

Evaluation of a Hydrogen Peroxide-Based System for High-Level Disinfection of Vaginal Ultrasound Probes

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Objectives—Because of the complex process and the risk of errors associated with the glutaraldehyde-based solutions previously used at our institution for disinfection, our department has implemented a new method for high-level disinfection of vaginal ultrasound probes: the hydrogen peroxide-based Trophon system (Nanosonics, Alexandria, New South Wales, Australia). The aim of this study was to compare the time difference, safety, and sonographers' satisfaction between the glutaraldehyde-based Cidex (CIVCO Medical Solutions, Kalona, IA) and the hydrogen peroxide-based Trophon disinfection systems.

Methods—The Institutional Review Board approved a 14-question survey administered to the 13 sonographers in our department. Survey questions addressed a variety of aspects of the disinfection processes with graded responses over a standardized 5-point scale. A process diagram was developed for each disinfection method with segmental timing analysis, and a cost analysis was performed.

Results—Nonvariegated analysis of the survey data with the Wilcoxon signed rank test showed a statistical difference in survey responses in favor of the hydrogen peroxide-based system over the glutaraldehyde-based system regarding efficiency ($P = .0013$), ease of use ($P = .0013$), ability to maintain work flow ($P = .026$), safety ($P = .0026$), fixing problems ($P = .0158$), time ($P = .0011$), and overall satisfaction ($P = .0018$). The glutaraldehyde-based system took 32 minutes versus 14 minutes for the hydrogen peroxide-based system; the hydrogen peroxide-based system saved on average 7.5 hours per week. The cost of the hydrogen peroxide-based system and weekly maintenance pays for itself if 1.5 more ultrasound examinations are performed each week.

Conclusions—The hydrogen peroxide-based disinfection system was proven to be more efficient and viewed to be easier and safer to use than the glutaraldehyde-based system. The adoption of the hydrogen peroxide-based system led to higher satisfaction among sonographers.

Key Words—infection control; transvaginal ultrasound; ultrasound technology

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Abbreviations

FDA, Food and Drug Administration

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Evaluation of the female pelvis with ultrasound involves both transabdominal and transvaginal images for increased specificity and sensitivity. Because nondisposable invasive ultrasound probes are needed for transvaginal image acquisition, there is a potential for contamination of these instruments with blood, pathogens, or debris and, thus, cross-contamination in future patients.

High-level disinfection—currently defined by the US Food and Drug Administration (FDA) as a 6-log reduction in bacterial, viral, and fungal pathogens—is necessary to prevent disease transmission.¹ Multiple FDA-approved methods achieve high-level disinfection. Manual chemical immersion of reusable medical devices with a glutaraldehyde-based solution (Cidex; CIVCO Medical Solutions, Kalona, IA) is a widely practiced form of high-level disinfection that this institution previously used.²

In a busy practice, a particular transvaginal ultrasound probe may be used up to 5 times per day in a diverse patient population. The glutaraldehyde-based method, although effective, is quite tedious and involves several steps and quality control measures. Along with manual disinfection and 3 sequential glutaraldehyde-based baths, multiple variables must be monitored during the process, including temperature, solution concentration, and soaking time. Because liquid glutaraldehyde can burn the skin³ and vaporized glutaraldehyde can irritate respiratory mucosa,^{3,4} proper chemical protection attire and ventilation are required. Thus, repeating this complicated procedure several times per day is logistically difficult, is time-consuming for the sonographer, and introduces the possibility of error. Any failure during this process can lead to inadequate disinfection, damage to the medical device, or even personal injury.

Recently, our institution adopted a new disinfection method that addressed several of these problems. The Trophon system (Nanosonics, Alexandria, New South Wales, Australia) is a self-contained, FDA-approved unit for high-level disinfection of transvaginal ultrasound probes.^{5,6} This process involves the instillation of hydrogen peroxide mist inside the device chamber with a mechanized process controlling the temperature, mist concentration, and disinfection time. Although manual disinfection and periodic chemical concentration evaluations are still performed, the process is much more automated and time-efficient. Also, because the unit is self-contained, the risk of injury to the operator's skin and respiratory tract is minimal.

The aim of this study was to compare the time difference, cost, and sonographers' satisfaction between the glutaraldehyde- and hydrogen peroxide-based high-level disinfection systems.

Materials and Methods

The Institutional Review Board approved a 14-question survey that was administered to the 13 sonographers in our ultrasound department. The data were collected anonymously by the head sonographer and evaluated by the pri-

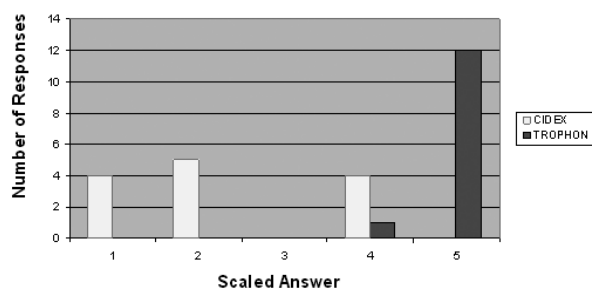
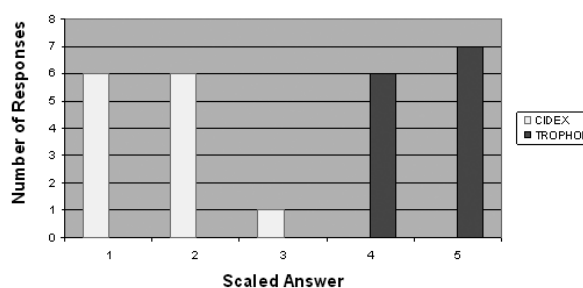
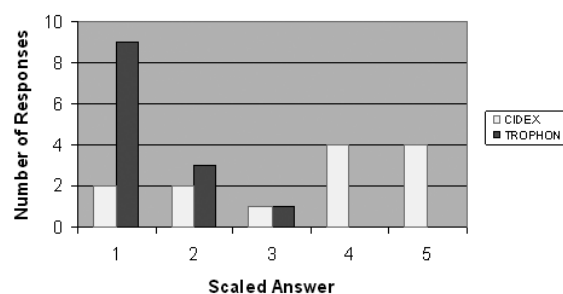
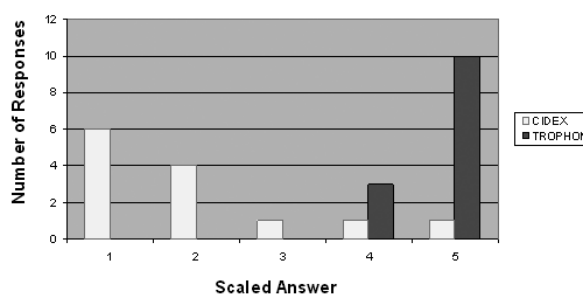
mary authors. The survey covered a variety of topics, including the ability to disinfect the probe, ease of disinfection, problems with the disinfection process, efficiency, work flow, safety, documentation, and time needed to disinfect the probe (Table 1). The survey included a 5-point standardized scale ranging from strongly disagree to strongly agree. The same questions were applied to both the glutaraldehyde-based disinfection system and the hydrogen peroxide-based system (Figures 1–4 and Table 2).

In addition, the head sonographer generated process diagrams for both the glutaraldehyde-based and hydrogen peroxide-based disinfection processes. Segmental time increments were measured for each step of the disinfection process (Figures 5 and 6).

We performed a cost analysis for both systems. For the glutaraldehyde-based disinfection process, these costs included solutions, containers, disposal of the liquids, and safety equipment. We did not include the cost for the ventilation system and maintenance because of the substantial variation in data among sample institutions. The costs of the hydrogen peroxide-based system included the unit, maintenance, and documentation. We calculated the time required by each disinfection process and the time saved per ultrasound examination (Figures 5 and 6). The time saved was extrapolated to determine the average number of ultrasound examinations performed by week, month, and year. Nonvariegated statistical analysis involved the Wilcoxon signed rank test (2 paired samples).

Table 1. Survey Questions

Question
1. I am always able to disinfect the probe per the guidelines.
2. I am always certain that the probe is disinfected with this method.
3. Disinfection is easy with this method.
4. In general, this method is easy to use.
5. Problems arise frequently with this disinfection method.
6. I am able to fix problems easily when they arise with the disinfection process.
7. Disinfecting the probe takes little time.
8. This method makes me more efficient.
9. I perform examinations more efficiently with this method.
10. I feel the need to skip disinfection steps to maintain work flow.
11. I am concerned about safety using this disinfection method.
12. There is a lot of required documentation with this method.
13. Overall, I am happy using this equipment.
14. Please document average disinfection time.

Figure 1. Scaled responses for the ease-of-use question.**Figure 2.** Scaled responses for the efficiency question.**Figure 3.** Scaled responses for the safety question.**Figure 4.** Scaled responses for the happiness question.

Results

On the basis of the Wilcoxon analysis, we found a statistically significant difference in favor of the hydrogen peroxide-based system over the glutaraldehyde-based system on all 14 questions, including ease of use ($P = .0013$), efficiency ($P = .0013$), safety ($P = .0026$), and overall satisfaction with the system ($P = .0018$; Table 2).

Time analysis demonstrated that the glutaraldehyde-based system took 32 minutes versus 14 minutes for the hydrogen peroxide-based system (Figures 5 and 6). The hydrogen peroxide-based system saved on average 7.5 hours per week based on the time difference between systems (18 minutes) and the assumption that a typical probe is used for 5 scans per day or 25 scans per week, as is the case in our department. The results of the sonographer survey also supported these findings (Figure 7). The median reported disinfection time for the glutaraldehyde-based system was in the 31- to 40-minute range, and the time for the hydrogen peroxide-based system was in the 11- to 20-minute range ($P = .0011$; Figure 7 and Table 2).

The average cost of disinfecting 1 vaginal ultrasound probe for a week assuming 5 scans per day was \$34.43 with the glutaraldehyde-based system (cost included the Cidex solution and solution concentration testing strips) versus \$137.72 for the hydrogen peroxide-based system (cost included the Trophon solution and testing diskettes).

When extrapolated for the year, the daily costs to disinfect and maintain the hydrogen peroxide-based system were \$2427.36 more than the costs for the glutaraldehyde-based system (Table 3). The standard reimbursement at our facility for a pelvic ultrasound examination (including transvaginal and transabdominal portions) is \$185. Given the above maintenance costs, the number of additional studies that would need to be performed with the hydrogen peroxide-based system to make up the cost difference is less than 1 per week or 14 per year (Tables 4 and 5).

Table 2. Statistical Significance of Survey Responses by Question

Question	<i>P</i>
1. Able to disinfect per guidelines	.0082
2. Certainty of disinfection	.0263
3. Disinfection is easy	.0013
4. Method is easy to use	.0013
5. Problems arise frequently	.0024
6. Able to fix problems	.0158
7. Disinfection takes little time	.0019
8. Method makes operator more efficient	.0013
9. Perform examinations more efficiently	.0020
10. Need to skip disinfection steps	.0260
11. Concerned about safety of method	.0026
12. Required documentation	.0026
13. Overall happiness	.0018
14. Average disinfection time	.0011

Figure 5. Time study flowchart for the glutaraldehyde-based disinfection method.

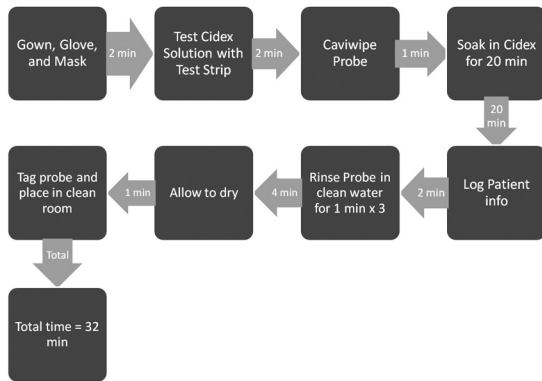


Figure 6. Time study flowchart for the hydrogen peroxide-based disinfection method.

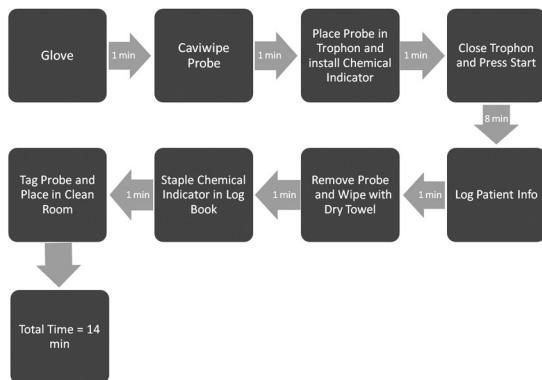


Figure 7. Scaled responses for the average disinfection time question.

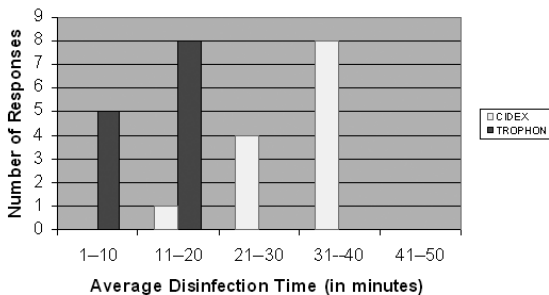


Table 3. Maintenance Cost Difference Between the Glutaraldehyde- and Hydrogen Peroxide-Based Disinfection Systems Averaged Over Various Periods

Maintenance Cost	Cidex, \$	Trophon, \$	Difference, \$
Weekly cost, 1 unit, 25 scans/wk	34.43	85.00	50.57
Monthly cost, 1 unit, 100 scans/mo	137.72	340.00	202.28
Yearly cost, 1 unit, 1200 scans/y	1,652.64	4,080.00	2,427.36

The initial upfront cost of a single hydrogen peroxide-based disinfection system is approximately \$12,000. If the initial costs are spread over the first year, an additional expenditure of \$231 per week, or \$1000 per month, would have to be added to the maintenance costs. Thus, with the corrected cost difference (maintenance plus unit cost averaged over a year), the number of additional studies that would need to be performed with the hydrogen peroxide-based system to make up the difference is less than 2 per week, or 78 per year, for the first year (Tables 4 and 5). Once the cost of the unit is covered after 1 year, only the maintenance fees would be required (Table 3). With the additional time saved during the disinfection process, it would be quite feasible to perform 1 additional pelvic ultrasound examination per week to cover the cost difference. Any additional studies would add to department productivity.

These data are based on the conservative estimate of performing 5 transvaginal ultrasound examinations for each hydrogen peroxide-based system because this number is the average in our department. A hydrogen peroxide-based system could be used more or less than 5 times per day on average depending on the ultrasound department. If the hydrogen peroxide-based system were used just 2 times per day, 3 hours would be saved each week, and 4 more scans could be performed each week, which would cover the cost of the hydrogen peroxide-based system more than twice over. If the hydrogen peroxide-based system were used 10 times per day, 15 hours would be saved each week, 20 more studies could be performed each week, and the cost of the hydrogen peroxide-based system could be covered in just 3.5 weeks.

Discussion

The safe use of medical devices is vital. Part of the popularity of ultrasound stems from the fact that it is considered harmless with no complications or potential adverse effects. Therefore, ensuring that invasive medical instruments are appropriately disinfected is critical. Recently, concerns about safety in the disinfection of medical equipment have been raised regarding colonoscopies.⁷ Although no reports of disease transmission with transvaginal ultrasound probes

Table 4. Maintenance Cost Difference Between the Two Disinfection Systems Averaged Over Various Periods: Number of Additional Scans Needed to Cover the Cost Difference With the Hydrogen Peroxide-Based System

Cost Difference	No. of Additional Scans
Weekly cost, \$50.57	1/wk
Monthly cost, \$202.28	2/mo
Yearly cost, \$2,427.36	14/y

have been documented, sensitivity to potential problems is heightened, and preemptive action is recommended.

Methods for disinfecting probes have evolved over the years. Initially, safety parameters required merely soaking the probes in a glutaraldehyde-based solution for 20 minutes. In time, recommendations changed and required probes to be soaked using a self-filtering system to eliminate hazards to employees from the chemical fumes. Most recently, the recommendations have required stringent disinfection procedures after soaking as well as timed documentation of each process. Thus, the identification of an efficient, simple, reliable, and safe method of transvaginal ultrasound probe disinfection is important.

There are many systems for high-level disinfection, but because we only have had direct experience working with two systems, we were only able to compare a glutaraldehyde-based disinfection system and a hydrogen peroxide-based system. Although the time saved and costs might be slightly different with other systems, such as a phthalaldehyde-based solution (Cidex OPA), replacing these harsh chemicals with a hydrogen peroxide-based system that is automated and standardized removes variables and improves safety for sonographers and patients. Another limitation with our study was that our cost analysis did not take into account the cost to install a hood and ventilation

system that would be needed to implement a glutaraldehyde-based system. Costs to install a ventilation system vary widely depending on the institution, but for our institution in a typical hospital, the initial upfront cost would be approximately \$5000. The initial upfront difference would only be \$7000 and would be even easier to make up than the \$12,000 deficit due to the cost of the hydrogen peroxide-based system on which our analysis was based. However, because the ventilation costs vary so greatly, and most institutions would be considering an alternative to a glutaraldehyde-based system, the cost of the ventilation system was not included in our direct cost analysis.

The transition to the hydrogen peroxide-based system has eliminated many of the variables that decreased confidence with the glutaraldehyde-based system. The hydrogen peroxide-based system has proven to be easier to use, more efficient, and safer and has engendered greater satisfaction among the sonographers. The hydrogen peroxide-based system is also more cost-effective. The initial upfront costs are more substantial than those of the glutaraldehyde-based system, but the time saved allows more studies to be performed. The costs of the hydrogen peroxide-based system and its maintenance would be paid for by performing 1.5 more ultrasound examinations per week, and the system's efficiency would create 7.5 additional hours for more ultrasound examinations per week. After the first year, only 1 additional ultrasound examination per week would need to be performed to cover the cost of maintenance. In our busy department, we have purchased 4 hydrogen peroxide-based disinfection systems, and we hope to implement them in outlying ultrasound departments in our medical system as well.

The hydrogen peroxide-based system has proven to be easier to use, more efficient, safer, and more cost-effective. We recommend the adoption of the hydrogen peroxide-based system for high-level disinfection of vaginal ultrasound probes.

Table 5. Maintenance Cost Difference Added to Unit Cost Difference for the Two Disinfection Systems Averaged Over Various Periods: Number of Additional Scans With the Hydrogen Peroxide-Based System That Would be Needed to Cover the Total Cost Difference

Maintenance Cost Difference	Unit Cost Over 1 y, \$	Total Cost Difference, \$	No. of Additional Scans
Weekly cost, \$50.57	231	281.57	1.5/wk
Monthly cost, \$202.28	1,000	1,202.28	7/mo
Yearly cost, \$2,427.36	12,000	14,427.36	78/y

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