Monitoring of steam sterilization process by biologic indicators—a necessary surveillance tool

To the Editor:

Sterilization of instruments is an important step in the infection control protocol. Inadequate sterilization is an important cause of exogenously acquired infections. Rates of surgical site infection differ in different studies, varying from less than 1 to over 9 per 100 procedures. Surgical site infections along with urinary tract infections and respiratory tract infections are the most commonly encountered hospital acquired infections. Several international and national authoritative bodies have recommended regular use of biologic indicators as a process control tool. A study about monitoring the efficacy of steam sterilization employing biologic indicators as well as chemical indicators evaluated on a monthly basis for a period of 1 year was conducted in 11 hospitals, which functioned exclusively as eye care hospitals.

METHODS

Hospitals in the study group were using downward displacement steam sterilizers (autoclaves) for the process of sterilization. The efficacy of steam sterilization was assessed using biologic and chemical indicators simultaneously on the first Saturday of every month from October 2001 to September 2002. The hospitals were supplied with spore strips containing approximately $10^5$ spores of Bacillus stearothermophilus ATCC-7953 obtained from Hi-Media Ltd, Mumbai, India. Spore strips were inserted wrapped in a cotton cloth measuring 90 $\times$ 120 cm placed at the bottom center compartment of drum along with a complete set of instruments, gadgets, and accessories required for performing 1 cataract operation. Cloth of the same material was used in all hospitals. Subsequent to the autoclaving, the spore strips were processed as per established standards. A level 2 Bio safety cabinet was used to transfer the strips to the broth. The broth was incubated at $56^\circ$C for 7 days. The broth, which appeared turbid on visual assessment, was subcultured on a blood agar plate, and the subsequent growth was assessed by staining and biochemical methods conforming to that for B stearothermophilus. Adequate positive and negative controls were used with each cycle. Chemical indicator strips (Chempack India Ltd, Pune, India) were tagged to the cloth containing the biologic monitor.

RESULTS

The sterilization cycles were studied 132 times, using both types of indicators simultaneously. On 7 occasions, the biologic indicator spore strips were misplaced, lost, or inadvertently opened subsequent to autoclaving. These 7 cycles were excluded when compiling results. Biologic indicators demonstrated bacterial growth from spore strips on 15 (12%) out of 125 cycles indicated by development of turbidity in the growth medium. The subculture from broth confirmed growth of B stearothermophilus on all occasions. Chemical indicators revealed a change of color to black after all 125 cycles. The chemical indicators thus failed to demonstrate ineffective sterilization on the 15 occasions. The failure rates among the cycles assessed in hospitals varied, and no single hospital had clearly high failure rate. Subsequent to reported failure, an engineer examined the autoclave for malfunctioning and rectified any fault that was found. The failure rate was high during first quarter of the study year, and there was a reduction in the failure rates over subsequent quarters. Statistical analysis was performed using ANOVA software. Analysis depicted a trend toward reduction in subsequent quarters, which was not statistically significant because the $P$ value was .53.

DISCUSSION

Biologic indicators are ideal monitors of sterilization process because, unlike chemical indicators, they measure the sterilization process directly by using spores. Ineffectiveness of the sterilization process could be caused by many problems such as trapping of air, grossly wet material, faulty pressure gauge, overloading of drums, and/or inadequate holding time. These problems could arise because of faulty autoclaves and/or inadequately trained staff. In our study, the biologic indicators demonstrated a failure rate of 12%. The results of our study supplement the fact that biologic indicators as process control tools are superior to the commonly used chemical indicators. Monthly surveillance led to a trend of reduction in failure rates, thus substantiating the important need of regular surveillance. Most of the hospitals in developing countries recommend regular use of biologic indicators.
countries use steam sterilizers for sterilization. The sterilization process has very strict regulatory requirements in developed countries where conducting validation tests such as the Bowie-Dick test, Chamber leak test, air detector test, and load dryness tests are mandatory. Centers for Diseases Control recommendations include biologic monitoring of the sterilization process under Category IB. In developing countries such as India, until some form of process control and documentation becomes mandatory, chemical indicators need supplementation with biologic indicators regularly.

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References

No routine surface disinfection

To the Editor:

We write in response to the article by Rutala and Weber in the American Journal of Infection Control, on which we wish to comment.

We admire Dr Rutala’s continued crusade for routine surface disinfection in hospitals, although the Hospital Infection Control Practices Advisory Committee (HIC-PAC), which he serves as a consultant, suggests and does not recommend routine surface disinfection in noncritical patient areas. In other words, their advice is based on suggestive studies only (category II). W. Rutala and J. Weber’s knowledge of the scientific literature is remarkable. However, their knowledge of the German language and, correspondingly, interpretation of the German literature demand some improvement. By no means does the Robert Koch-Institute in Germany recommend “the use of surface disinfectants for patient equipment surfaces and non-critical housekeeping surfaces in patient care areas.” Rather, the Robert Koch-Institute divides the hospitals into different areas, according to infectious risks for patients and recommends cleaning for most surfaces, and surface disinfection only for surfaces in frequent contact with hands and skin of patients and personnel. Thus, most surfaces should be cleaned and not disinfected, even in operating theatres and intensive care and isolation units (see Table 1). Category IB denotes an expert opinion, and category II means neither recommended nor required, but only “suggested” for implementation. Thus, a targeted strategy is recommended, but not routine disinfection of all noncritical patient care surfaces.

May we also correct the authors’ interpretation of our German paper. By no means do we recommend “that the MRSA-patient room be disinfected three times a day on intensive care units and once a day on normal wards (including floors).” In this paper, we recommend disinfection only of surfaces frequently touched by patients, which does not include the floors, and we only recommend floor disinfection after discharge of a multidrug-resistant Staphylococcus aureus (MRSA) patient.

The main reason we recommend surface disinfection in certain patient areas with MRSA patients is that the United Kingdom and Germany are the 2 countries in Europe with the highest annual increase in MRSA; therefore, we have increased our MRSA-infection control efforts to keep the MRSA level from reaching that of the United States.

We are also intrigued as to the type of computer search used by Dr. Rutala for his review of the literature from 1996 to April 2004, which provided no evidence that the use of low-level disinfectants results in allergic symptoms in health care workers. In just 10 minutes of searching, we found 2 articles describing allergy to benzalkonium chloride in health care workers.

Polish authors examined 223 nurses with suspected occupational dermatoses and found benzalkonium chloride (23.8%), nickel (21.5%), and formaldehyde (20%) as the most frequent sensitizers. Nettis et al reviewed their data base from 1994 to 1998 and selected 360 consecutive patients working in health care environments who experienced contact dermatitis on their hands, wrists, and forearms. The major relevant agents that induced occupational allergic contact dermatitis were nickel, glutaraldehyde, benzalkonium chloride, and rubber chemicals.