Comparison of Soap and Antibiotic Solutions for Irrigation of Lower-Limb Open Fracture Wounds

A Prospective, Randomized Study

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Background: Irrigation of open fracture wounds is a commonly performed procedure, and irrigation additives have been used in an attempt to reduce the risk of infection. In vitro and animal studies have suggested that irrigation with detergent solution is more effective than irrigation with a solution containing antibiotic additives. This study was performed to compare the efficacy of those two solutions in the treatment of open fractures in humans.

Methods: Adult patients with an open fracture of the lower extremity were prospectively randomized to receive irrigation with either a bacitracin solution or a nonsterile castile soap solution. The patients were followed clinically to assess for the development of infection, healing of the soft-tissue wound, and union of the fracture.

Results: Between 1995 and 2002, 400 patients with a total of 458 open fractures of the lower extremity were entered into the study. One hundred and ninety-two patients were assigned to the bacitracin group (B), and 208 were assigned to the castile soap group (C). Outcomes were available for 171 patients with a total of 199 fractures in group B and 180 patients with a total of 199 fractures in group C. The mean duration of follow-up was 500 days. There was no difference between groups B and C in terms of gender, the Gustilo-Anderson grade of the open fracture, the time between the injury and the irrigation, smoking, or alcohol use. There were significant differences in the mean age (thirty-eight compared with forty-two years, p = 0.01), duration of follow-up (560 compared with 444 days, p = 0.01), prevalence of hypotension (23% compared with 14%, p = 0.04), and duration of treatment with intravenous antibiotics (eleven compared with nine days, p = 0.02). An infection developed at thirty-five (18%) of the 199 fracture sites in group B and at twenty-six (13%) of the 199 fracture sites in group C. This difference was not significant (p = 0.2). Bone-healing was delayed for forty-nine (25%) of the 199 group-B fractures and forty-six (23%) of the 199 group-C fractures (p = 0.72). Wound-healing problems occurred in association with nineteen group-B fractures (9.5%) and eight group-C fractures (4%). This difference was significant (p = 0.03).

Conclusions: Irrigation of open fracture wounds with antibiotic solution offers no advantages over the use of a nonsterile soap solution, and it may increase the risk of wound-healing problems.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

The optimal care of open fracture wounds involves surgical débridement and irrigation of the wound to remove the devitalized tissue, foreign material, and contaminating bacteria that lead to wound infection. Although irrigation and débridement is not very glamorous, it is one of the most common procedures done in trauma centers, and adequate performance of this operation is believed to be the most important factor in reducing the prevalence of infection following open fracture. Despite its importance, there is a surprising paucity of scientific information regarding the parameters of wound care, particularly irrigation[1]. Controversy surrounds the issues of adequate volumes of fluid, delivery systems, and the use of additives in the irrigation solution.

Antibiotics (typically bacitracin) are the most common additives used in irrigation solutions for open fractures despite the absence of evidence that it is effective in humans and

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the scanty evidence that it is effective in animals. The observation of profuse foaming with antibiotic irrigation led to the speculation that any beneficial effect on the prevalence of wound infection may be the result of increased cleansing activity due to a detergent-like action rather than local antibacterial activity. In vitro studies of irrigation for the removal of slime-producing Staphylococcus growing on metal surfaces support that hypothesis[2,3]. A multi-year research project[4-8] comparing irrigation with various detergents with antibiotic irrigation in an animal model of contaminated musculoskeletal injury suggested that detergent was at least as effective as antibiotic irrigation for reducing infection. To extend those findings to the human clinical situation, I prospectively compared antibiotic and detergent irrigation in a randomized trial of lower-extremity open fractures. At the time of the study, the standard treatment at our institution consisted of irrigation with normal saline solution containing bacitracin. My hypothesis was that detergent irrigation would be as effective as or superior to antibiotic irrigation for reducing infection.

Materials and Methods

The treatment and study protocols were approved by the institutional review board. The study was performed from January 1995 until September 2002. Adult patients presenting to the emergency department with an open fracture of the lower extremity were identified by the orthopaedic resident on call. All patients with an acute open fracture of the pelvis or the lower extremity were considered for inclusion. Exclusion criteria were prisoner status, inability to obtain adequate informed consent, use of immunosuppressive medication, previous or preexisting infection at the site of the fracture, and a history of allergic reaction to one of the study treatments. The study was explained to the patient or family member giving consent for the treatment of the injury, and written or verbal consent for participation in the study was obtained prior to treatment. The patient was randomized to one of two treatment groups, designated as "C" (castile soap) and "B" (bacitracin), by drawing a card from envelopes kept in the emergency department. The patients were stratified by the grade of the open fracture according to the Gustilo-Anderson system[9], as determined by the resident evaluating the patient. Grade-I and II fractures were randomized separately from grade-III fractures. Patients with more than one open lower-extremity injury were randomized only once, on the basis of the most severe injury, and all of the fractures in that patient were then irrigated with the same solution.

All patients with an open fracture of the lower extremity were treated emergently according to protocol. They were taken as quickly as possible to the operating room, where they were treated with irrigation and débridement of the open wound. Irrigation was performed with use of a power irrigator system (Pulsavac; Zimmer, Dover, Ohio). The irrigation solution was prepared at the time of surgery, with the amount of irrigation fluid determined by the grade of the fracture: 3 L was used for grade-I fractures; 6 L, for grade-II fractures; and 9 L, for grade-III fractures. The castile soap solution was prepared by adding approximately 80 mL (sixteen packets) of liquid castile soap (Triad Medical, Franklin, Wisconsin) to each 3-L bag of normal saline solution. The small packets of soap solution were opened into a clean, but not sterile, basin; the solution was then drawn up into a large syringe and injected into the injection port of the irrigation bag. The soap solution is not packaged sterilely and cannot be sterilized without destroying its chemical properties. In the first year of the study, multiple surveillance cultures of the soap that were performed before it was used revealed no growth. The bacitracin solution was prepared by injecting 100,000 U of bacitracin (Baciim; Pharma-Tek, Huntington, New York) into each 3-L irrigation bag of saline solution.

Culture specimens were obtained from the wound before and after irrigation at each surgical procedure. The number of planned irrigation-and-débridement procedures was also determined by the grade of the fracture; according to the study protocol, one procedure was used for grade-I open fractures; two, for grade-II fractures; and three, for grade-III fractures. The protocol called for the use of the same irrigation solution for all irrigation procedures done for the same patient. Decisions regarding the type of implant used for, and the timing of, fixation were made by the attending physician, as were decisions regarding wound closure or coverage. Antibiotic use was planned according to a protocol based on fracture grade. Grade-I and grade-II open fractures were slated to be treated with a three-day course of cephalosporin and grade-III open fractures, with a five-day course of cephalosporin and aminoglycoside antibiotics. The actual selection and duration of antibiotic use was frequently modified by either the orthopaedic or the general trauma team on the basis of other clinical criteria and conditions. The protocol guidelines in this area functioned more to define the minimum amount of antibiotics that all patients should receive.

Data were recorded on three different data sheets. Sheet A contained information about the patient and the injury. These data included age; gender; mechanism of injury; time to treatment; medical history and prior treatments; presence of hypotension; other injuries; the Orthopaedic Trauma Association fracture classification[10]; the MESS (mangled extremity severity score)[11]; smoking, alcohol, and drug history; and the ISS (injury severity score)[12]. This information was obtained on or near the day of admission by the admitting orthopaedic resident. Sheet B contained intraoperative data regarding the treatments used for each injury, including the dates of the treatments, types of procedures, operative time, blood loss, anesthesia type, type and volume of irrigation solution, antibiotic use, wound closures or treatments, placement or removal of internal or external fixation, and dressings applied. This information was collected, usually soon after the procedure and often from the medical record, by nursing staff providing assistance for the research project. Sheet C contained postoperative and follow-up data regarding outcomes and subsequent treatments, which were collected primarily by me with assistance from various nursing and research staff. Data regarding the outcomes of patients treated by other surgeons were obtained from the medical record or by correspondence with the treating physicians. Although there was no formal blinding with regard to the randomly assigned treatment group during treatment or afterward and the group could have been discovered during data collection, in actuality the persons collecting data were rarely, if ever, aware of the patient's treatment group.

The primary outcomes of interest were wound infection, nonunion or delayed union, and failure of soft-tissue healing. Wound infection was designated as deep or superficial. It was defined as deep if there was drainage of culture-positive, purulent fluid from the open fracture wound or positive cultures of deep tissue. It was defined as superficial according to the clinical criteria of erythema, streaking, swelling, warmth, increasing tenderness, fever, and other signs and symptoms requiring antibiotic treatment. Primary wound-healing problems were defined as dehiscence of a suture line, death of a flap or graft, or failure of a closure to heal that was not due to underlying deep infection. In the case of wounds treated open with the expectation of secondary healing, wound-healing problems were defined as failure of the wound to progress to satisfactory closure. This meant that the wound became larger rather than smaller over time, granulation failed, or the wound became necrotic and underwent desiccation, requiring additional intervention or a change in treatment. Delayed union was defined as any fracture that required additional treatment (use of bone stimulators and/or surgery) to stimulate osseous union on the basis of the attending surgeon's evaluation of the clinical findings and radiographs. Patients were followed until an infectious or healing complication developed or until they were discharged from care with a healed fracture and a restored soft-tissue envelope. Patients were enrolled into the study until the planned sample size had been obtained.

Statistical Methods

Sample size was calculated for a desired power of 0.8 and an α value of 0.05, with estimation of a 20% prevalence of infection in the control group and a 10% difference in the prevalence in the treatment group chosen as a clinically relevant difference in outcome. With use of a dichotomous uncorrected chi-square test for significance, the required sample size was calculated to be 199 cases. Anticipating that 10% of the fractures would be lost to follow-up, the study size was set at approximately 450 fractures. Completion of the study was expected to take five years, but in fact it took seven years. Inclusion of additional groups (for example, a control group in which saline solution alone was used for irrigation) would have increased the number of patients required and the time for completion beyond the anticipated capacity.

The data were analyzed with use of Excel data analysis tools (Microsoft, Redmond, Washington), SPSS 12.0 for Windows (SPSS, Chicago, Illinois), and Systat 5.03 for Windows (Systat, Evanston, Illinois). A two-tailed Student t test with the assumption of unequal variances was used to compare continuous variables, and Pearson chi-square analysis was used to compare categorical variables. The level of significance was set at 0.05.

Results

Patients

Four hundred patients with a total of 458 open fractures were entered into the study. Forty-nine patients with fifty-five open fractures were lost from the study before the outcome could be adequately determined, leaving 351 patients with 403 fractures in the study population reported here. Group B, treated with irrigation with bacitracin solution, consisted of 171 patients with 199 fractures. Group C, which received irrigation with castile soap solution, included 180 patients with 199 fractures.

The mean age of the patients was thirty-eight years in group B and forty-two years in group C. This difference was significant ($p = 0.01$). The patients were grouped into three age categories: eighteen to forty-five, forty-six to sixty-five, and more than sixty-five years old. Twenty-two group-C and six group-B patients were in the oldest age category ($p = 0.01$). Group B included 108 male and sixty-three female patients, and group C included 107 male and seventy-three female patients (no significant difference). Similar proportions of both groups used tobacco, alcohol, or illegal drugs at the time of injury with 49% in group B and 44% in group C using tobacco ($p = 0.59$), 52% in group B and 51% in group C using alcohol ($p = 0.98$), and 5% in group B and 6% in group C using illegal drugs ($p = 0.46$).

Forty-three (25%) of the 171 patients in group B and fifty-seven (32%) of the 180 patients in group C had a single open fracture without another injury ($p = 0.156$). The mean ISS was 13.26 points in group B and 12.21 points in group C ($p = 0.22$). Systemic hypotension (systolic blood pressure of <100 mm Hg) was observed at least transiently in thirty-nine (23%) of the group-B patients and in twenty-six (14%) of the group-C patients ($p = 0.044$).

In both groups, the most common mechanism of injury (sustained by 136 patients in group B and 121 in group C) involved an internal combustion engine (automobile, motorcycle, all-terrain vehicle, automobile-pedestrian, or automobile-train collision). A fall caused the injury in sixteen patients in group B and in thirty-two in group C. Other mechanisms, including gunshots, lawnmowers or farm equipment, animals, boating accidents, crush injuries, and falling objects, accounted for the remainder of the injuries (nineteen patients in group B and twenty-seven patients in group C). Thus, group B had a higher proportion of fractures caused by motor-vehicle accidents, whereas group C had more caused by falls and other mechanisms. This difference in mechanism distribution was significant, with a p value of 0.025. Generally, motor-vehicle collisions result in higher-energy injuries than do falls, although there is a wide spectrum in both categories. This difference in mechanism distribution may be partially explained by the difference in age, as group C had a higher proportion of older patients, who are more susceptible to falls.

TABLE I Patient Demographics*

	Group B (N = 171)	Group C (N = 180)	P Value†
Gender distribution	108 M/63 F	107 M/73 F	0.475 (NS)
Mean age *(yr)*	38	42	0.01
Distribution by age groups (18-45/46-65/>65 yr)	122/43/6	115/43/22	0.01
Distribution by mechanism of injury (motor-vehicle acc./fall/other)	136/16/19	121/32/27	0.025
Tobacco user	83 (49%)	79 (44%)	0.59 (NS)
Alcohol user	89 (52%)	92 (51%)	0.98 (NS)
Illegal drug user	9 (5%)	11 (6%)	0.46 (NS)
Hypotension	39 (23%)	26 (14%)	0.044
Isolated injury	43 (25%)	57 (32%)	0.156 (NS)
Mean ISS *(points)*	13.26	12.21	0.22 (NS)
Mean duration of follow-up *(days)*	560	444	0.01

*The values are given as the number of patients unless otherwise indicated. †NS = not significant.

The mean duration of follow-up for the entire group was 500 days (range, thirty-five to 2422 days). The minimum duration of follow-up for the patients who were discharged from care with a united fracture and no problems with infection or wound-healing was 180 days. Group-B patients were followed for a mean of 560 days and group-C patients, for a mean of 444 days; this was a significant difference (p = 0.01).

Patient data are displayed in Table I.

Fractures

There were 199 fractures in each group. The mean mangled extremity severity score (MESS) was 3.61 points for group B and 3.44 points for group C (p = 0.26). The locations of the fracture were divided into five groups: thigh (femoral neck and shaft), knee (distal part of the femur, patella, and tibial plateau), leg (tibial shaft), foot and ankle (pilon, malleolus, tarsus, metatarsals, and toes), and pelvis/acetabulum (pelvic ring and acetabular fractures with or without hip dislocation). There was no difference in the distribution of fracture locations between the two groups (p = 0.687).

According to the Gustilo-Anderson classification, 15% of the fractures in group B were grade I, 38% were grade II, 25% were grade IIIA, 21% were grade IIIB, and 2% were grade IIIC. In group C, 18% of the fractures were grade I, 39% were grade II, 19% were grade IIIA, 21% were grade IIIB, and 3% were grade IIIC. There was no significant difference between the groups with regard to the distributions of these grades (p = 0.632). Eighty-one fractures (41%) in group B and seventy-three fractures (37%) in group C were found to be grossly contaminated (p = 0.41). There was no difference between the two groups with regard to the prevalence of skin loss (p = 0.8), muscle loss (p = 0.4), or bone loss (p = 1.0). Eleven fractures (5.5%) in group B and fifteen (7.5%) in group C were associated with complete vascular disruption causing ischemia distal to the fracture (p = 0.42).

Fracture data are displayed in Table II.

Treatment

The mean time from the injury to the irrigation was 6.24 hours (range, one to twenty hours) in the entire group, whereas it was 6.2 hours in group B and 6.28 hours in group C (p = 0.81). Intravenous antibiotics were administered for a mean of eleven days (range, zero to sixty-six days) in group B and nine days (range, zero to forty-seven days) in group C (p = 0.02).

The open fracture wound was handled in a variety of ways, according to the preference and judgment of the attending physician or the plastic surgery consultant. Three limbs (one in group B and two in group C) were amputated before closure of the wound. The most common treatment was delayed primary closure, in which the wound was initially left open and was later closed at a subsequent irrigation procedure. This was performed 116 times in group B and ninety-nine times in group C. In the interval between the initial irrigation and the closure, the wounds were most commonly treated with wet-to-dry dressings with use of gauze and normal saline solution, although, later in the series, the vacuum-assisted closure technique (Kinetic Concepts, San Antonio, Texas) became popular. In a few instances, antibiotic bead pouches were used. A flap was used for coverage of three wounds in each group, and a skin graft was used eleven times in group B and twelve times in group C. Ninety-three fractures (forty-one in group B and fifty-two in group C) had only partial wound closure, with a portion of the wound left to heal by secondary intention with the use of wet-to-dry dressings or vacuum-assisted closure. Fifty-eight wounds (twenty-seven in group B and thirty-one in group C) were left entirely open to heal by granulation and scarring. There was no difference in the distributions of these wound treatments between the groups (p = 0.65).

There were deviations from the irrigation protocol for 112 fractures in group B and ninety-nine in group C (p = 0.192). The large majority of these deviations involved the number of irrigation procedures (for example, a grade-III fracture was treated with only two irrigation-and-débridement

TABLE II Characteristics of the Open Fractures*

	Group B (N = 199)	Group C (N = 199)	P Value†
MESS	3.61	3.44	0.26 (NS)
Gustilo-Anderson grade			0.632 (NS)
I	29 (15%)	36 (18%)	
II	75 (38%)	77 (39%)	
IIIA	49 (25%)	38 (19%)	
IIIB	42 (21%)	42 (21%)	
IIIC	4 (2%)	6 (3%)	
Location‡			0.687 (NS)
Thigh	31 (16%)	36 (18%)	
Knee	44 (22%)	40 (20%)	
Leg	57 (29%)	54 (27%)	
Foot/ankle	59 (30%)	65 (33%)	
Pelvis/acetabulum	8 (4%)	4 (2%)	
Skin loss	40 (20%)	42 (21%)	0.8 (NS)
Muscle loss	33 (17%)	27 (14%)	0.4 (NS)
Bone loss	35 (18%)	35 (18%)	1.0 (NS)
Vascular disruption	11 (5.5%)	15 (7.5%)	0.42 (NS)
Gross contamination	81 (41%)	73 (37%)	0.41 (NS)

*The values are given as the number of fractures. †NS = not significant. ‡Thigh = femoral neck and shaft; knee = distal part of the femur, patella, and tibial plateau; leg = tibial shaft; foot/ankle = pilon, malleolus, tarsus, metatarsals, and toes; and pelvis/acetabulum = pelvic ring fractures or dislocations, acetabular fractures, and hip dislocations.

procedures rather than the three suggested by the protocol), the volume of irrigation fluid used (for example, a grade-II fracture was washed with 9 L rather than 6 L), or the timing of the procedures (more than forty-eight hours were allowed to go by between irrigation procedures). Seven patients with a total of eight fractures had a major deviation from the protocol in that they received the wrong fluid for irrigation. Five patients randomized to group B received castile soap instead, although three of them received the wrong fluid during only one of three procedures. Two patients, with a total of three fractures, who had been randomized to group C received bacitracin irrigation during one of two or three irrigation procedures. These patients were all analyzed with their randomization group, in accordance with the "intention-to-treat" principle[13].

Treatment factors are displayed in Table III.

Outcomes

There was no significant difference between the groups with

TABLE III Treatment

	Group B (N = 199)	Group C (N = 199)	P Value*
Mean time from injury to irrigation *(hr)*	6.2	6.28	0.81 (NS)
Duration of administration of intravenous antibiotics *(days)*	11	9	0.02
Protocol deviation†	112	99	0.192 (NS)
Wound management†			0.65 (NS)
Amputation	1	2	
Delayed closure	116	99	
Flap	3	3	
Skin graft	11	12	
Partial closure	41	52	
Open	27	31	

*NS = not significant. †The values are given as the number of fractures.

TABLE IV Complications*

	Group B (N = 199)	Group C (N = 199)	P Value
Infection	35 (18%)	26 (13%)	0.2
Delayed union or nonunion	49 (25%)	46 (23%)	0.72
Failure of wound-healing	19 (9.5%)	8 (4%)	0.03

*The values are given as the number of fractures.

regard to the development of infection or bone-healing. An infection developed at the sites of thirty-five fractures (18%) in group B and twenty-six fractures (13%) in group C ($p = 0.2$). Forty-nine fractures (25%) in group B and forty-six (23%) in group C had delayed union or nonunion ($p = 0.72$).

There was a significant difference between the groups in terms of the development of primary wound-healing problems. Wound-healing or flap-healing failure or dehiscence that was not due to an underlying purulent infection complicated nineteen fractures (9.5%) in group B and eight (4%) in group C ($p = 0.03$). Moreover, two of the eight fractures in group C that were associated with this complication actually had been irrigated with bacitracin (a protocol deviation, as noted above).

The development of an infection was associated with the Gustilo-Anderson grade ($p < 0.0001$), gross contamination ($p = 0.007$), muscle loss ($p = 0.002$), and hypotension ($p = 0.012$). It was not related to bone loss ($p = 0.119$), skin loss ($p = 0.062$), vascular disruption ($p = 0.568$), age group ($p = 0.679$), or tobacco use ($p = 0.411$). Problems with bone-healing were associated with the age group ($p = 0.01$). Bone-healing problems were not associated with the Gustilo-Anderson grade ($p = 0.107$); gross contamination ($p = 0.08$); skin ($p = 0.480$), muscle ($p = 0.581$), or bone ($p = 0.102$) loss; vascular disruption ($p = 0.393$); hypotension ($p = 0.135$); or use of tobacco ($p = 0.474$). Wound-healing problems were associated with skin loss ($p = 0.007$) but not with the Gustilo-Anderson grade ($p = 0.166$), gross contamination ($p = 0.146$), muscle ($p = 0.282$) or bone ($p = 0.512$) loss, age group ($p = 0.343$), hypotension ($p = 0.189$), or tobacco use ($p = 0.107$).

The outcomes are displayed in Table IV.

Discussion

Open fractures continue to be common, with a high risk of complications such as wound infection and problems with healing of bone or soft tissues. The occurrence of any complication in the course of fracture care increases morbidity, mortality, and treatment cost[14,15]. The philosophy of modern treatment of open fractures dictates the use of methods believed to reduce the risk of complications, including urgent or emergent treatment, removal of all foreign material, sharp débridement of devascularized host tissues, and reduction of the bacterial load introduced by disruption of the soft-tissue envelope. Irrigation of the open fracture wound is an essential component of care for these injuries, and it is a very commonly performed orthopaedic procedure.

Open fracture wounds are commonly irrigated with sterile normal saline solution, with or without additives. Additives have been used in an attempt to improve removal or killing of bacteria in the wound, or to optimize wound-healing. The most frequently used and studied additives have been antiseptics and antibiotics. Because of unclear efficacy and potential toxicity, antiseptic irrigation should not be routinely employed[1,16-23].

Irrigation with a solution containing antibiotics, particularly bacitracin, is commonly used for open fractures. Studies of animal soft-tissue wound models have shown that antibiotic irrigation reduces the infection rate compared with that following saline-solution irrigation[1,5,24,25]. Only two of those studies involved skeletal injury, and, with the use of very different models, they resulted in contradictory findings. Instillation of antibiotic solution into the intramedullary canal of canine femora that had previously been drilled and injected with bacteria reduced the rate of positive cultures[25], but irrigation of a contaminated musculoskeletal wound in rats showed no benefit to the use of antibiotic additives[5].

Reviews of the clinical literature on antibiotic irrigation in humans have shown that most studies had either major flaws in methodology or inconclusive results or demonstrated no benefit, and the prospective randomized trials did not show that antibiotic irrigation improves the results in patients treated with systemic antibiotics[26-28]. There are at least three reasons not to use antibiotics if they are not effective: unnecessary cost, rare but serious risk of toxicity[29-31], and promotion of antibiotic resistance.

The observation of foaming with antibiotic irrigation led to the speculation that the efficacy of the technique may be due to some detergent-like action. We began a series of experiments to explore that hypothesis. Irrigation of metallic surfaces coated with a layer of glycocalyx-producing *Staphylococcus epidermidis* showed that soap solutions removed significantly more bacteria ($p < 0.05$) than did antibiotic solutions[2,3]. This finding suggested that the mechanism of antibiotic irrigation was not a detergent action, or at least not a strong one; however, it also suggested an alternate strategy for wound care, which was further investigated in the laboratory[4-6,32]. The use of soap to clean traumatic wounds was once commonly advocated and practiced by surgeons[33-36]. With the advent of the antibiotic age, the use of soap in traumatic wounds has been largely abandoned and is not a part of standard treatment.

The present study was limited to lower-extremity wounds because of some suggestions in the literature that there is a difference in the infection rates associated with open fractures of the upper extremity and those associated with open fractures of the lower extremity. A saline-solution-only treatment arm was not included because of concerns about the number of patients that would be required to achieve significance and because irrigation with antibiotic solution was the clinical standard at our institution.

The patients entered into this study were randomly assigned treatment according to cards pulled blindly from an envelope, which is now known to be a suboptimal method. Despite randomization, the two groups differed significantly in terms of mean age (the patients in group C were a mean of four years older), age-group distribution (sixteen more patients in group C were older than sixty-five years of age), the distribution of the mechanisms of injury (there were proportionally more falls and fewer motor-vehicle collisions in group C), the prevalence of hypotension at the time of the initial injury (9% higher in group C), and the mean duration of follow-up (116 days longer in group B). These differences are unexplained, but I do not believe that they are of sufficient importance or magnitude to alter the conclusions. There were no significant differences in important fracture parameters such as grade, time to treatment, fracture location, MESS, or loss of skin, muscle, or bone.

The results of this study showed that the use of a nonsterile liquid soap additive to irrigate open fracture wounds is at least as effective as the use of bacitracin. I found fewer infections and problems with fracture union in the group treated with the soap, although those differences were not significant. I did find a significant increase in problems with soft-tissue healing (wound dehiscence or necrosis, incision breakdown, or flap or graft failure) in the group treated with antibiotic irrigation. Weaknesses of the study include the performance of the follow-up clinical evaluation by the treating physician and the lack of strict blinding with regard to the treatment group, although the physicians were not usually aware of the treatment group at the time of follow-up. Also, the study did not include a control group treated with normal saline solution, and it is possible that saline solution alone would achieve the same results as irrigation with soap solution. I currently advocate irrigation of open fracture wounds with castile soap solution, particularly for the first irrigation and for wounds with gross contamination. ■

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