A Prospective Study of Prolonged Central Venous Access in Leukemia

Janet L. Abrahm, MD, James L. Mullen, MD

• **A three-year prospective study was conducted to evaluate right atrial silicone elastomer catheters for long-term venous access in adults with acute leukemia. Objectives included establishing the safety of catheter insertion in thrombocytopenic patients and the feasibility of maintaining the catheter during septicemia. Seventy-one catheters were placed in 57 consecutive patients entering intensive leukemia therapy. Excessive bleeding occurred at three catheter insertion sites. Eight catheter-related infections occurred. In 34 of 36 noncatheter-related and two catheter-related bacteremias, catheters were left in place with intensive monitoring. In 20, bacteremia cleared. Fourteen patients died; in eight autopsies, no evidence of catheter-related mortality was found. Catheters were in use 6,799 days, including 3,932 home use and 2,570 granulocytopenic days. The data indicate that thrombocytopenia does not preclude catheter insertion and that catheters can be safely maintained in septicemic granulocytopenic patients.**

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IN THE treatment of adults with acute leukemia, maintaining venous access is a persistent problem. Major morbidity is associated with the steel needles used for venous access in such patients, including local inflammation (36.1%), local infection (5.4%), and septicemia (2.1%).[1] In patients receiving parenteral hyperalimentation who also require such access, indwelling central venous catheters have remained safely in use for years.[2] Patients receiving parenteral hyperalimentation, however, are hematologically normal; adult patients with acute leukemia have prolonged periods of thrombocytopenia and granulocytopenia and are frequently infected.

From the Hematology-Oncology Section, Department of Medicine (Dr Abrahm), and the Department of Surgery (Dr Mullen), University of Pennsylvania School of Medicine, Philadelphia.

Reprint requests to Hematology-Oncology Section, Hospital of the University of Pennsylvania, 3400 Spruce St, Philadelphia, PA 19104 (Dr Abrahm).

At the time this study began, there was little information about the safety of placing indwelling central venous catheters in such patients. Prolonged bleeding might be expected in those whose platelet counts could not be raised, even by transfusion, above 60,000/cu mm, the level usually required for surgical procedures, or in patients with leukemia-associated disseminated intravascular coagulation. Data were also lacking on complications caused by infusing the heparin needed to keep the catheters patent into patients who were thrombocytopenic or in whom chemotherapy-induced mucosal lesions might be made more susceptible to bleeding by even small amounts of heparin. In addition, there were no data on whether the catheters should be removed once bacteremia occurred, a common event in this population. Ideally, one would like the catheter, once implanted, to remain in place for the entire time the patient required supportive care. Hence, one would need evidence that the catheter could remain safely in place during episodes of bacteremia, so long as there was no indication that a catheter-related extravascular or intravascular infection was present.

We designed a prospective study to evaluate these questions. After completing an initial study that suggested long-term central venous catheterization was safe,[3] we extended the study. We report herein the results at three years of the use of 71 silicone elastomer catheters in 57 patients. (Data from the preliminary study were incorporated into the present report, including the experience of the 14 patients who died before the study was extended. Only the experience of those 14 has been previously reported in full.)

METHODS

We offered central catheters to consecutive patients scheduled to receive intensive chemotherapy for treatment of their leukemias who could be expected to require prolonged intravenous (IV) supportive care. One patient refused; 57 patients accepted. Fifty had acute nonlymphocytic leukemia; three had chronic myelogenous leukemia in blast cell phase; and four had acute lymphocytic leukemia. All patients received intensive chemotherapy for induction or relapse.[4-8]

Catheter Insertion and Maintenance

Seventy-one silicone elastomer catheters were used. Sixty-three were Hickman catheters, which are 16 bore, and eight were Broviac catheters, which are 18 bore. Catheters were placed with the same tech-

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niques as used for the insertion of parenteral hyperalimentation catheters.[9] Briefly, an incision is made in the deltopectoral groove. A subcutaneous tunnel is created from there to a second incision made about 6 cm lower on the chest wall. The catheter is a 90-cm silicone elastomer catheter with two polyester (Dacron) cuffs on the extravascular segment. The catheter tip is pulled up from the lower site through the tunnel to the upper incision. One polyester cuff is positioned in the tunnel near the upper, venous entrance site, and the other near the skin exit site. The cephalic vein is located in the deltopectoral groove, and the catheter is placed in it and threaded to the right atrium under fluoroscopic guidance. The deltopectoral groove incision is then closed. (The deltopectoral groove wound is referred to as the "insertion site" and the lower chest wall wound as the "exit site" in discussions of catheter-related infections.) If the platelet count was less than 30,000/cu mm, preoperative platelet transfusion was given. If the platelet count was less than 30,000/cu mm postoperatively, compression was applied to the insertion site area. Further platelet transfusions were given if continued local bleeding occurred. Prophylactic cephalosporin therapy (1 g of cefazolin sodium) was given preoperatively and every eight hours for the next 48 hours postoperatively. The catheter exit site was redressed every 48 hours, using strict aseptic technique. The area was scrubbed with acetone, rinsed with saline, then scrubbed for two minutes with 2% iodine. Iodine-containing ointment was applied to the exit site, and it was covered with a sterile occlusive dressing. If the patient was not receiving continuous infusions, the catheter was capped with a male Luer lock cap. Catheters were flushed with heparin (1,000 units in 10 mL of normal saline solution) whenever blood had passed into or out of the line (eg, with blood product transfusion, blood drawing, or blood backflow in the line) and whenever continuous IV fluid control was discontinued. Capped catheters were flushed once daily. To prevent catheters from clogging, all infusions were administered by means of continuous infusion pumps. Before discharge, patients and their families were taught catheter dressing and flush procedures and given written instructions. Inpatient catheters were removed only for confirmed or suspected complications. Outpatient catheters were removed for the same indications or when no longer needed. Removal was an office procedure, with the patient under local anesthesia.

Use of Catheters

The catheters were used both for blood drawing and for the administration of antibiotics, antifungal agents, medications given by IV injection, electrolyte solutions, blood products, and parenteral hyperalimentation. Before June 1980, chemotherapy agents were infused if they were not locally irritating. After that date, catheters were used for vesicant chemotherapy as well, but only after a catheter angiogram showed the catheter to be free of clot and that there was no dye leakage into subcutaneous tissues.

Catheter-Related Complications

All patients who had central catheters were housed in a single inpatient unit. Nurses and physicians caring for the patients were instructed in the protocol for maintenance of the catheter insertion and exit site and flush procedures.

Bleeding and Clotting.—To determine whether there might be lower limits for catheter insertion, platelet counts at the time of insertion were recorded, as were bleeding complications related to placement. Levels of fibrinogen and fibrin split products, prothrombin time, and partial thromboplastin time (PTT) were determined in all patients to learn whether there was disseminated intravascular coagulation. At the discretion of the patients' physicians, catheters were inserted before specific antileukemic therapy in patients who had disseminated intravascular coagulation thought to be under control with heparin infusion. The preliminary study had indicated that RBC transfusion through Broviac catheters did predispose to catheter clotting when a continuous infusion pump was not monitoring the transfusion. Transfusions given through the catheters were recorded to determine whether any particular number or type of blood product infusion resulted in catheter clotting.

Angiograms were performed on malfunctioning catheters. Local or systemic measures to reopen clogged or clotted catheters were recorded.

Infections.—Catheter insertion and exit sites were examined for evidence of infection by one of us at the time of dressing changes.

All patients were evaluated according to a standard protocol for oral temperatures of more than 38.1 °C. Every effort was made to determine whether a catheter-related intravascular or extravascular infection existed or whether another infection source was present. This evaluation included physical examination by a physician, examination and culture of urine, throat culture, fungal and bacterial blood cultures drawn both peripherally and through the catheter, and relevant roentgenograms. If indicated, cultures were obtained of sputum, stool, CSF, mucosal ulcers, sinuses, and skin lesions. In 13 cases, skin lesions were biopsied. Pulmonary lesions were evaluated when possible by bronchoscopy with appropriate cultures and biopsies. Bronchoscopy was done in 13 patients, and an open lung biopsy specimen was obtained on one occasion. In two patients, an exploratory laparotomy was performed; two patients underwent liver biopsies, and four underwent esophagogastroscopy. Cultures were classified as representing contaminants, colonization, or true infection. Patterns of abnormalities on chest roentgenogram (alveolar, nodular, bilateral, unilateral) were recorded and their progress or resolution noted.

All catheters were cultured and examined for clot at the time they were removed. At autopsy, the catheter, the vessel in which it lay, and the heart and pulmonary vasculature were examined histologically for the presence of thrombus, bacteria, and fungi. If a clot was present around a catheter, it was cultured and examined histologically for pathogens. Quantitative catheter tip cultures were unavailable at the time of this study. Possible sources of catheter-related infections included the catheter itself, the catheter insertion site, and the catheter exit site. Infections at each site were classified as definite or probable.

The definition of a definite catheter infection included two circumstances: (1) If there was pus or an exudate at the insertion site while the catheter remained in place, and if blood cultures drawn both at a peripheral site and through the catheter yielded the same organism as that found at the insertion site, the infection was classified as a definite catheter infection, even if the culture of the catheter tip was not positive. (2) If no insertion or exit site infection was present, but the catheter tip on removal in life or at autopsy yielded the same organism as had grown in blood cultures drawn through the catheter before catheter removal, the infection was also defined as a definite catheter infection. No judgment could be made in the latter instance as to whether the catheter was the primary source or had secondarily become infected.

Infections were classified as probable catheter infections if patients had sepsis, blood cultures drawn both through the catheter and peripherally were positive, there was evidence of septic pulmonary emboli without other verified source, and cultures of the catheter itself on removal were negative or the catheter was not removed.

Extravascular catheter-related infections included insertion site and exit site infections. Insertion site or exit site infection was defined as definite if bacteria grew from cultures of pus or exudate from the site. If the catheter had been removed before development of the septicemia, the site was termed a putative source of an episode of septicemia if the organism

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cultured from the site and from the blood was identical. Insertion site or exit site infection was defined as probable if the site was erythematous, warm, and painful beyond the usual postoperative period and the clinical impression was that the inflammation resolved after antibiotic therapy, even if there was no exudate present or cultures of the site were negative.

Maintenance of the Catheter During Septicemia

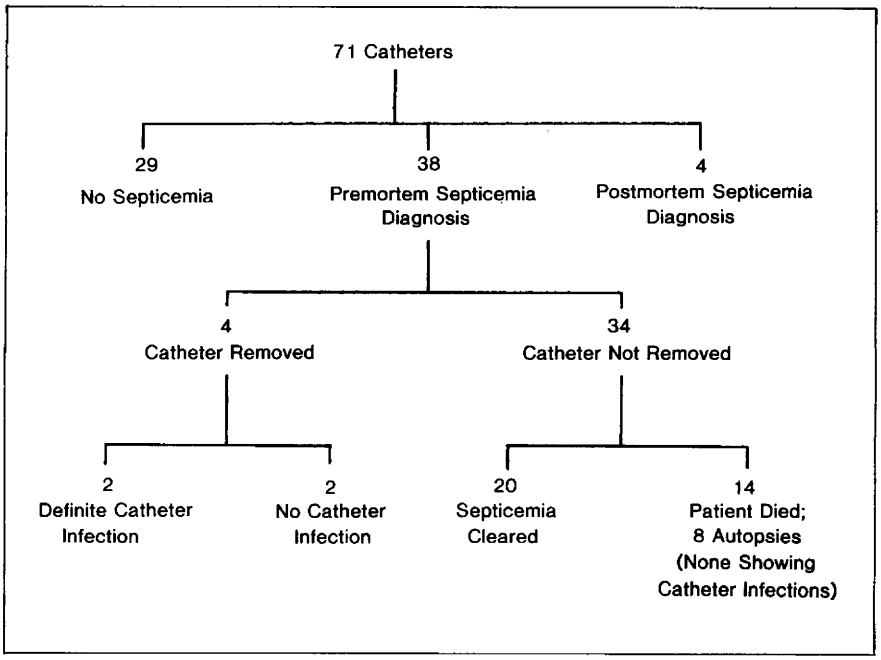
An inpatient catheter was removed only for one of the following reasons: (1) It was clotted. (2) The patient was to be discharged and was unable to learn home care procedures. (3) There was a suspicion of a catheter-related endovascular infection manifested by (*a*) bacteremia with catheter-associated clot, (*b*) bacteremia with the same organism grown from an infection of the catheter's insertion site, (*c*) bacteremia with septic or bland pulmonary emboli without deep venous thrombosis present, (*d*) fungemia confirmed by positive blood culture, or (*e*) persistent bactermia with positive cultures only from blood drawn through the catheter, but not peripherally. In the absence of these indications, catheters were left in place with intensive clinical and bacteriologic monitoring during episodes of sepsis, including those of confirmed bacteremia.

RESULTS

Seventy-one central venous catheters in 57 patients were in place for a median of 44.8 days (range, five to 704 days). Nineteen catheter-related complications occurred during a total of 6,799 days of catheter use, including 3,932 days of home use (Table 1).

Table 1.—Complications Occurring During Use of 71 Venous Catheters

	No. of Complications	No./1,000 Patient-days
Bleeding/hematoma	3	0.4
Clotted catheter	4	0.6
Catheter-related infection		
Catheter		
Definite	2	0.3
Probable	1	0.2
Insertion site		
Definite	2	0.3
Probable	3	0.4
Exit site		
Definite	0	0
Probable	0	0
Miscellaneous	4	0.6
Total	**19**	**2.8**



Flow chart illustrates that septicemia was diagnosed in life during use of 38 of 71 catheters. Outcome of maintaining 34 of 38 in place during septicemia is also shown.

Catheter-Related Complications

Bleeding.—Fifty-four percent of patients were thrombocytopenic (platelet count, <60,000/cu mm) at the time of central catheter placement, despite platelet transfusion. In eight, the count could not be raised above 20,000/cu mm. In no patient did thrombocytopenia prevent catheter insertion or removal. Continued postoperative bleeding at the catheter insertion site occurred in three patients. Two had platelet counts below 20,000/cu mm postoperatively, and one had uncontrolled disseminated intravascular coagulation. In the two without disseminated intravascular coagulation, postoperative platelet transfusion stopped the bleeding without raising the peripheral cell count.

Three patients with disseminated intravascular coagulation had central catheters inserted before they received antileukemic chemotherapy. As already mentioned, a hematoma developed at the catheter insertion site in the one patient with poorly controlled disseminated intravascular coagulation at the time of catheter insertion. The hematoma resolved without surgical evacuation and without catheter removal. The other two patients whose disseminated intravascular coagulation was controlled with heparin administration had minimal oozing from the insertion site that was managed with local pressure. The heparin flushes did not result in elevation of the PTT or systemic bleeding complications. (Blood for PTT determinations must be drawn peripherally, since heparin effect persists in blood drawn through the catheter.)

Clotting.—Four catheters were removed because they had clotted. In two instances, this was caused by inadvertent omission of the heparin flush. Neither packed RBC, WBC, nor platelet transfusion led to catheter clotting. In three instances, catheter flow was suboptimal; it was improved in one case by mechanical clot removal and in two by brief instillation of urokinase.[10] Forty-two patients died with central catheters in place; 21 underwent autopsy. In one case, the vessel in which the catheter lay was

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thrombosed; in no other instance did the heart or major systemic or pulmonary vessels show any catheter-related thrombosis.

Infections.—Ninety percent of patients were granulocytopenic (neutrophil count, <500/cu mm) while the catheters were in place. The median duration of granulocytopenia was 28 days (range, five to 233 days), and there were 2,570 total days.

Of the 71 central catheters, 29 were in place in patients not found to have any systemic infections in life or at autopsy. Four patients were found only at post mortem to have been infected. None of their catheters when examined in situ at autopsy showed any evidence of infection. Organisms found in these four patients included *Mycobacterium flavescens* and *Staphylococcus aureus* in one patient, lung *Aspergillus* and disseminated *Candida* in one, lung *Aspergillus* alone in one, and lung *Aspergillus* and disseminated *Candida pseudotropicalis* in one.

All eight catheter-related infections occurred in the group of 38 patients with systemic infections verified in life. There were two definite and one probable catheter infections and two definite and three probable catheter insertion site infections. No exit site infections developed.

One of the definite catheter infections occurred in an outpatient. This patient had demonstrated poor wound healing by dehiscence both of insertion site and splenectomy wounds. *Staphylococcus aureus* insertion site infection as well as *S aureus* septicemia and septic pulmonary emboli followed. The septicemia cleared with antibiotic therapy after catheter removal. No organisms were grown from the catheter tip itself. The patient died of other causes. No vascular or cardiac seeding source was found at autopsy. The other definite infection was in a catheter that had been in place in a patient with disseminated intravascular coagulation and diffuse upper-extremity thrombosis. The patient had been given empirical therapy with carbenicillin disodium, gentamicin sulfate, and oxacillin sodium for an oral temperature of more than 38.1 °C. When, two days later, catheter dysfunction developed and blood cultures yielded *Staphylococcus epidermidis*, the catheter was removed. Cultures of the catheter tip were positive for *S epidermidis*. Another catheter was placed and the infection resolved. The patient with the probable catheter infection had *S aureus* septicemia. The patient had septic embolic phenomena without other obvious endovascular source. The patient refused catheter removal, and the infection cleared with antibiotic therapy.

Table 2.—Infections That Resolved With Catheter in Place

Organism in Blood	No. of Infections	Sources
Pseudomonas aeruginosa	4	Tooth (2), perirectal abscess (1), unknown (1)
Klebsiella pneumoniae	4	Urine (1), bowel (1), mouth ulcer (1), periodontal (1)
Enterococcus	2	Small bowel (1), unknown (1)
Escherichia coli	2	Periodontal (1), unknown (1)
Staphylococcus epidermidis	2	Catheter insertion site (1), unknown (1)
Serratia marcescens	1	Pharynx
Staphylococcus aureus	1	Catheter
Micrococcus	1	Unknown
Enterobacter cloacae	1	Hemorrhoid
α-hemolytic streptococcus	1	Lung
Polymicrobial bacteremia: *Proteus*, *P aeruginosa*, and enterococcus	1	Abdominal wound

There were two definite insertion site infections. In one, the patient had received high-dose prednisone therapy for eight months for idiopathic thrombocytopenic purpura before leukemia developed. The catheter itself had clotted and been removed before the infection became apparent, and a second catheter had been placed at a different site. When the infection of the insertion site of the first catheter became apparent, *S epidermidis* septicemia, verified both peripherally and through the catheter, also occurred. The infection resolved without removal of the second catheter, and it remains in place. In the second patient with a definite insertion site infection, no bacteremia occurred, and the catheter was not removed. The infection cleared with intravenous antibiotic therapy. There were three probable catheter-related insertion site infections. Empiric antibiotic therapy was given with catheters remaining in place, and the inflammation resolved.

Miscellaneous.—One patient had had "mantle" irradiation therapy and combination chemotherapy for Hodgkin's disease that preceded his leukemia. Arm and chest edema developed on the side of catheter insertion. The catheter and vessel were normal on angiogram. The catheter was left in place and the edema resolved.

Leaks developed in subcutaneous portions of three catheters. All three were removed. This complication only occurred in the first eight lines placed and was probably caused by excessive bolus flushing of clogged catheters, each of which was a Broviac. No leaks occurred in the Hickman catheters or in either type of catheter after controlled-volume infusions were instituted.

Outpatients.—Thirty-five patients, discharged with catheters in place, maintained them at home for a median of 9.7 weeks (range, 0.5 to 79 weeks). Two patients were unable to learn home care procedures and had their catheters removed before they left the hospital. One patient had an infected catheter removed, as already discussed. Nine catheters were removed from outpatients: six from patients who no longer needed them, two that were thrombosed, and one that was in a thrombosed vein. Cultures of all tips were negative. There were no unsuspected thrombi found. Thus, only four patients (11%) had any complication during 3,932 days of home care.

Maintenance of the Catheter During Bacteremia

Of the 71 catheters, 38 were in place during a septicemia confirmed in life (Figure). Of the 38, four catheters met the criteria for catheter removal defined in the "Methods" section.[3] Two of these were in fact infected and have been described in the previous sections as catheter-related infections. The two other catheters removed because of the suspicion that

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they were sources of infection proved not to be primarily or secondarily infected. One was removed after cultures both from peripheral sites and the catheter yielded *Candida tropicalis*. The line itself had no thrombus, was culture negative, and patent. A liver biopsy specimen obtained two weeks later demonstrated multiple *Candida* abcesses. Amphotericin B therapy was begun and another catheter was placed one month later. The infection resolved. The other noninfected catheter was removed because cultures drawn through it remained positive for *Klebsiella pneumoniae* when cultures drawn peripherally had ceased to be positive. The right maxillary sinus was later found to be the source of the septicemia. Gentamicin, carbenicillin, and clindamycin hydrochloride, and then cefazolin, had been given through the catheter for two days before its removal, and the catheter tip culture was negative.

Thirty-four of the 38 catheters were thus left in place during treatment of the bacteremia. In 20 instances, the infection resolved, and in 14 instances, the patient died without resolution of the infection. The putative sources of the 20 infections that cleared are listed in Table 2. The catheter in the infected insertion site had clotted and been removed. The second catheter inserted did not meet the criteria for removal and so was left in place. The patient with the probable catheter infection met the criteria for removal but refused to allow it. Thirteen of the other 18 lines were later removed, examined, and cultured. All were patent, and cultures of their tips were negative. The remaining five catheters are still in place and functioning well.

Fourteen of the 38 catheters were still in place when the patient died without resolution of the infection. In eight cases, the catheters were examined at autopsy. The organisms in the blood in those cases were *Pseudomonas aeruginosa* (one), *S epidermidis* (two), *P aeruginosa* and *Escherichia coli* (one), *P aeruginosa* and *S epidermidis* (one), *E coli* and *Candida kruzeii* (one), *Enterobacter cloacae* (one), and *K pneumoniae* (one). All the catheters were patent, culture negative, and histopathologically uninvolved. None was believed to have contributed to the patient's death.

We wondered whether the three catheters that had become infected were those that had been in place for the longest time or those that had been in the patients who were granulocytopenic for the longest number of days. Since the number of infected catheters was so small, only if all three had been at the extremes of duration of catheter use and duration of granulocytopenia would there have been strong evidence that these were important factors to be considered in deciding whether a catheter infection was likely. This was not the case. One patient with a definite catheter infection had the catheter in place for a total of 55 days (including 47 days at home) and was granulocytopenic for six days with the catheter in place. The other had the catheter in place for a total of 87 days (27 at home) and was granulocytopenic for 19 days. The catheter that was probably infected continues in place and has been in place the longest, for 704 total days (521 at home) and for 163 granulocytopenic days. In the group of 31 patients without catheter infection, however, the median duration of catheter use was 59 days (range, five to 488 days); in those who had catheters in place at home, 97 days (range, 19 to 435 days); and in those who had granulocytopenia, 25.5 days (range, 0 to 233 days).

COMMENT

The use of right atrial silicone elastomer catheters was studied prospectively in a consecutive series of adult patients with acute leukemia who underwent intensive chemotherapy. Specific study objectives included establishing the safety of catheter insertion in patients whose platelet counts could not be raised above 60,000/cu mm and in patients with leukemia-associated disseminated intravascular coagulation, determining complications from heparin-containing flush solutions, confirming catheter-related infections, and deriving guidelines for catheter removal during bacteremia in this group of granulocytopenic patients. The results indicate that catheter placement and prolonged use in this high-risk group of patients were associated with a small number of serious complications and no mortality.

With aggressive platelet support and local measures to control bleeding, catheter insertion is possible even in patients with very low platelet counts. Because of the difficulty ensuring control of disseminated intravascular coagulation in the perioperative period, we recommend delaying catheter placement until the induction therapy has resulted in eliminating the blast cell–associated disseminated intravascular coagulation. It was possible, however, to effect catheter placement in those patients in whom a catheter was thought to be required before antileukemic therapy was instituted. In two of three instances, catheter placement was accomplished without major complication when the disseminated intravascular coagulation was controlled by peripherally administered heparin. Heparin-containing flush solutions did not elevate the PTT and added no extra risk of systemic bleeding. Clotting of the catheter or of the vasculature was infrequent after the introduction of controlled-volume infusion and the larger-bore Hickman catheters.

With the 71 catheters, there were eight catheter-related infections. Two of the infected catheters were removed. All of the infections resolved with appropriate antibiotic therapy, and none of the catheter-related infections contributed to patient mortality.

The criteria applied to determine whether catheters needed to be removed during septicemia proved useful and are still being applied. Even though no catheter infection was found at autopsy in those with evidence of disseminated fungemia, and the catheter seemed uninvolved in the candidemia confirmed in life, the number of instances of fungemia in our unit is so small that we have elected not to study systematically the question of whether catheters can safely remain in place.

Catheter infection did not seem to correlate with length of time the catheter was in place or the number of granulocytopenic days. The type of organism present during the bacteremia was not a factor. Both *S aureus* and *S epidermidis* bacteremias cleared while catheters remained in place, as did other gram-positive and gram-negative bacteremias. Thus, in

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those patients with bacteremias who do not meet the criteria for catheter removal, it is our practice to leave the catheter in place while monitoring the patient closely for evidence of primary or secondary catheter infections. In both patients with evidence of poor wound healing, however, insertion site and/or catheter infection did develop. When catheters are required in such cases, an increased incidence of infection might be anticipated.

Hickman et al[11] reported the use of their catheter in marrow transplant recipients. They concluded that, compared with an historical control group, the routine use of the right atrial catheters had not increased the incidence of septicemia or its persistence. The records of all patients treated in the Oncology Unit of the Hospital of the University of Pennsylvania, Philadelphia, before the routine use of catheters was begun were also reviewed, but we noted that these patients were unsuitable as historical controls because both the chemotherapies and supportive care given differed considerably from those administered to the current group of patients who had catheters placed.

We observed a significantly lower rate of exit site infections (0%) than the 56% rate reported by others.[12] This may be due partly to differences in local care of the exit site. We observed no catheter-associated thrombophlebitis, in contrast to the 23% incidence of thrombophlebitis reported in patients with peripherally inserted central catheters.[13] In addition, the use of a centrally placed line does not require the presence of adequate upper-extremity peripheral veins. The catheters produced no greater morbidity than steel needles in a similar group of patients.[1] Moreover, they avoided the problems associated with these lines: phlebitis from needles or solutions infused, multiple venipunctures, pain from products being infused, and limb immobilization.

Prolonged venous access is required in a variety of other conditions, such as aplastic anemia, sickle cell anemia, solid-tumor chemotherapy, therapy for certain fungal infections, endocarditis, and osteomyelitis, especially in cases in which the drug administered requires a large vessel for safe infusion. Recently, a retrospective study of prolonged catheter use in such a mixed patient population found catheter-related complications in 20% of patients, but catheter-related sepsis during only eight of 6,308 catheter days.[14] None of the complications was fatal, and about half were thrombotic rather than septic. It is hoped that other prospective studies of right atrial silicone elastomer catheters will confirm an acceptably low complication rate in these other groups of granulocytopenic or septicemic patients requiring prolonged parenteral support.

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