

ASGE Technology Status Evaluation Report: disposable endoscopic accessories

To promote the appropriate use of new or emerging endoscopic technologies, the American Society for Gastrointestinal Endoscopy Technology Assessment Committee has developed a series of status evaluation papers. By this process, relevant information about these technologies may be presented to practicing physicians for the education and the care of their patients. In many cases, data from randomized controlled trials are lacking, and only preliminary clinical studies are available. Practitioners should continue to monitor the medical literature for subsequent data about the efficacy, the safety, and the socio-economic aspects of the technologies.

BACKGROUND

Endoscopic procedures are important for the diagnosis and the treatment of many GI diseases. During these procedures, disposable or reusable accessories, (e.g., biopsy forceps, wire snares, guidewires, cytology brushes, needles, baskets, balloons, sphincterotomes) often are used for sampling or therapy.^{1,2} This report will summarize the advantages and the disadvantages of disposable and reusable devices, with consideration of their efficacy, ease of use, safety, and financial and medical-legal issues.

TECHNICAL CONSIDERATIONS

Disposable accessories are delivered by manufacturers in sterile packages and are designed for single use. Their advantages include convenience, variety, lower cost per unit, potential for custom design, consistent performance, and safety as a result of their low risk for cross contamination. Their disadvantages include potential higher per procedure and cumulative costs, the need for disposal after use, and the impact of such disposal on the environment.³ Reusable accessories are designed to allow for cleaning and sterilization or high-level disinfection after each use.³ The advantages of the reusable accessories include reduced disposal burdens and potentially reduced environmental impacts and cost savings over time. Disadvantages include

higher per unit purchase costs, an increased risk for cross contamination, wear and decline in function, storage costs, and increased personnel costs for maintenance.³

Many endoscopy centers, realizing the cost disadvantages of disposable accessories have tried to further reduce costs by reprocessing and reusing single-use devices.⁴ This practice grew after some studies suggested that reuse of some single-use devices could be done safely and cost-effectively,⁵⁻⁸ leading to the emergence of an industry of third-party reproducers. The primary problems associated with reuse of disposable accessories are concerns about their sterility and proper performance subsequent to reprocessing.^{3,9} Third-party companies that specialize in reprocessing of single-use devices are responsible for providing essential quality control pertaining to sterility and integrity of the equipment after processing.^{3,10} Liability issues that result from reuse of single-use devices are complex, may vary by state, and are beyond the scope of this report.

Before August 2000, the third-party reprocessing industry was unregulated.^{4,11} To ensure that reprocessed devices are equivalent to the original products, the Food and Drug Administration (FDA) provided enforcement guidance stipulating that all regulatory requirements applicable to original equipment manufacturers, including premarket submission requirements, will be enforced on both hospital and third-party reproducers.¹² Thus, reproducers were mandated to submit validation data on cleaning, sterilization, and functional performance of reprocessed single-use devices to obtain FDA approval to market them. This guidance, updated in November 2004 after a review of supplemental data submitted by some reprocessing firms, is posted on the FDA Web site.¹³ The FDA Web site also provides a list of reprocessed single-use devices that can or cannot be commercially distributed after reprocessing.

COMPARATIVE STUDIES

Numerous prospective studies that examine issues related to disposable and reusable endoscopic accessories, as well as reprocessing of single-use accessories, have been published.¹⁴⁻²² Many of these studies compared reusable and disposable biopsy forceps with respect to cost and performance.¹⁵⁻²² The durability, purchase and reprocessing costs, and, hence, cost-effectiveness of

reusable vs. disposable accessories varied greatly between studies. Based upon then current data, most investigators concluded that reusable biopsy forceps are cheaper than disposable forceps if they are used frequently. Estimates for durability of reusable biopsy forceps range from 20 to 91 uses without repair and up to 315 uses with serial repairs.^{17,19,22} A Belgian unit that reported 315 uses per reusable forceps noted a cost of \$6.65 per biopsy session in 1996.¹⁹ A U.S. study reported a rapid decline in function of reusable devices after 20 uses. In this study, done in 2000, 25% of reusable forceps malfunctioned after 16 to 20 uses, whereas 80% malfunctioned after 21 to 25 uses. With 2000 data, the investigators noted that the costs for disposable and reusable forceps were similar if reusable forceps were used 15 to 20 times. Reusable forceps became less expensive if they were used more than 20 times; however, their performance diminished at that point. This study concluded that cost differences between disposable and reusable forceps were minimal when reusable forceps sold for \$415, disposable biopsy forceps were less than \$40, and reprocessing costs were \$16.56 ± 0.07.¹⁷ In a retrospective cost-minimization analysis, a French study that used a \$364 reusable forceps approximately 90 times reported a comprehensive cost per biopsy session of \$6.84, compared with their then current costs of \$10.70 to \$15.60 for disposable forceps.²⁰ A prospective U.S. study that evaluated reprocessing, function, and adequacy of tissue specimens obtained with reusable biopsy forceps concluded that they can be sterilized and used a mean of 91 times, that mechanical problems were minor until the time of breakage, and that reusable devices were cost-saving with this frequency of use.²²

In one randomized trial, the performance of reusable forceps was rated as inadequate (2%) or poor (12%) during 48 uses, whereas disposable forceps received no inadequate or poor ratings. Reusable forceps were disassembled after an average of 12 uses and were noted, by light microscopy, to have residual human debris but no microbiologic testing was performed.²¹ Another study, which used radiolabeled human blood in an experimental setting, investigated the adequacy of reprocessing of single-use and reusable biopsy forceps, single-lumen papillotomes, and a reusable stone-retrieval basket to determine if they would meet the functional standards of a new device and the regulatory standards for sterility. This study found that all devices remained contaminated after cleaning. After disinfection and sterilization, the reusable devices were effectively disinfected, but none of the reprocessed single-use instruments were effectively disinfected or sterilized.¹⁵

Several studies have evaluated accessories used in ERCP. A 1997 study published in 1999 found that reusable sphincterotomes could be safely and efficiently used a mean of 3.1 times. When comparing disposable and reprocessed disposable sphincterotomes, their use became cost effective after 2.2 and 7.9 uses, respectively.²³

A recent study of the reliability, the cost-effectiveness, and the safety of reusable sphincterotomes and stone-removal baskets also demonstrated that reuse was safe in terms of infectious hazards and that these reusable instruments were cost effective when compared with single-use accessories.¹⁶ Based on 342 ERCPs, during which 50 accessories were used, this study found that, for optimal efficiency, the median number of uses for each accessory was 10. Cost analysis based upon 2002 data revealed that internal reprocessing was a more cost-effective option than external reprocessing or use of disposable devices.¹⁶

There are limited data on the impact of the FDA action in 2000 on the safety of reprocessed single-use devices. A recent study among 54 Michigan hospitals with over 200 beds noted a shift from on-site reprocessing toward third-party reproducers for all varieties of medical devices and that no hospitals were reprocessing sphincterotomes.²⁴

FINANCIAL CONSIDERATIONS

Prices for single-use devices change rapidly, vary significantly, and often are determined by local contracts. Reuse of single-use devices reprocessed by third-party companies costs significantly less than new devices. However, even then, costs vary and are dependent on acquisition and reprocessing costs, as well as the number of procedures performed and devices contracted. Some studies have suggested that any extra cost generated by the use of disposable forceps is offset by simplified inventory control and by the theoretical reduction of the risk of cross contamination.¹⁸⁻²¹

The number of uses required to equate the costs of reusable and single-use items can be estimated by the formula:

$$\text{number of uses} = \frac{\text{reusable device cost}}{\text{disposable device cost} - \text{reprocessing cost}}$$

For example, if a reusable biopsy forceps costs \$500, a single-use forceps costs \$15, and reprocessing costs \$10, it would require the reusable forceps to have a life span of 100 uses to become cost effective. Estimates of reprocessing costs for reusable biopsy forceps vary between \$3.25 and \$16.56.¹⁷

Reimbursements for disposable and reusable devices used during a procedure are increasingly incorporated into global facility fees and vary based upon the setting, the payer, and individual components of the procedure. The details of varied procedures are beyond the scope of this review.

SUMMARY

Uncertainty still exists regarding the relative costs and the clinical effectiveness of disposable vs. reusable

endoscopic accessories. Intuitively, single-use devices do not pose a risk for transmission of infection. Properly maintained and reprocessed reusable devices remain safe and effective. Both single-use and reusable accessories function well, and the selection of one or another class of devices must be based upon local purchase costs, reprocessing costs and abilities, storage and disposal facilities, and personal preferences.

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