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Major article

Sterile reprocessing of surgical instruments in low- and middle-income countries: A multicenter pilot study

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Background: Surgical site infections increase the morbidity, mortality, and costs associated with surgical care. An estimated 96.2 million surgical procedures are performed in low- and middle-income countries (LMICs) each year. This pilot study assessed the steam sterilization aspect of the surgical instrument reprocessing practice in LMIC hospitals.

Methods: Surgeons representing 26 hospitals in 9 different LMICs were consented to test the single most frequently used autoclave in their respective surgical departments. Participants conducted 10 chemical integrator tests and recorded the total cycle time, exposure temperature, and pressure on each test. Data were analyzed with descriptive statistics and reviewed by medical reprocessing experts.

Results: Nine of the 26 (35%) study sites representing 7 countries returned their autoclave data and test strips (n = 90). Of the sites, 78% obtained acceptable readings on all 10 tests. When the data were compared against the recommended parameters for sterility, the results were less favorable. All 90 tests had at least 1 variable not within the target exposure time, temperature, or pressure.

Conclusion: This pilot study presents concerns in regard to the effectiveness of steam autoclaves used in LMIC hospitals and the subsequent risks this presents to surgical patients. We acknowledge the resource limitations in many LMIC hospitals. However, the international medical community must ensure that basic sterile practice guidelines are adhered to despite these constraints.

Surgical site infections (SSIs) dramatically increase the morbidity, mortality, and economic costs associated with surgical care.[1] In high-income countries (HIC), tremendous resources are used by hospitals and health authorities to meet national standards on instrument reprocessing and SSI surveillance.[2-4]

Approximately 81% of the world's 7 billion people live in low- and middle-income countries (LMICs).[5] A 2008 study estimated that 96.2 million surgical procedures are performed in LMIC each year.[6] Resource constraints in LMIC hospitals often inhibit the ability to follow internationally accepted infection control guidelines for reprocessing of surgical instruments, subjecting this population to an increased risk of SSIs and the associated complications.[7,8]

There are many important steps to ensure the sterility of medical instruments, including instrument disassembly, inspection, cleaning, and packaging prior to sterilization. Steam under pressure using an autoclave is the most common and cost-effective method of achieving instrument sterilization. The steam autoclaves used for medical device reprocessing in LMIC hospitals are often antiquated models that have been donated and may not be appropriate for the given power supply, water pressure, and steam capacity.[9,10] Insufficient numbers of trained technical personnel employed by LMIC hospitals restrict the capacity for routine maintenance on autoclaves and the complimentary infrastructure. The Centers for Disease Control and Prevention and Pan-American Health Organization have published guidelines on necessary disinfection and sterilization processes.[7,11] However, a literature review found no previous studies on the effectiveness of surgical instrument

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Conflicts of interest: None to report.

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Table 1
Description of study sites and their autoclaves

Site	1	2	3	4	5	6	7	8	9	Mean
Demographics										
Hospital type	Tertiary	Tertiary	Tertiary	Tertiary	District	District	Tertiary	District	Tertiary	-
Hospital funding	Government-publicly funded	Charity-NGO	Government-publicly funded	Government-publicly funded	Government-publicly funded	Charity-NGO	Government-publicly funded	Government-publicly funded	Government-publicly funded	-
Size of hospital (beds)	≥300	100-199	200-299	≥300	200-299	≥300	100-199	≥300	≥300	-
Annual number of surgery	6,000	2,009	Not reported	3,840	2,000	9,000	7,104	8,256	10,298	6,063
Frequency of autoclave testing	Daily	Monthly	Not inspected	Not inspected	Not inspected	Monthly	Weekly	Daily and monthly	Monthly	-
Type of autoclave testing	Chemical indicators	Chemical indicators	N/A	N/A	N/A	Biologic indicator, visual inspection	Visual inspection	Biologic, chemical indicators and visual inspection	Biologic, chemical indicators and visual inspection	-
Autoclave tested										
Type	Prevacuum	Prevacuum	Prevacuum	Prevacuum	Prevacuum	Prevacuum	Prevacuum	Prevacuum	Prevacuum	-
Age (y)	16	16	16	24	36	46	16	39	19	25.3
Last serviced (d)	101	206	443	183	20	181	7	28	120	143.2
Sterilization cycles per week (average)	42	14	18	50	70	30	43	42	60	41.0

N/A, not applicable.; *NGO*, Non-Governmental Organization

sterile reprocessing in LMIC hospitals, and given the resource constraints, it is questionable as to whether these or other guidelines are followed in practice or achievable in this setting.[12]

The objective of our study was to evaluate the effectiveness of the steam sterile reprocessing practice of surgical instruments in LMIC hospitals. Autoclaves in these facilities were characterized and assessed for their ability to meet international parameters for steam sterilization. This pilot study is an important initial inquiry into the effectiveness of current reprocessing systems in LMIC hospitals with high surgical volumes.

METHODS

Surgeons from LMICs participating in a scientific conference (Institute for Global Orthopaedics and Traumatology International Research Symposium) in the United States in September 2013 were invited to participate in the study. These surgeons, representing 26 hospitals in 9 different LMICs, were consented to test the single most frequently used autoclave in their respective surgical departments.

Participants were provided with 10 class 5 chemical integrator test strips (3M Comply SteriGage Chemical Integrator; 3M, St. Paul, MN) and asked to perform 1 test per day on the first sterile reprocessing cycle of each day for a total of 10 days. The study participants were instructed to place the test strip inside a clean linen wrap and insert the wrapped test strip into the center of the middle rack of the autoclave for a full sterilization cycle. Flash sterilization was not permitted for the purpose of this study.

For each test cycle, the participants also recorded the total cycle time, exposure temperature, pressure maintained during the cycle, and number of items placed inside the sterilizer. These data were then compared against internationally recognized parameters for sterilization.[13,14] Additional information was collected on the specifications and maintenance schedule of the autoclave along with usage data and surgical volume at the enrolled hospitals.

The 3M Comply SteriGage Chemical Integrator was chosen to evaluate the performance of autoclaves because of its ability to be used without reliance on additional devices or laboratory support. The test strip has a black marking that appears when the appropriate temperature and steam saturation are sustained for an appropriate time based on the following formula[15]:

$$t = F_o \times 10^{(250-T)/Z}$$

where t = time for 100% kill at temperature T; T = processing temperature; F_o = kill time for *Geobacillus stearothermophilus* with a z value of 18°F (10°C) and D value of 1 minute at 250°F (121°C); and z = rise in temperature required to increase the rate of kill by a factor of 10 (usually about 18°F [10°C]).

Data were collected from October-December 2013. The findings collected by each site were digitally photographed and e-mailed to the investigators for analysis. Medical reprocessing experts reviewed data on cycle time, exposure temperature, and pressure for additional insight into the effectiveness of the sterilization process. Descriptive analysis were conducted to evaluate the characteristics of the study's hospital size, autoclave maintenance, and autoclave function.

RESULTS

Nine of the 26 (35%) study sites representing 7 countries (Nepal: n = 2, Nigeria: n = 2, Tanzania: n = 1, Ecuador: n = 1, The Philippines: n = 1, Kenya: n = 1, and Haiti: n = 1) returned their autoclave data and 10 test strips (n = 90). Reasons for