Durability of Flexible Cystoscopes in the Outpatient Setting

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OBJECTIVE To ascertain cystoscope durability in relation to usage and cost in the outpatient setting.

METHODS Six flexible cystoscopes were provided to our outpatient clinic by 2 vendors. Five Wolf 7305.006S02 cystoscopes (Richard Wolf Medical Instruments Corporation, Vernon Hills, IL) and 1 Olympus CYF-5 (Olympus America, Center Valley, PA) were used 2477 times over a 14-month study period. Prospective data were accumulated on each cystoscope including type of procedure, number of uses until mechanical failure, physician usage, and maintenance costs. All staff was trained in proper handling and maintenance of cystoscopes utilizing an Occupational Safety and Health Administration (OSHA) approved protocol. Retrospective comparison was performed of 1346 cystoscopic procedures during the previous 8 months before implementation of the processing protocol, with data including type and quantity of mechanical failures along with maintenance costs.

RESULTS Five total study period failures occurred in 4 cystoscopes, with a mean of 495.4 procedures/failure. In 3 separate cystoscopes, failure occurred after 70 (perforation of working channel), 194 (leak in bending rubber), and 236 uses (hole in bending rubber). One cystoscope had 2 failures after 168 (cut in bending rubber) and 255 uses (failed leak test). During the retrospective period, there were 10 failures, with a mean of 134.6 procedures/failure. Four failures were secondary to crushed insertion tubes. Comparison of retrospective and study period costs revealed a 43.9% decrease from $9.64 per procedure to $5.41 per procedure.

CONCLUSION Outpatient flexible cystoscope durability seems directly related to optimization of handling and storage of cystoscopes. Costs related to mechanical failure were reduced with a rigorous reprocessing protocol. UROLOGY 81: 932–937, 2013. © 2013 Elsevier Inc.

Flexible cystoscopy is widely used as a diagnostic and therapeutic modality to identify lower urinary tract pathology. First described by Tsuchida and Sugawara[1] in 1973, flexible cystoscopy has become an integral component in the evaluation and treatment of urologic patients. In an era of rising health care costs and continued development of cystoscopic instruments, data regarding cystoscope durability, cost, maintenance, and safety are lacking.

In this study, we prospectively studied the durability of 6 commercially available flexible cystoscopes. Our specific aims were to first, elucidate the effect of a rigorous handling protocol on the durability of flexible cystoscopes in the outpatient setting, and second, to analyze the costs associated with maintenance related to mechanical failure. Although other investigators have evaluated repair patterns of flexible cystoscopes, this is the first study, to our knowledge, focusing on durability and performance in relation to a rigorous reprocessing protocol, mechanical failure, and maintenance costs.[2,3] Our hypothesis is that a rigorous maintenance protocol will reduce overall cystoscope repairs and costs related to mechanical failure.

MATERIAL AND METHODS

We prospectively investigated cystoscope processing and repair costs from July 1, 2008, through August 31, 2009, in an academic urology outpatient clinic. The practice consists of 11 urologists with over 23,000 patient encounters annually. Six commercially available flexible cystoscopes were provided without charge by 2 vendors. Five Wolf 7305.006S02 cystoscopes (Richard Wolf Medical Instruments Corporation, Vernon Hills, IL) and 1 Olympus CYF-5 (Olympus America, Center Valley, PA) were used. All cystoscopes before the study period were refurbished and during the study period were new. Costs associated with cystoscope purchase were excluded from our analysis. Internal review board approval was obtained for the study. Prospective data were accumulated on each cystoscope including the type of procedure, presence and type of mechanical failure, number of usages until mechanical failure, physician usage, and uroseptic events. Procedures were labeled as diagnostic, biopsy related, and those used for ureteral stent removal. Before the study period, all cystoscopes underwent high level

Financial Disclosure: *The authors declare that they have no relevant financial interests.*
Funding Support: *Richard Wolf Medical Instruments Corporation provided support for this research in the form of reduced materials cost and complimentary training.*

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Submitted: October 17, 2012, accepted (with revisions): January 20, 2013

0090-4295/13/$36.00
http://dx.doi.org/10.1016/j.urology.2013.01.029

Table 1. OSHA approved cleaning procedure for urology cystoscopes[5,6]

Step 1: Leak test the flexible cystoscope. Keep the needle on the leak tester in the green area. If the cystoscope passes the leak test, remove all air out of the cystoscope while leaving the leak tester attached for 30-60 seconds. If the cystoscope fails the leak test, do not put into the Steris 1 System Processor. Manually clean the cystoscope and send for repair.
Step 2: Fill a sink with warm water and add enzyme cleaner.
Step 3: Submerge all equipment in the sink and disassemble them fully. This includes removal of light post adapters.
Step 4: Brush and flush all channels and open ports with enzyme cleaner 3 times.
Step 5: Using a soft cloth or 4 × 4 soaked in enzyme cleaner, wipe down the outside of the equipment.
Step 6: Drain, rinse, and refill sink with warm water. Repeat steps 4 and 5 using warm water alone.
Step 7: Once the device is cleaned, place in the appropriate Steris tray and attach the appropriate STERIS Quick Connect.

OSHA, Occupational Safety and Health Administration.

disinfection (HLD), which included manual cleaning and flushing with a glutaraldehyde-based sterilizing agent before storage in a carrying case. All reprocessing during the retrospective period was in full accordance with Occupational Safety and Health Administration (OSHA) standards and manufacturer recommendations.[4] There was no standardized office reprocessing protocol at that time. The total number of uses for each specific cystoscope and the number of uses before mechanical failure for each cystoscope were not documented before the study period.

During the study period, cystoscopes were cleaned and flushed by urology nursing staff trained in proper handling and maintenance of cystoscopes, utilizing an OSHA approved handling and reprocessing protocol in addition to the protocol of the Steris 1 System Processor (SS1, STERIS Corporation, Mentor, OH) (Table 1).[5,6] The SS1 was used in this study secondary to the fact that it was Food & Drug Administration (FDA) approved at the time of study. Eleven total urology nurses and medical assistants were trained on proper reprocessing. Implementation of the reprocessing protocol did not require additional full time equivalents for the study period as existing office personnel were trained by the cystoscope manufacturer at no cost. Office personnel were constant during the retrospective and study period.

All cystoscopes were leak tested, disassembled, and submerged before manual cleaning with enzyme detergent. They were then rinsed and placed in the appropriate Steris tray (Table 1). After sterilization, the cystoscopes were then stored in a drying cabinet. A user log was kept prospectively throughout cystoscope reprocessing and use. Records were prospectively maintained and each cystoscope was analyzed after each use to evaluate for damage. Information provided by the endoscope manufacturer included maintenance pricing and the type of repair. Damaged cystoscopes underwent a multipoint inspection by the endoscope manufacturer in order to determine the cause of failure. Retrospective cost and maintenance analysis of cystoscope procedures from November 1, 2007, through June 30, 2008, was collected. During the 8-month period before the study, 5 refurbished Wolf 7305.006S02 cystoscopes were used. Invoices comparing maintenance costs from the 8-month period before the study and before adoption of the reprocessing protocol (November 1, 2007 through June 30, 2008) and the 14 months of the study (July 1, 2008 through August 31, 2009) were analyzed and compared. There was no difference in vendor costs between the retrospective and study periods.

RESULTS

A total of 1346 outpatient cystoscopy procedures were performed during the 8-month period preceding the study from November 1, 2007, through June 30, 2008. During the study period of July 1, 2008, through August 31, 2009, a total of 2477 cystoscopy procedures were performed with a mean of 412.8 procedures/cystoscope and also 495.4 procedures/failure. During the 8 months before the study, 1346 procedures and 10 different repairs were required for all 5 cystoscopes with a mean of 269.2 procedures/cystoscope and 134.6 procedures/failure. Four of the 10 total failures included crushed insertion tubes. Three failures included a broken deflection, 2 of which also had a hole in the working channel. One failure was secondary to a leak at the strain relief, 1 biopsy port was broken, and channel damage was noted during 1 recorded failure. These results are detailed in Table 2. There were 2 episodes of urosepsis during the retrospective period.

This was compared to the study period in which 5 total repairs for 4 different cystoscopes were recorded. The number of uses until damage occurred along with the type of procedure which caused the damage and the associated cost of repair during the study period is shown in Table 3. Cystoscopes #2-4 were noted to have mechanical failure at 194 (leak in bending rubber), 236 (hole in bending rubber), and 70 (perforation of working channel) uses, respectively (Table 3). Cystoscope #5 had 2 failures during the study period at 168 and 255 uses secondary to a cut in the bending rubber and a failed leak test, respectively. There were no episodes of urosepsis during the study period.

Further quantification of the types of procedures used for each cystoscope before mechanical failure is shown in Table 4. The cystoscope with the earliest failure (Wolf #4) had the highest percentage of total stent removals, biopsies, and fulgurations (21 of 70 or 30%). Mechanical failure generally occurred earlier in cystoscopes with a higher percentage of uses secondary to stent removals, biopsies, and fulgurations (Table 4). Analysis of maintenance and repair costs revealed a 43.9% reduction per procedure from $12,970.00, or $9.64 per procedure, during the 8 months preceding the study as compared to $13,406.00, or $5.41 per procedure during the study period.