A Multicenter Comparison of Tap Water versus Sterile Saline for Wound Irrigation

Ronald M. Moscati, MD, James Mayrose, PhD, Robert F. Reardon, MD, David M. Janicke, MD, PhD, Dietrich V. Jehle, MD

Abstract

Objectives: To compare wound infection rates for irrigation with tap water versus sterile saline before closure of wounds in the emergency department.

Methods: The study was a multicenter, prospective, randomized trial conducted at two Level 1 urban hospitals and a suburban community hospital. Subjects were a convenience sample of adults presenting with acute simple lacerations requiring sutures or staples. Subjects were randomized to irrigation in a sink with tap water or with normal saline using a sterile syringe. Wounds were closed in the standard fashion. Subjects were asked to return to the emergency department for suture removal. Those who did not return were contacted by telephone. Wounds were considered infected if there was early removal of sutures or staples, if there was irrigation and drainage of the wound, or if the subject needed to be placed on antibiotics. Equivalence of the groups was met if there was less than a doubling of the infection rate.

Results: A total of 715 subjects were enrolled in the study. Follow-up data were obtained on 634 (88%) of enrolled subjects. Twelve (4%) of the 300 subjects in the tap water group had wound infections, compared with 11 (3.3%) of the 334 subjects in the saline group. The relative risk was 1.21 (95% confidence interval = 0.5 to 2.7).

Conclusions: Equivalent rates of wound infection were found using either irrigant. The results of this multicenter trial evaluating tap water as an irrigant agree with those from previous single institution trials.

ACADEMIC EMERGENCY MEDICINE 2007; 14:404–410 © 2007 by the Society for Academic Emergency Medicine

Keywords: wound irrigation, tap water, saline, infections

Approximately eight million traumatic wounds requiring primary closure are treated in emergency departments (EDs) in the United States every year.[1] Wound infection, while infrequent, is the most common complication of treating these lacerations, occurring in 3%–5% of cases.[2] Standard care requires adequate decontamination of lacerations before skin closure to reduce wound infection rates. High-pressure irrigation (>8 psi) with sterile saline (SS) is more efficacious in removing debris and bacteria than is cleaning with antibacterial solutions.[3–5]

The current standard of care for simple skin lacerations is irrigation with SS using a syringe and splash shield. However, there are several potential drawbacks to this method, including cost of supplies, clinician time, and risks associated with exposure to the splatter of body fluids.[6] Clinician time and the cost of supplies may be decreased with the use of tap water (TW). Additionally, in many cases, TW irrigation does not require the health care provider to be in such close proximity to the patient as is required with syringe irrigation. The ability to have a larger distance between the health care provider and the wound therefore reduces the risk of body fluid contamination due to splatter.

It has been shown that 35-mL and 65-mL syringes with a 19-gauge needle are able to achieve pressures of 25–35 psi for irrigation.[7] A standard water faucet has also been shown to provide sufficient pressure (about 45 psi) for adequate wound irrigation.[8] We previously compared TW with SS in an animal model and determined that bacterial decontamination of simple lacerations was not compromised and was actually improved with TW irrigation.[8,9] Several other studies have suggested that TW is

a safe and efficacious alternative to SS in the irrigation of lacerations in the ED.[10–14] Each of these studies has been conducted at single institutions, and none of the individual studies have sufficient power to definitively state that no difference exists. The objective of this study was to conduct a multicenter comparison of wound infection rates in simple lacerations when irrigated with TW versus SS before primary closure in the ED.

METHODS

Study Design
This study was a multicenter, prospective, randomized, unblinded trial using a convenience sample of adults presenting to the ED with acute lacerations requiring sutures or staples. The experimental protocol was reviewed and approved by the institutional review boards of the participating hospitals. Informed consent was obtained before study participation.

Study Setting and Population
The study was conducted at two urban Level 1 trauma centers and a suburban community hospital. Each of the EDs has emergency medicine residents, medical students, and physician assistants working under the supervision of attending emergency physicians. Subjects were recruited from patients presenting to the participating ED who were older than 17 years and had uncomplicated skin lacerations requiring staple or suture repair. Exclusion criteria included the following: puncture wounds; bite wounds; self-inflicted wounds; wounds more than eight hours old; wounds involving tendon, joint, or bone; wounds with gross contamination requiring scrubbing or surgical debridement; patients taking antibiotics; diabetic patients; patients with significant peripheral vascular disease; patients with human immunodeficiency virus or other immunocompromised conditions; patients on corticosteroids; prisoners; patients unable to give consent; or pregnant patients.

Study Protocol
Eligible subjects were initially approached at one hospital by a research student present from 8 AM to midnight, or at the other two hospitals by their medical provider during all hours, who explained the study and obtained informed consent. After obtaining consent, subjects were randomized to SS or TW irrigation by opening the next numbered study envelope for that institution. Envelopes were prerandomized at each institution using a computer-based random number generator. The medical provider caring for the subject then administered a local anesthetic as appropriate before irrigation. The provider instructed subjects in the TW group with wounds to the upper extremities on how to irrigate their wound under the water tap for a minimum of 2 minutes. The area to be irrigated was held beneath an unmodified tap in a steel sink. The provider was not required to remain in the room. For other wound locations, the provider attached a 3-ft length of clear plastic tubing to a tapered tap outlet to facilitate irrigation (Watts Premier, Phoenix, AZ). The tubing was not sterile, but it was used only once and then discarded. The lacerations of subjects in the saline group were irrigated by the pro-

vider using a minimum of 200 mL of SS (Baxter Healthcare Corp., Deerfield, IL), administered with a sterile 35-mL syringe (Tyco Healthcare Group, Mansfield, MD) with a splash shield (Combiguard II; Ethox Corp., Buffalo, NY). There were no maximum times or volumes of irrigation for either group. After irrigation, all wound care including closure was in the standard fashion at the discretion of the treating clinician. No prophylactic antibiotics were given. Use of any skin preparations (e.g., povidine-iodine) on the area surrounding the wound, but not inside the wound, was at the discretion of the treating clinician.

All subjects were instructed to return to the ED in 5–14 days, depending on the location of the wound, for removal of staples or sutures and wound follow-up. Providers in the ED removing staples or sutures were blinded to the subject's allocation and judged the presence of wound infection. Subjects who did not return to the ED were contacted by telephone and questioned about the possible presence of wound infection using the same criteria. Callers were also blinded to allocation. Subjects who returned to the ED were given a $10 stipend for their time.

Measurements
Upon enrollment in the study, the following data were recorded for each subject: wound location and length, mechanism of injury (blunt or sharp), presence of subcutaneous sutures, number of sutures or staples, and suture size. For the purpose of this study, wound infection was defined as wounds that, after closure, required a significant change in their course of treatment, such as surgical debridement, antibiotics, or early removal of sutures or staples. If present, wound infection was noted at the time of suture or staple removal, or as reported by the patient on questioning at the time of telephone contact.

Information was also obtained regarding the cost of supplies, including SS, 35-mL syringe, splash shield, TW use, and plastic extension tubing. The costs represent prices paid by the hospital to suppliers for each of these items. Prices were determined at the time of the study for the primary hospital involved in the study.

Data Analysis
Descriptive variables are reported as percentages of the applicable population. The primary outcome variable was wound infection rates in the TW versus SS groups.

The data were examined as an equivalence trial between an alternative therapy (TW) and a standard therapy (SS).[15] Equivalence between the two irrigants would be accepted if the infection rate in the TW group was <10%. This number was chosen as a doubling of what was estimated to be the rate of infection when irrigating with saline based on published reports.[2] We believed that TW could still be considered equivalent despite a potentially higher infection rate, because it has other advantages to saline. The study sample size was calculated to be 1,000 based on a power of 0.8 to detect a 5% absolute difference in wound infection rates between groups with an α of 0.05 and a 15% estimated attrition rate.

Comparisons between groups were made by comparing their proportions. Relative risks with 95% confidence intervals (CIs) are reported. Statistical significance would be achieved if the CI did not cross 1.

RESULTS

A total of 715 subjects were enrolled in the study. There were 377 subjects enrolled at Erie County Medical Center from June 1999 to August 2003, 216 subjects enrolled at Hennepin County Medical Center from August 1999 to December 2000, and 122 subjects enrolled at Millard Fillmore Suburban Hospital between September 2000 and December 2002. Eighty-one subjects were not included in the analysis, with 71 of these due to lack of follow-up (see Figure 1). Those who could not be reached for follow-up included 35 subjects in the SS group and 36 subjects in the TW group. Other reasons for exclusion were initial use of prophylactic antibiotics after enrollment, finding of a more complex laceration after enrollment, or inadvertent enrollment of a patient younger than 18 years. Of the patients who were followed up, approximately 54% returned to the ED, with the remaining 46% contacted by telephone.

Wounds were categorized by anatomic region: upper extremity, head or neck, lower extremity, and trunk (Table 1). There was no difference in distribution of location with respect to irrigation method. Table 2 presents data on wound characteristics by treatment group. Because data were missing from some patients (number is presented for each variable in Table 2), we did not perform comparative analysis but present the appropriate numbers and applicable percentages. The groups were very equivalent with respect to these characteristics.

There were 334 subjects in the SS group and 300 subjects in the TW group. In the SS group, 11 subjects developed wound infections, for a rate of 3.3%. In the TW group, 12 subjects developed wound infections, for a rate of 4%. The difference in wound infection rates between the groups was 0.7% (95% CI = −2.24% to 3.64%). The relative risk for infection for the TW group in this study was 1.21 (95% CI = 0.5 to 2.7). One patient with a wound infection required debridement and hospitalization for intravenous antibiotics. The patient was in the SS group and had a facial wound. All other wound infections were managed on an outpatient basis.

We made a rough estimate of cost differences for the two irrigation groups with the understanding that supply prices can vary considerably. At Erie County Medical Center, the patient charge for irrigation supplies was $9.11 (500-mL SS, $3.08; 35-mL syringe, $0.90; and splash shield, $5.13). Other supplies such as lidocaine, suture material, suture kits, and staplers would be the same in both groups. In our study, wounds were irrigated with TW for a minimum of 2 minutes, which used approximately 13.54 L of water. The cost of TW is $0.00011/L, resulting in a cost per patient of $0.0015. Due to wound location, 36% of subjects in our study required extension tubing for irrigation. At a cost of $0.60 per 3 ft of tubing,
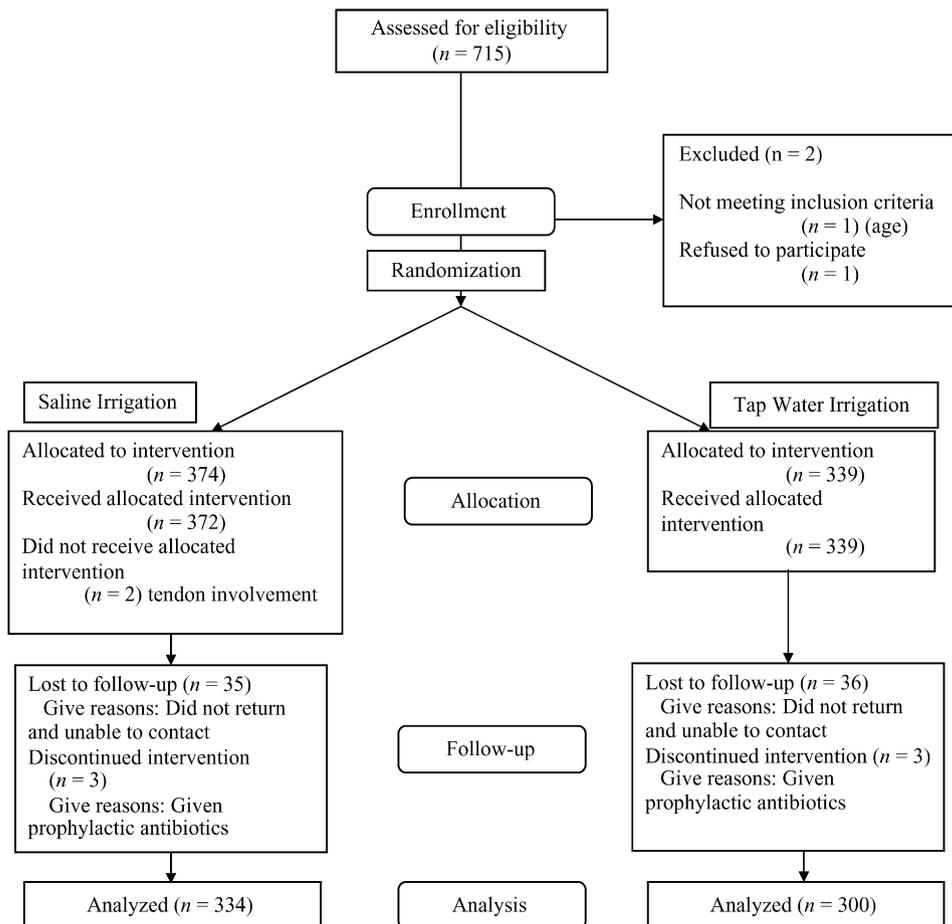

Figure 1. Consort diagram of subject enrollment.

Table 1
Anatomic Distribution of Lacerations

	Sterile Saline ($n = 334$)	Tap Water ($n = 300$)
Head/neck	95 (28.5%)	78 (26%)
Upper extremity	205 (61.5%)	199 (66.3%)
Lower extremity	29 (8.7%)	16 (5.3%)
Trunk	1 (0.3%)	1 (0.3%)
Unknown	4 (1.2%)	6 (2%)

the average charge spread over all patients for extension tubing would be $0.22. In this study, there was a 0.7% higher infection rate in the TW group versus the SS group. To use the worst-case scenario of the upper limit of the CI for the percent difference in infection rates of 3.64%, this results in a potentially greater number of patients who would need antibiotic therapy in the TW group. Using these numbers, we calculated the possible additional cost of treating these infections as $0.69 per patient (cephalexin 500 mg four times a day for ten days at $19.00, Internet price). Using these crude costs and conservatively estimating the worst possible difference in infection rates for TW irrigation, the cost would be $0.91 per patient for all patients irrigated.

Extrapolating our calculated cost of irrigation to eight million lacerations per year in the United States, the total additional cost of wound irrigation with saline amounts to $72,880,000 compared with $7,280,000 for irrigation with TW. The adjusted annual savings nationally of irrigating wounds with TW rather than saline is $65,600,000.

DISCUSSION

Our results from the first multi-institutional comparison of irrigants agree with the outcomes of previous studies performed at single institutions, none of which have demonstrated superiority of SS as an irrigant. One of our previous animal studies showed no significant difference for irrigation with TW compared with SS, while the other showed improved efficacy of TW.[8,9] The other human studies have shown superiority of TW in one and no difference in the other four, although none of them met statistical significance.[10–14] While the difference in infection rates is small in our larger study, the CI for the difference in infection rates crosses 1 and is still too wide to state that there is not a significant difference in either direction.

In terms of wound location, our data contain a higher proportion of upper extremity wounds. This may have occurred because of the tendency to enroll patients with upper extremity lacerations due to the ease of cleansing these wounds under a tap. However, the study protocol did not intentionally select for these lacerations. This may have made the overall infection rate higher; however, both the SS and TW groups had the same proportion of upper extremity lacerations. The results showing a higher wound infection rate for the upper extremity versus head or neck agree with previous studies showing a similar trend. It has been shown that there is a lower infection rate of the face and scalp due to the increased vascularization of these anatomic regions.[12,16]

In the past, a variety of solutions, including antiseptic solutions, SS, and TW, have been used to irrigate wounds. Antiseptic solutions have been shown to cause tissue damage and hinder the healing process.[13] Because TW is hypotonic, there is the theoretical risk of tissue damage due to cell lysis. Although we did not examine pathologic specimens to determine if there was cell damage, our results did not demonstrate significantly increased infection rates.

It has been proven that wounds become infected when they contain more than 10^5 bacteria per gram of tissue.[17] Drinking-quality TW contains an insufficient number of bacteria to cause wound infection. The few bacteria isolated from TW are not skin pathogens.[17] This makes it unlikely that exposure to TW would itself cause infection.

The pressure used for irrigation has repeatedly been shown to be an important variable in the infection rates of wounds. It has been demonstrated that using a bulb syringe or a bag of saline as low-pressure irrigation is not sufficient,[6] although sufficient pressure can be achieved with a proper syringe setup.[8] High-pressure irrigation (>8 psi) effectively removes small particulate matter and bacteria from wounds.[5,11,12,18] Although the effectiveness of wound cleansing improves as irrigation pressure increases, pressures of 70 psi have been shown to have deleterious effects on tissue.[19,20] As we previously reported, typical municipal sources of TW have a pressure of about 40–45 psi and therefore fall within the range of efficacious and acceptable pressures. We measured the pressure of the taps in the ED before our study and found it to be 45 psi. The addition of tubing or tapered spouts does not make any significant difference in the pressure, because the system pressure is not changed. It is possible that different areas or specific buildings may have different pressures, but it seems unlikely that these would be <10 psi.

Table 2
Wound Characteristics for Study Groups

Wound Characteristic	Saline	Tap Water
Wound mechanism (blunt/sharp) ($n = 610$)	Blunt, 89 (29%) Sharp, 221 (71%)	Blunt, 80 (29%) Sharp, 200 (71%)
Wound length (cm) ($n = 598$)	Range, 0.5–15 cm Mean, 3.0 cm	Range, 0.5–17 cm Mean 2.8 cm
No. of sutures per wound ($n = 535$)	Range, 1–41 Mean, 6.4	Range, 1–30 Mean, 6.2
Wounds closed with staples, n (%)	25 (8)	31 (11)
Wounds requiring subcutaneous sutures, n (%)	22 (8)	11 (5)

Our study has some important differences from prior studies. Most notably, our study took place at multiple centers. The population was selected from two Level 1 hospitals in two different cities and a suburban community hospital. Another distinguishing factor of this study is that all anatomic sites of lacerations were included. Some previous studies have limited their examinations to specific anatomic regions. Finally, our study included a larger sample size than other studies. Despite the demographic differences in study design, all studies on this topic have had similar outcomes.

Cost management is an increasingly important issue in all aspects of health care. As mentioned in the Results, the cost to the patient to irrigate a wound with TW (including the use of extension tubing) is approximately $0.91, using the highest estimate of increased infections, compared with the $9.11 that it costs to use SS, based on our rough estimates for materials. Although this is a small cost savings for the individual patient, the difference is large when applied to the eight million traumatic lacerations seen in EDs each year. Even adjusting for the possible use of antibiotic therapy for wound infection (3.64% higher in the TW group using the upper limit CI), the annual patient savings still amounts to $65,600,000.

There are other benefits from the use of TW for irrigation of simple lacerations. Using TW may reduce the risk of body fluid contamination due to splatter to health care providers because it does not require the provider to be in close proximity to the patient during the irrigation process. Also, considering the higher pressure of TW and therefore the higher volume per minute, the length of irrigation time may be reduced. The decrease in clinician time, in addition to the reduction in cost of supplies, amounts to significant annual savings for hospitals.

LIMITATIONS

The study patients were enrolled as an unblinded convenience sample, with nonconsecutive enrollment. The providers were not blinded due to the variation in the two irrigation methods and ability to easily distinguish the irrigant being used. However, on follow-up, wound infection was determined based on preset criteria, limiting the amount of bias. For those subjects who returned to the ED, the providers judging the presence of wound infection were not aware of the irrigation method. For subjects followed up by telephone, the caller from the ED was blinded to the irrigation method, although the patient responding to the questions regarding infection would have known the irrigation technique. While this may have introduced bias to those results, there is no way to judge if it favored one group or the other.

Subjects were not consecutively enrolled because the personnel utilized for enrollment were not present at all hours, as described in Methods. Enrollment also required cooperation of providers, who in some instances chose to not include their patients for enrollment. Any of these conditions could have resulted in subject selection bias. Although some patients who met the inclusion criteria may not have been enrolled in the study due to lack of personnel, patients were not intentionally left out. Because randomization occurred following enroll-ment, the effect of this potential selection bias should have been minimized.

Another limitation is the lack of patient follow-up. Unfortunately, this is a risk associated with conducting a study in an ED. Because the wound infection rates were low and the rate of being lost to follow-up was approximately 10%, it is possible that some wound infections may have occurred in the group lost to follow-up. However, the number of subjects lost to follow-up was nearly identical in each group, which suggests that the outcomes in these subjects would likely be nearly identical as well.

Patients who did not return to the ED were contacted by telephone and self-reported the presence or absence of wound infection. This method may have altered the reported wound infection rate; however, the same questioning sequence for establishing wound infection in the ED was used by the telephone examiner. Although the exact data for this were not available, it would make sense that there would be more infections reported in subjects who returned to the ED.

A final limitation is a small sample size and therefore insufficient power to definitively state that no difference exists. Our prestudy sample size calculation estimated a need for approximately 1,000 patients to complete the study. We concluded the study in 2003 with fewer than that number of subjects enrolled for two primary reasons. Our sample size calculation was based on a 5% rate of infection, as is published in the literature, with the study designed to look for a doubling of the wound infection rate to potentially 10%. With 715 subjects enrolled, we had a 3.3% wound infection rate in our control group. Doubling this infection rate and reevaluating sample size estimates indicated we would need 1,500 subjects for sufficient power to detect differences in infection rates between the two groups. We also had stopped enrolling subjects at two of the three sites due to personnel changes. The reality of more than doubling our enrollment for the whole study using the single remaining site after more than four years of study was not feasible. The study was therefore concluded with fewer subjects than originally planned. Our experience is not unique in this regard, and we believe that this study, in conjunction with previous similar studies, could be included in meta-analysis methodology, which in turn may be a good foundation for evidence-based clinical practice.

CONCLUSIONS

Compared with SS, TW for wound irrigation is more cost-effective and appears to be equally safe and efficacious. TW should be considered in the ED setting as a reasonable alternative to saline for wound irrigation.

References

1. Singer AJ, Thode HC. National epidemiology of lacerations [abstract]. Ann Emerg Med. 2002; 40:S41.
2. Stone S, Carter W. Wound preparation. In: Tintinalli JE, Kelen G, Stapczynski J (eds). Emergency Medicine: A Comprehensive Study Guide, ed 5. New York: McGraw-Hill, 2000, pp 284–7.

3. Brown LL, Shelton HT, Bornside GH, Cohn I Jr. Evaluation of wound irrigation by pulsatile jet and conventional methods. Ann Surg. 1978; 187:170–3.

4. Gross A, Cutright DE, Bhaskar SN. Effectiveness of pulsating water jet lavage in treatment of contaminated crushed wounds. Am J Surg. 1972; 124: 373–7.

5. Dire DJ, Welsh AP. A comparison of wound irrigation solutions used in the emergency department. Ann Emerg Med. 1990; 19:704–8.

6. Pigman EC, Karch DB, Scott JL. Splatter during jet irrigation cleaning of a wound model: a comparison of three inexpensive devices. Ann Emerg Med. 1993; 22:1563–7.

7. Singer AJ, Hollander JE, Subramanian S, Malhotra AK, Villez PA. Pressure dynamics of various irrigation techniques commonly used in the emergency department. Ann Emerg Med. 1994; 24:36–40.

8. Moscati RM, Reardon R, Lerner EB, Mayrose J. Wound irrigation with tap water. Acad Emerg Med. 1998; 5:1076–80.

9. Moscati R, Mayrose J, Fincher L, Jehle D. Comparison of normal saline with tap water for wound irrigation. Am J Emerg Med. 1998; 16:379–81.

10. Angeras MH, Brandford A, Falk A, Seeman T. Comparison between sterile saline and tap water for cleaning acute traumatic soft tissue wounds. Eur J Surg. 1992; 158:347–50.

11. Bansal BC, Wiebe RA, Perkins SD, Abramo TJ. Tap water for irrigation of lacerations. Am J Emerg Med. 2002; 20:469–72.

12. Valente JH, Forti RJ, Freundlich LF, Zandieh SO, Crain EF. Wound irrigation in children: saline solution or tap water. Ann Emerg Med. 2003; 41:609–16.

13. Griffiths RD, Fernandez RS, Ussia CA. Is tap water a safe alternative to normal saline for wound irrigation in the community setting? J Wound Care. 2001; 10: 407–11.

14. Godinez FS, Grant-Levy TR, McGuirk TD, Letterle S, Eich M, O'Malley GF. Comparison of normal saline vs tap water for irrigation of minor lacerations in the emergency department [abstract]. Acad Emerg Med. 2002; 9:396–7.

15. Armitage P, Berry G, Matthews J (eds). Statistical Methods in Medical Research, 4th ed. Malden, MA: Blackwell Science Ltd, 2002, pp 636–8.

16. Hollander JE, Richman PB, Werblud M, Miller T, Huggler J, Singer AJ. Irrigation in facial and scalp lacerations: does it alter outcome? Ann Emerg Med. 1998; 31:73–7.

17. Riyat MS, Quinton DN. Tap water as a wound cleansing agent in accident and emergency. J Accid Emerg Med. 1997; 14:165–6.

18. Eldlich RF, Rodeheaver GT, Morgan RF, Berman DE, Thacker JG. Principles of emergency wound management. Ann Emerg Med. 1988; 17:1284–302.

19. Wheeler CB, Rodeheaver GT, Thacker JG, Edgerton MT, Edlich RF. Side-effects of high pressure irrigation. Surg Gynecol Obstet. 1976; 143:775–8.

20. Rodeheaver GT, Pettry D, Thacker JG, Edgerton MT, Edlich RF. Wound cleansing by high pressure irrigation. Surg Gynecol Obstet. 1975; 141:357–62.

REFLECTIONS

Bedside Manner: Restoring an Ancient Art

Several months ago, I accompanied my mother to an eye appointment to follow up on a retinal tear, which had created a sudden profusion of brown-black spots in her visual field. She lives in China and had seen an ophthalmologist there, but we were visiting this clinic, a university practice in the United States, for the first time. A technician ushered us into a room and tested her visual acuity.

The resident came in next. She seated herself near my mother but swiveled around completely so she could lean on the desk and write in the medical chart. Her back faced my mother squarely. "Soooo, visiting from China," she said, over her shoulder, to no one in particular. She then launched into her history-taking, using the extremely loud voice that people reserve for the hard-of-hearing or the foreign-born.

My parents have lived in Jilin Province, in northeastern China, for exactly one year, working as missionaries. They were born in Korea, however, and spent most of their adult lives in the United States, in a small town in Ohio. They speak English fluently, albeit with a half-Korean, half-Midwestern accent. My mother makes a mean meatloaf, and she churns out Mrs. Field's cookies as if her life depends on it. She also teaches conversational English at a university in China.

So I jumped at the volume to which the resident had cranked up her voice, and I tried not to laugh. We were there for her eyes, not her ears, I thought. I winked encouragingly at my mother, who was doing her best to handle the rapid-fire interrogation. Whenever she hesitated, trying to think of how to describe her symptoms, the resident repeated the question LOUDLY and CLEARLY. Each time my mother got beyond the first few words of an answer, the resident galloped on to the next question.

I had to bite my tongue to resist saying, "Slow down a second! She's trying to talk to you!" I wanted to ask, "Where is your bedside manner?" Where was the handshake, the eye-to-eye contact, the introduction, the creation of some sort of connection that would make this interview a pleasant, meaningful interaction?