

End Points

The main end point was the time to occurrence of systemic catheter-related sepsis as defined below. Catheter-related septicemia and significant catheter colonization defined secondary end points.

The definitions were adapted from Raad and Bodey[10] and Brun-Buisson et al[2] as follows: *Systemic catheter-related sepsis* includes catheter-related sepsis without septicemia and catheter-related septicemia. *Catheter-related sepsis without septicemia* was defined as a temperature of 38.5°C or higher or hypothermia of 36.5°C or lower and a catheter-tip culture of at least 10^3 colony-forming units (CFU) per milliliter and (*a*) pus at the insertion site (or in the subcutaneous tunnel) or (*b*) resolution of clinical sepsis after catheter removal and no other infectious site. *Catheter-related septicemia* was defined as 1 or more positive cultures of blood sampled immediately before or within 48 hours after catheter removal. In case of coagulase-negative *Staphyloccocus* septicemia, 2 positive blood cultures were mandatory as well as either a quantitative tip culture of at least 10^3 CFU/mL with isolation of the same organism from the catheter or, in case of purulence at the insertion site (or in the subcutaneous tunnel), isolation of the same microorganism from the catheter and the bloodstream. *Significant catheter colonization* was defined by a quantitative tip culture of at least 10^3 CFU/mL.[2]

As the study was not blinded, all forms including all reported data (and, if necessary, all relevant data concerning the patient's hospitalization) were reviewed by 2 of the authors (J.F.T. and J.C.F.) blindly for the 2 study groups.

Sample Size

The hypothesis was that tunnelization decreases the rate of internal jugular catheter sepsis to that of subclavian catheter sepsis. We computed the sample size necessary to detect a decrease in the rate of systemic catheter-related sepsis from 15% with the nontunneled catheter, as estimated from the preliminary results of our group,[11] to 4% with the tunneled catheter. Accordingly, with a power of 80% and a type I error of 5%, a sample size of 208 catheters was required.

Follow-up

Severity of illness was assessed on admission and on the day of catheterization using the patient's SAPS,[9] Multiple Organ System Failure score,[12] and presence of mechanical ventilation. Other parameters such as use of parenteral nutrition, antibiotic therapy, and inotropic support were documented during catheter maintenance.

Chest x-ray films were obtained after catheter placement to ensure proper catheter position in the right atrium and diagnose mechanical complications. Intravenous tubing and transparent dressings were changed immediately in case of dressing violation or routinely every 48 hours. Catheter dressings were inspected twice a day by trained nurses for the appearance of local signs of infection. Any use of the catheters except through-the-line blood samples was allowed, including total parenteral nutrition, administration of blood products or medication, and central venous pressure monitoring.

Catheters were removed and culture specimens obtained according to the preestablished rules in the event of signs of catheter-related sepsis, uselessness, malfunction, discharge of the patient from the ICU, or death. Schematically, catheter-related infection was suspected and the catheter immediately removed and culture specimens obtained in case of (1) purulence of the catheter insertion site (or along the subcutaneous tunnel, if appropriate); (2) occurrence of fever (temperature ≥38.3°C) or hypothermia (temperature ≤36.5°C) and associated shock; (3) occurrence of fever (temperature ≥38.3°C) or hypothermia (temperature ≤36.5°C) with erythema or tenderness at the insertion site (or of the subcutaneous tunnel) of the catheter and no other cause of sepsis; or (4) occurrence of fever (temperature ≥38.3°C) or hypothermia (temperature ≤36.5°C) with positive blood cultures.

Decisions to remove catheters and to start or stop antibiotic therapy were made by the medical staff without input from the investigators. Catheter-tip specimens were cultured using a simplified quantitative broth-dilution culture technique previously reported to have a 97.5% sensitivity and an 80% specificity for the diagnosis of catheter-related sepsis of at least 10^3 CFU/mL.[2] Broth cultures were subcultured onto aerobic and anaerobic agar plates, and all organisms recovered from any culture were identified and their antibiotic susceptibilities determined by prescribed methods. Peripheral blood cultures were obtained in the event of fever (temperature ≥38.3°C) or hypothermia (temperature ≤36.5°C) or local signs of catheter-related infections or other indications (eg, chills or sudden shock) and processed by the clinical microbiology laboratory according to standard methods. In case of suspected catheter-related sepsis, at least 2 blood cultures were performed within 24 hours.

Statistical Analysis

Analysis was made on an intention-to-treat basis. The Wilcoxon rank sum test and Fisher exact test were used to compare baseline characteristics between randomized groups. Time-failure data were computed from randomization, estimated by the Kaplan-Meier method, and compared between randomization groups by the log rank test. The 95% confidence interval (CI) of the relative risk of each end point in the tunneled vs nontunneled groups was determined with Cox models. Estimation of the effect of tunnelization on the 3 end points was finally rerun, after adjusting for imbalanced or prognostic covariates by fitting a multivariate Cox model. We used a graphical method for checking the proportional-hazards assumption.

Treatment groups were compared by using 2-sided tests, with P values of .05 or less denoting statistical significance. We used the SAS software package, version 6.09 (SAS Institute, Inc, Cary, NC)

Table 1.—Comparison of the 231 Patients According to Catheter Randomization*

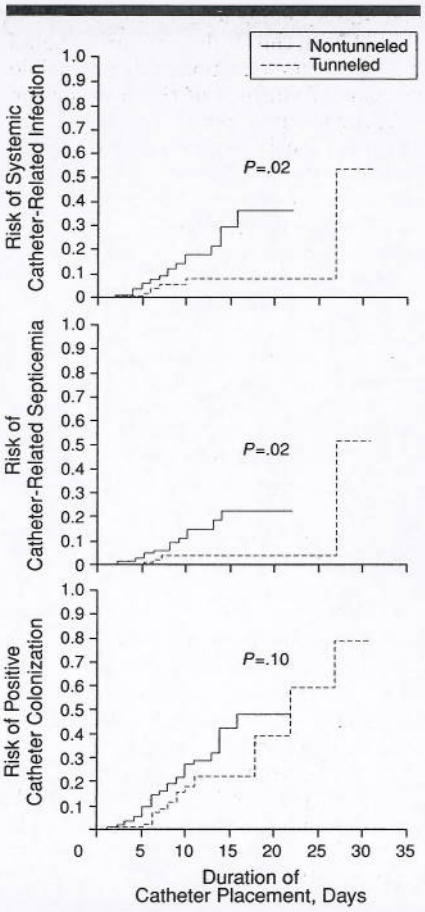
Variable	Nontunneled (n=114)	Tunneled (n=117)	P
Patient characteristics			
Medical/surgical patients, No. (%)	62 (66)/52 (34)	68 (65)/49 (35)	.80
Age, mean±SD, y	66.9±13.7	63.4±16.1	.15
Male sex, No. (%)	84 (73.7)	82 (70.0)	.56
Cancer, No. (%)	9 (8.0)	18 (15.4)	.10
SAPS, mean±SD	13.0±4.6	12.9±4.8	.87
Catheter-placement parameters			
SAPS, mean±SD	14.0±4.6	13.2±5.2	.92
OSF score, mean±SD	1.5±1.0	1.5±0.9	.76
Use of antimicrobials, No. (%)	70 (61.4)	66 (56.4)	.50
Use of mechanical ventilation, No. (%)	98 (86)	102 (87)	.85
Shock, No. (%)	52 (45.6)	55 (47.0)	.90
Bilumen catheter, No. (%)	95 (83.3)	98 (84.0)	>.99
First puncture of the site, No. (%)	86 (75.4)	87 (74.4)	.88
Arterial punctures, No. (%)	8 (7)	8 (7)	>.99
Insertion by a senior physician, No. (%)	38 (33.3)	41 (35.0)	.89
Duration of catheter placement, min	21.4±14.4	39.2±26	<.001
Platelet count, mean±SD, $\times 10^3$/L	258±155	282±262	.39
Prothrombin time, mean±SD, %	68±22	67±29	.73
Reason for catheter removal			
Uselessness	31 (27)	42 (36)	.16
Patient discharged from the ICU	4 (3.5)	3 (2.6)	.72
Death of patient	20 (17.5)	23 (20.0)	.74
Signs of catheter-related sepsis	56 (49)	43 (37)	.06
Malfunction	3 (2.6)	5 (4.3)	.72
Catheter torn out by patient	0 (0)	1 (0.85)	>.99

*The Wilcoxon test was used for quantitative data, expressed as mean±SD, and the Fisher test was used for qualitative data, expressed as number (percentage). SAPS indicates Simplified Acute Physiologic Score; OSF, Organ System Failure; and ICU, intensive care unit.

Table 2.—Estimated Relative Risk of Each End Point With Tunneled vs Nontunneled Catheters (n=231)

End Point	No. of Events/ No. of Patients		Relative Risk (95% Confidence Interval) of the Event	
	Tunneled Catheters	Nontunneled Catheters	Crude Estimate	Adjusted Estimate*
Systemic catheter-related sepsis	7/117	18/114	0.33 (0.13-0.83) P=.02	0.25 (0.10-0.67) P=.006
Bacteremic catheter-related sepsis	4/117	13/114	0.23 (0.07-0.81) P=.02	0.19 (0.05-0.69) P=.01
Positive catheter colonization	20/117	29/114	0.62 (0.35-1.10) P=.10	0.83 (0.42-1.64) P=.59

*The effect of catheter tunneling was adjusted for the remaining 5 variables: the sex of the patient, cancer, duration of catheter placement (±20 minutes), insertion by a senior physician, and use of antibiotics.



Effect of tunnelization of internal jugular catheter according to the end points. Top, Estimated time to systemic catheter-related sepsis according to randomization. Center, Estimated time to bacteremic catheter-related sepsis according to randomization. Bottom, Estimated time to positive catheter colonization according to randomization.

RESULTS

Patients

From March 1, 1993, to July 17, 1994, 241 patients were enrolled in the trial. Ten patients (6 with nontunneled and 4 with tunneled catheters) were excluded due to failure of the jugular puncture (3 puncture attempts by a senior physician and 7 by a resident). Thus, 231 patients (117 in the tunneled and 114 in the nontunneled group) were retained for analysis. Their main characteristics at ICU admission are displayed in Table 1. Only 4 patients were immunocompromised (3 patients infected with human immunodeficiency virus and 1 with Wegener granulomatosis). Twenty-seven patients had underlying malignancies, but no patient was neutropenic during the catheter insertion and none received interleukin therapy.

The median SAPS value was 13 (range, 2-26). The 2 groups were roughly similar in both patient characteristics and catheter placement procedure, except for 2 imbalances (Table 1): There were more cancer patients in the group with tunneled catheters (15% vs 8% in the nontunneled group), and the median time to catheter placement was longer in the tunneled group (30 minutes compared with 16.5 minutes in the nontunneled group). The suspicion of catheter-related sepsis led more frequently to the removal of the inserted catheter in the nontunneled group than in the tunneled group ($P=.06$, Fisher test). However, the duration of catheter placement was about the same in both groups (8.48±4.8 days [mean±SD] in the tunneled group vs 8.19±4.8 days in the nontunneled group; $P=.61$). A comparison of the 2 randomized groups with regards to the 3 end points is presented in Table 2 and the Figure. Twenty-five cases (17 of them bacteremic) of systemic catheter-related sepsis occurred, 24 of which were associated with a positive catheter colonization (including 16 of the cases of bacteremic sepsis). Three patients with systemic catheter-related sepsis experienced a tunnel infection.

Systemic catheter-related sepsis occurred more frequently and more rapidly in the nontunneled than in the tunneled group ($P=.02$, log rank test), with 18 events (1.9 per 100 catheter-days) in the former vs 7 (0.7 per 100 catheter-days) in the latter and a relative risk of 3. At day 8, for instance, the systemic catheter-related sepsis rate was estimated at 12.5% (95% CI, 5.5%-19.5%) in the nontunneled and 6% (95% CI, 1%-11%) in the tunneled group (Figure, top). Similarly, the time to bacteremic catheter-related sepsis was

Table 3.—Microorganisms Isolated During Episodes of Systemic Catheter-Related Sepsis in Patients With Tunneled vs Nontunneled Catheters (n=231)*

Microorganism	Catheter-Related Sepsis		Catheter-Related Septicemia		Tip Culture ≥10^3 CFU/mL	
	Tunneled	Nontunneled	Tunneled	Nontunneled	Tunneled	Nontunneled
Coagulase-negative staphylococci	1	2	0	1	9	11
Staphylococcus aureus	3	7	2	6	5	8
Enterococcus species	0	1	0	1	0	1
Other gram-positive species	0	0	0	0	0	1
Pseudomonas aeruginosa	2	1	1	1	2	2
Acinetobacter species	1	3	0	2	2	3
Klebsiella species	2	3	2	3	3	3
Enterobacter species	0	2	0	0	1	2
Other gram-negative species	0	0	0	0	1	1
No. of microorganisms/No. of episodes	9/7	19/18	5/4	14/13	23/20	32/29

*CFU indicates colony-forming units.

less in the nontunneled group, with 13 (1.3 per 100 catheter-days) events vs 4 (0.4 per 100 catheter-days) in the tunneled group ($P=.02$, log rank test) (Figure, center). At day 8, the bacteremic catheter-related sepsis rate was estimated at 9.2% (95% CI, 3.0%-15.4%) in the nontunneled and 3.8% (95% CI, 0%-8%) in the tunneled group, although the numbers of blood cultures sampled when the catheter was in place were close in both groups (1213 in the tunneled, 1032 in the nontunneled group). Finally, 49 positive catheter colonizations were observed, 29 in the nontunneled (3.1 per 100 catheter-days) vs 20 (2 per 100 catheter-days) in the tunneled group ($P=.10$, log rank test) (Figure, bottom), with the relative risk of colonization estimated at 1.6 in the nontunneled group vs the tunneled group (Table 2).

The microorganisms recovered from catheter-tip cultures did not vary between the 2 groups (Table 3). These results were slightly modified after stratifying for center and adjusting for the 5 baseline variables (Table 2, adjusted estimation) that were either imbalanced (cancer and duration of catheter placement [Table 1]) or prognostic (sex, cancer, insertion by a resident, and use of antibiotics at catheter placement [Table 4]).

Table 4.—Prognostic Value of Catheter- and Patient-Related Variables According to the End Point*

Variable	*P* Value (Log Rank Test) End Point		
	Systemic Catheter-Related Sepsis (25 Events)	Bacteremic Catheter-Related Sepsis (17 Events)	Positive Catheter Colonization (49 Events)
Patient characteristics			
Aged ≥65 y	.75	.99	.51
Male sex	.35	.08	.65
Cancer	.19	.12	.07
SAPS ≥12	.53	.36	.60
OSF score ≥1	.72	.79	.55
Catheter-placement parameters			
Use of antimicrobials	.02	.33	.025
Use of mechanical ventilation	.46	.99	.79
Shock	.74	.21	.51
Bilumen catheter	.82	.21	.29
First puncture of the site	.47	.99	.61
Arterial punctures	.76	.96	.31
Insertion by a senior physician	.45	.02	.53
Duration of catheter placement ≥20 min	.86	.44	.007

*SAPS indicates Simplified Acute Physiologic Score; and OSF, Organ System Failure.

Sepsis Treatment and Outcome

In the nontunneled group, the episodes of catheter-related sepsis in 3 of the 17 patients resolved spontaneously after catheter removal without antibiotic therapy and the patients survived. Fourteen patients required antibiotic therapy for a mean±SD duration of 9.6±10.2 days. Six of these 14 patients died: Two died of septic shock within the first 48 hours, 2 died later of persistent septic shock and septicemia related to tricuspid endocarditis, and 2 died of septic metastasis. Eight patients survived catheter-related sepsis after a mean±SD duration of antibiotic therapy of 13.14±10 days and mean±SD ICU stay of 38.3±28.5 days. In the tunneled group, 1 of the 7 patients with catheter-related sepsis did not receive antibiotic therapy and survived. Six required antibiotic treatment for a mean±SD duration of 7±9.2 days. Two patients died of septic shock due to catheter-related sepsis within 2 days. One died of septic shock related to nosocomial pneumonia after 5 days. Three patients survived catheter-related sepsis after a mean±SD 10±4.4-day duration of antibiotic therapy and a mean±SD 23.3±21-day ICU stay.

Adverse Effects

There was 1 case of pneumothorax among the 241 catheterized patients, observed after an unsuccessful catheterization. Arterial puncture occurred in 16 cases and required a compression of the neck for 1 to 10 minutes. In none of the cases was it associated with severe complications (eg, hemorrhage requiring blood products or laryngeal obstruction), as only 2.5% of the patients studied had a platelet count less than 50×10^9/L.

Finally, the rate of catheter malfunction was not different between the 2 groups (Table 1).

COMMENT

Our prospective randomized clinical study demonstrates that subcutaneous tunneling of internal jugular central venous catheters (CVCs) reduced by 3-fold the risk of catheter-related sepsis in critically ill patients and reduced by more than 4-fold the risk of catheter-related septicemia. These results contradict previously reported data about tunneled catheters. However, several explanations could be proposed. (1) The patients studied were severely ill, and consequently the risk of catheter-related infection was greater. (2) In patients with short-term catheters, there is a strong correlation among colonization at the skin insertion site, external catheter colonization, and catheter-related sepsis.[13] Therefore, factors that decrease the intercutaneous migration of organisms might decrease the risk of acquiring catheter-related infections. (3) A perfect occlusion of adhesive dressings is easier to obtain when jugular catheters are tunneled to the homolateral shoulder.

One well-conducted randomized study

failed to demonstrate any benefit from subcutaneous tunnel insertion of long-standing (mean duration, 109 days) CVCs in immunocompromised patients.[14] However, for long-term CVCs, the degree of colonization and biofilm formation on the internal surface is at least twice that on the external surface.[10] It is therefore possible that prolonged use of the CVC with the same hub would result in a high degree of internal surface colonization that would exceed the external surface colonization originating from the insertion skin site.

However, in previously reported data, tunnelization of short-term catheters failed to significantly reduce catheter-related infection. Keohane et al[15] randomized 83 patients receiving total parenteral nutrition to either tunneled or nontunneled subclavian catheters. Tunneled catheters reduced the incidence of catheter-related sepsis, but mainly when they were being monitored by untrained personnel. Another randomized study failed to demonstrate any efficacy of polyvinyl chloride catheter tunnelization in preventing infection related to total parenteral nutrition catheters.[16] In both studies, the rate of catheter-related infection was unsignificantly decreased in the tunneled group, but the small number of patients studied resulted in a high type II error.

We chose to perform a study in severe ICU patients who had a high risk of catheter-related sepsis, assuming that it was possible to obtain a sufficient power. The rate of systemic catheter-related sepsis after jugular catheterization was similar to that in previous ICU studies[3] and to our previous results.[11]

It is possible that other infection-control procedures such as the use of 2% chlorhexidine[17] would have decreased the rate of catheter-related sepsis. However, 2% chlorhexidine was not available in France during the study. Similarly, the use of a silver cuff has been associated with encouraging results in preventing short-term catheter-related infection,[18,19] although there are no definite conclusions about its use in patients receiving mechanical ventilation.

We chose the jugular access because subclavian catheterization is associated with a higher risk of pneumothorax,[20] which is a major and risky iatrogenic complication, particularly in patients with acute lung injury who are receiving mechanical ventilation.[21] Complications of subclavian puncture were reported in 9.7% of patients in a previous study[20] (including misplacement in 6.0% of patients, arterial puncture in 3.7%, pneumothorax in 1.5%, and mediastinal hematoma in 0.6%).[20] In our study, we observed a 0.4% rate of barotrauma and a 7% rate of arterial puncture, which was easily compressed and never associated with subsequent complications. The low rate of barotrauma, which is the main complication for mechanically ventilated patients, argues for the use of jugular access in this type of patient, although it seems to increase the risk of catheter-related sepsis.[1-3] The severity of arterial puncture is probably a more important problem in patients with severely impaired hemostasis (such as patients with hematologic malignancies and thrombocytopenia). Similarly, the consequences of pneumothorax in patients breathing spontaneously might be considered less severe in such patients.

Although tunnelization reduced the incidence of catheter-related infection and septicemia, it is appropriate to question whether it is economically cost-effective. First, although it is difficult to approximate attributable mortality in an ICU, the number of patients dying of catheter-related sepsis was higher in the control group (6 patients) than in the tunneled group (3 patients). In our study, the catheter-related infections observed in the tunneled group did not require a longer duration of antibiotic treatment or ICU stay than that of the nontunneled group.

Not considering the case-fatality associated with catheter-related bacteremia, the average cost per episode of catheter-related infection has been estimated at $3707.[22]

In our ICU, 80% of catheters inserted are bilumen. The extra cost of tunneled catheters is $4 for monolumen and $20 for bilumen catheters. Other infection-control procedures might decrease the rate of catheter-related infection to 5%. With these assumptions, we calculate that a 66% decrease in infections would result in a $10 677 cost saving per 100 catheters inserted.

Nevertheless, the design of our study does not allow us to affirm the superiority of tunneled jugular access over subclavian access.

We conclude that in critically ill patients receiving mechanical ventilation for whom internal jugular access is chosen, tunnelization is more suitable as it is associated with a lower rate of infectious complications than nontunneled access.

We thank the Plastimed Company, Saint Leu, France, for donation of 50 tunneled catheters and the Lederle Company for its financial contribution to the study's insurance fees.

We thank Gerard Nitenberg, MD, for his advice and review of the manuscript.

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