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Prospective Randomized Comparison of Two Preoperative Skin Preparation Techniques in a Developing World Country

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Abstract. Povidone-iodine (PI) is a scarce and expensive item for some hospitals in developing countries. This prospective, randomized study was performed at Baptist Medical Centre (BMCO) in Ogbomoso, Nigeria to determine if the use of PI for preoperative skin preparation would result in a lower postoperative wound infection rate and to identify other factors influencing the infection rate. Two hundred patients undergoing inguinal hernia repair were randomized to receive skin preparation with either: (1) locally available, inexpensive market soap and methylated spirit or (2) imported PI. The two groups were equally stratified. The overall postoperative wound infection rate was 5.5%, and there was no significant difference between the groups (5.1% vs. 5.9%). Factors that did not affect the infection rate included gender, age, type of anesthesia, type or duration of the operative procedure, and number of breaks in optimal technique. There were eight abscesses and three cases of cellulitis without suppuration diagnosed an average of 10 days postoperatively. *Staphylococcus* was the only bacterium identified on Gram stain or culture. The expense of procuring PI is not justified at BMCO. Available funds may better be used for preoperative antibiotics or for improvement in hospital infrastructure, which should result in fewer breaks in optimal operating room technique.

Povidone-iodine (PI), used routinely for preoperative skin preparation in more developed countries (MDCs), is a scarce and expensive item for many hospitals in developing world countries (DWCs). Wound surveillance studies from hospitals in MDCs show an infection rate of 1% to 9% for clean cases [1–4]. Some wound surveillance studies from Sub-Saharan Africa [5–7] report infection rates up to 40%. A 10% wound infection rate in an unpublished, prospective assessment of patients undergoing elective hernia repair at the Baptist Medical Centre (BMCO) in Ogbomoso, Nigeria served as the stimulus for this prospective, randomized comparison of a skin preparation technique using locally available, inexpensive market soap and methylated spirit (methyl alcohol) with a skin preparation technique using PI. The study was undertaken to determine if the benefit of a lower infection rate would justify the increased cost of procuring PI and to identify other factors contributing to wound infections at BMCO.

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Materials and Methods

A series of 200 patients of all ages undergoing elective hernia repair at BMCO from June 1994 to December 1995 were prospectively randomized to receive one of two skin preparation techniques. This study was approved by the Ethics in Scientific Studies Committee at BMCO. All patients or guardians gave written, informed consent prior to enrollment. None of the patients was a known diabetic and none was receiving immunosuppressive medication. All patients came directly to the operating room on the day of operation. Adults were usually admitted for one night following operation, but children (less than 13 years) were managed as outpatients. Spinal anesthesia was used in 127 (86%) of the 147 adult patients, general anesthesia in 11 (8%), and local anesthesia in 9 (6%). Ketamine was used as the anesthetic agent in 49 (92%) of the 53 children and mask halothane in the remaining 4 (8%). Randomization was performed using a card-drawing system. All skin preparations were performed by the same investigator (D.A.).

The incisional area was shaved, if needed, in the operating room using a wet razor immediately before the skin preparation. All patients received a full 5-minute skin scrub. Locally available bath soap was used as the scrubbing agent for group 1 patients and PI scrub solution for group 2 patients. Excess scrubbing solution was removed with a sterile towel. Group 1 sites were then painted with methylated spirit (MS) and group 2 sites with PI paint solution.

All children underwent ligation of the processus vaginalis and 2 (4%) also underwent suture tightening of the medial portion of an enlarged internal inguinal ring. The following procedures were performed in adults: unilateral Bassini repair in 74 (51%), Cooper's ligament repair in 63 (43%), bilateral Bassini repair in 8 (5%), and high ligation of the indirect sac and tightening of the internal ring in 2 (1%).

Perioperative monitoring of the conduct of the operation was performed by one of the investigators and any break in optimal technique (OT) noted. Any of the following was considered a break in OT for this study: (1) autoclave indicator tape not completely changed in color; (2) well water used to prepare patient or surgeons' hands; (3) break in glove integrity; (4) air conditioner not working with resultant opening of doors or windows; and (5) any flying insect noted in the room. Additional parameters assessed perioperatively included patient age and gender, type of anesthesia, type and duration of the procedure, and operating room where the procedure was performed. Wound infection was defined for this study as any redness of the wound or purulent discharge from the wound that resulted in early removal of skin sutures, operative drainage, or treatment with antibiotics.

Patients were scheduled to be seen by one of the investigators 5 to 10 days postoperatively at the time of suture removal and again 4 to 8 weeks postoperatively. There was a 92% compliance rate with this regimen. All patients who developed a wound infection received antibiotics. Abscesses were drained, and Gram stain was performed on all purulent material. Data were then analyzed using the following statistical methods: chi-square test, Fisher's exact test, independent samples *t*-test, and Mann-Whitney test.

Results

There were 200 patients (182 males, 18 females) enrolled in this study. The mean age was 35 years (range 3 months to 80 years). There were 53 children (less than 13 years old) and 147 adults. Altogether, 98 patients were randomized to group 1 (soap and MS) and 102 patients to group 2 (PI). The groups were equally stratified according to age, gender, venue of operation, type of anesthesia, duration of procedure, type of procedure, and number of breaks in OT. There were 11 (5.5%) wound infections: 5 (5.1%) in group 1 and 6 (5.9%) in group 2. The difference in infection rate between the groups was not significant ($p = 1.000$). Although the infection rate in children (1.9%) was lower than that in adults (6.5%), this difference was not statistically significant ($p = 0.294$). Parameters that did not accurately predict wound infection included gender, age, operating room venue, type of anesthesia, type of procedure, duration of procedure, and number of breaks in OT. Wound infections were diagnosed an average of 10 days (range 6–15 days) postoperatively. Eight patients underwent abscess drainage, and three were treated with antibiotics alone for nonsuppurative cellulitis. *Staphylococcus* was identified by Gram stain or culture in seven of the eight patients with abscess. All patients with wound abscesses were successfully managed as outpatients.

Discussion

Like many hospitals in DWCs, BMCO has a subsistence type of existence without significant external subsidies. If hospital expenditures are too great, there is not enough money to pay the salaries for employees or to purchase pharmaceuticals and other supplies. Frugality is therefore an essential part of existence so long as it does not compromise patient care. This study was implemented to determine if the added expense of importing PI for operative skin preparation would result in a lower wound infection rate in clean, hernia operations. PI was not available for purchase in our locale and therefore had to be imported in a quantity sufficient to perform this study. After completion of the study, PI became sporadically available but at a cost per patient of 100 times the cost per patient of the soap and MS preparation technique. Elective herniorrhaphy was selected for study because it is the most commonly performed clean operation in our hospital.

Deficiencies in infrastructure are a major deterrent to the delivery of quality operative care in DWCs [6, 8]. The degree of deficiency varies from one country to another and indeed from one hospital to another within a given DWC. All hospitals in DWCs, however, face a common set of obstacles. This report specifically describes the conditions at BMCO. Some hospitals in Nigeria and in other DWCs are more technologically advanced than our hospital, and others are considerably less advanced. Under ideal circumstances chlorinated water and electricity are delivered to BMCO by the public utility systems, but ideal circumstances rarely exist. Even when electricity is supplied, the voltage is frequently too low to achieve optimal autoclave temperatures, and sterilization indicator tapes only partially change color during a sterilization run. "Sterility" therefore becomes a relative term. There is never enough water to "waste" on preoperative showers for patients. During times when water is not supplied by the public utility, nonchlorinated water is brought directly from a hand-constructed well into the operating room in a bucket and poured over the surgeons' hands for scrubbing. Whenever there is adequate electricity the doors and windows of the operating rooms are closed, and the air conditioners are used. When the electricity is deficient, however, doors and windows are opened for ventilation. Insect control is often a problem despite wire-screened windows and doors, and a fly swatter is frequently the most technologically appropriate piece of equipment in the operating room. There are only two operating rooms, and often it is necessary to perform a clean herniorrhaphy in a room that was used 30 minutes earlier for a case of perforated typhoid enteritis or drainage of an intraabdominal abscess.

With this realistic description it is not surprising that there were 98 breaks in OT occurring in 86 (43%) patients. It is surprising, however, that there was no correlation of wound infection with either the number or type of breaks in OT. BMCO is a training hospital for Nigerian physicians. As a result, most of the operations in this study were performed by interns and residents under consultant physician supervision. This may explain the relatively long mean duration of the operation (88 minutes). Spinal anesthesia is used extensively in our hospital because of its relative safety in elective cases and because it provides good anesthesia and relaxation for patients in a teaching environment. Ketamine is a safe, effective anesthetic agent for children undergoing hernia repair in our hospital [9].

The 5.5% wound infection rate in this study is comparable to rates reported from MDCs [1–4] and DWCs [10]. The delayed presentation of wound infections in this series (postoperative days 6–15) emphasizes the importance of prolonged postoperative surveillance, as demonstrated by the postoperative community surveillance programs that have greatly increased the detection of wound complications [2, 11, 12]. This study was designed to identify measures that could be taken to decrease the infection rate at BMCO. Simply performing the study appears to have lowered the infection rate from 10.0% in unpublished data to 5.5% during this study. Possible explanations for this decrease

include (1) a more conscientious effort by operating room personnel during the study and (2) performance of all skin preparations by the same person.

Our data clearly demonstrate that PI is no better than market soap and MS for preventing infections in clean, hernia operations at BMCO. Hospital money should not, therefore, be used to purchase PI just because it is the standard preparation in MDCs. Some reports have demonstrated the efficacy of preoperative antibiotics given parenterally [5, 13] or locally [14] in decreasing wound infections, but others have shown no benefit [4]. Antibiotics appropriate for *Staphylococcus,* the primary pathogen in our wound abscesses, are expensive; and a prospective, randomized trial in our hernia patients is needed prior to using prophylactic antibiotics routinely for all clean operative cases. Despite diligent efforts by the investigators of this study, economic and infrastructural deficiencies were responsible for numerous breaks in OT and probably contributed in an immeasurable way to the wound infection rate. The most effective way to decrease the wound infection rate at BMCO may be to use resources, when available, to construct an operating room, solely for clean cases, with a dependable supply of electricity and clean water.

Résumé

La polyvidone iodée (PVI) est rare et coûte chère pour les hôpitaux dans les pays en voie de développement. Cette étude randomisée a été réalisée au Baptist Medical Centre (BMCO) à Ogbomoso, Nigeria, afin de déterminer si l'utilisation de PVI pour la préparation cutanée préopératoire pouvait abaisser le taux d'infections postopératoires ainsi que pour identifier d'autres facteurs qui pourraient influencer le taux d'infection postopératoire. Deux cent patients ayant eu une cure de hernie inguinale ont été randomisés pour être préparés par soit: (1) du savon localement disponible, peu cher, et de l'eau méthylée ou (2) de la PVI, importée. Les 2 groupes étaient stratifiés de façon comparable. La taux d'infection postopératoire globale a été de 5,5%, et il n'y avait aucune différence significative entre les groupes (5,1%, 5,9%). Ni le sexe, l'âge, le type d'anesthésie, le type ou la durée du procédé opératoire ou le nombre de violations de la technique optimale n'ont affecté le taux d'infection. Il y avait 8 abcès et trois cas de cellulite sans suppuration, diagnostiqués en moyenne 10 jours après l'opération. Le staphylocoque a été la seule bactérie identifiée par coloration de Gram ou par culture. Ainsi les coûts nécessaires pour obtenir de la PVI ne sont pas justifiés. L'argent éventuellement disponible pourrait être mieux utilisé pour obtenir des antibiotiques préopératoires ou pour améliorer l'infrastructure hospitalière, ce qui pourrait se traduire par moins de violations de technique de salle d'opération.

Resumen

En los países en vía de desarrollo el compuesto yodado Povidone es un elemento escaso y costoso para algunos hospitales. El presente estudio prospectivo y aleatorizado se realizó en el Centro Médico Bautista en Ogbomoso, Nigeria, con el propósito de determinar si el uso del Povidone en la preparación preoperatoria de la piel resultaría en una tasa menor de infección postoperatoria de la herida y de identificar otros factores que influyen sobre la tasa de infección. Doscientos pacientes programados para reparación de hernia inguinal fueron aleatorizados para recibir preparación de la piel con: (1) jabón ordinario localmente disponible y alcohol metílico, o (2) Povidone importado. La tasa global de infección postoperatoria fue 5.5%, y no se encontró diferencia significativa entre los dos grupos (5.1%, 5.9%). Los siguientes factores no afectaron la tasa de infección: género, edad, tipo de anestesia, tipo o duración del procedimiento operatorio y número de violaciones de la técnica. Se observaron 8 abscesos y 3 casos de celulitis sin supuración, diagnosticados a los 10 días de la operación. El estafilococo fue la única bacteria identificada en la coloración de Gram o en el cultivo. El costo del Povidone no se justifica en nuestro hospital, y los recursos disponibles pueden ser mejor utilizados en antibióticos preoperatorios o en mejorar la infraestructura hospitalaria, lo cual debe dar como resultado menos violaciones de la óptima técnica en los quirófanos.

References

1. Cruse, P.J.E., Foord, R.: A five-year prospective study of 23,649 surgical wounds. Arch. Surg. *107*:206, 1973
2. Holmes, J., Readman, R.: A study of wound infections following inguinal hernia repair. J. Hosp. Infect. *28*:153, 1994
3. Public Health Laboratory Service: Incidence of surgical wound infection in England and Wales. Lancet 2:659, 1960
4. Taylor, E.W., Byrne, D.J., Leaper, D.J., Karran, S.J., Brown, M.K., Mitchell, K.J.: Antibiotic prophylaxis and open groin hernia repair. World J. Surg. *21*:811, 1997
5. Reggiori, A., Ravera, M., Cocozza, E., Andreata, M., Mukusa, F.: Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa. Br. J. Surg. *83*:356, 1996
6. Anoymous: Unrecognized, misunderstood, and undefined: infection control in developing countries. Africa Health *12*:40, 1990
7. Longombe, A., Nyankunde, C.M.E.: Postoperative dressings: are they really necessary? Trop. Doct. *20*:41, 1990
8. Coonick, M., Todd, I.: Surgery in the developing world: the challenge to Britain. J. R. Soc. Med. *85*:581, 1992
9. Meier, D.E., OlaOlorun, D.A., Nkor, S.K., Aasa, D., Tarpley, J.L.: Ketamine: a safe and effective anesthetic agent for children in the developing world. Pediatr. Surg. Int. *11*:370, 1996
10. Ofili, O.P.: A comparison of wound complications after inguinal hernia repair under local and general anesthesia. Trop. Doct. *21*:40, 1991
11. Law, D.J.W., Mishriki, S.F., Jeffery, P.J.: The importance of surveillance after discharge from hospital in the diagnosis of postoperative wound infection. J. R. Coll. Surg. Engl. *72*:207, 1990
12. Baily, I.S., Karran, S.E., Toyn, K., Brough, P., Tanaboldo, C., Karran, S.J.: Community surveillance of complications after hernia surgery. B.M.J. *304*:46, 1992
13. Platt, R., Zaleznik, D.F., Hopkins, C.C., Dellinger, E.P., Karchmer, A.W., Bryan, C.S., Burke, J.F., Wikler, M.A., Marino, S.K., Holbrook, K.F., Tosteson, T.D., Segal, M.R.: Perioperative antibiotic prophylaxis for herniorrhaphy and breast surgery. N. Engl. J. Med. *322*:153, 1990
14. Lazorthes, F., Chiotasso, P., Massip, P., Materre, J.P., Sarkissian, M.: Local antibiotic prophylaxis in inguinal hernia repair. Surg. Gynecol. Obstet. *175*:569, 1992