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Office Cystoscopy Urinary Tract Infection Rate and Cost before and after Implementing New Handling and Storage Practices

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Abstract

Introduction: Based on 2010 American Urological Association recommendations our practice transitioned from sterile to high level disinfection flexible cystoscope reprocessing and from sterile to clean handling practices. We examined symptomatic urinary tract infection rate and cost before and after policy implementation.

Methods: We retrospectively reviewed 30-day outcomes following 1,888 simple cystoscopy encounters that occurred from 2007 to 2010 (sterile, 905) and 2012 to 2015 (high level disinfection, 983) at the Malcom Randall Veterans Affairs Medical Center. We excluded veterans who had recent instrumentation, active or recent urinary tract infection, performed intermittent catheterization, or had complicated cystoscopy (dilation, biopsy etc). Patient/procedural factors and cost were collected and compared between groups.

Results: Both cohorts had similar age (mean 68 years), race (Caucasian, 82%), comorbidities (cancer history, 62%; diabetes mellitus, 36%; tobacco use, 24.5%), and cystoscopy procedural indications (cancer surveillance, 50%; hematuria, 34%). Urological complication rate was low between groups (1.43%) with no significant difference in symptomatic urinary tract infection events (0.99% sterile vs 0.51% high level disinfection, p=0.29) or unplanned clinic/emergency department visits (0.66% sterile vs 0.71% high level disinfection, p=0.91). Roughly 95% of the cohorts were given prophylactic antibiotics, most commonly fluoroquinolones (91%). High level disinfection was $82 cheaper per procedure than sterile with most cost disparity stemming from reprocessing. Total savings for our facility by switching to high level disinfection was more than $100,000 annually.

Conclusions: In an older, morbid veteran population receiving centralized care and prophylactic antibiotics we found no difference in symptomatic urinary tract infection or unplanned visits between sterile or high level disinfection techniques. However, high level disinfection was associated with a sizable cost savings, improved clinic workflow, and reduced use of personal protective equipment.

Key Words: cystoscopy, antibiotic prophylaxis, disinfection

Abbreviations and Acronyms

AUA = American Urological Association

GU = genitourinary

HLD = high level disinfection

SUNA = Society of Urologic Nurses and Associates

UTI = urinary tract infection

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Flexible cystourethroscopy (cystoscopy) is the most common genitourinary office procedure. It is traditionally performed using sterilized or high level disinfection (U.S. Food and Drug Administration approved liquid sterilant and disinfectants) instruments and with standard sterile technique (sterile drapes, prepping and gloves). After cystoscopy, reported rates of febrile, symptomatic urinary tract infection range anywhere from 0.85% to 6% in the literature depending on a number of clinical factors such as perioperative antibiotic use and preculture status.[1–4]

Due to U.S. Food and Drug Administration concerns about the automated Steris System 1 liquid sterilization reprocessor the American Urological Association and the Society of Urologic Nurses and Associates issued a joint white paper in March 2010 detailing new protocols for flexible cystoscope reprocessing including precleaning, leak testing, rinsing and drying.[5] The protocol also recommended ventilated cabinets to store clean scopes up to 10 days and effectively endorsed HLD technique as the minimum level of cystoscope sanitation. Following this publication in 2011 Veterans Affairs hospitals across Florida implemented new protocols to prepare GU flexible scopes in clinic, replacing the wet Steris System 1 scopes with dry scopes from a Reliance Endoscopic Reprocessor. As these scopes were no longer sterile, providers began wearing clean gloves out of a box. Sterile gowns were replaced with clean scrubs, and postcystoscope handling practices were standardized using manufacturer protocols.

Given the homogeneity of our veteran cohort and the closed Veterans Affairs electronic record system, our group was in a unique position to assess the sterile vs clean endoscope effect on UTI rate with only a minimal loss of expected followup in this uniquely captured population. In addition to a cost analysis, we hypothesized that symptomatic urinary tract infection rate after flexible cystoscopy would be similar in GU patients using sterile technique compared to highly clean techniques and tested this theory in our population.

Materials and Methods

Population and Inclusion/Exclusion Criteria

After obtaining University of Florida and Veterans Administration Institutional Review Board approval (IRB201501080), we generated our patient catalog by searching the national Veterans Affairs Computerized Patient Record System for all patients in the North Florida/South Georgia Veterans Integrated Service Network with Current Procedural Terminology code 52000 (simple cystourethroscopy) logged from 2007 to 2010 (sterile cystoscopy conditions) and 2012 to 2015 (HLD cystoscopy conditions). Encounters from 2011 were excluded due to our transition to new HLD protocols. We collected information on each patient including age, sex, race, indication for procedure, prophylactic antibiotic use, precystoscopy urinalysis/most recent urine culture result and problem list/medical history with any comorbidity that could raise UTI rate including diabetes/antihyperglycemic medications, HIV status, solid organ transplant history, dialysis/end stage renal disease status, cancer and chemotherapy history, steroid use, autoimmune disorders, tobacco use, UTI history, benign prostatic hyperplasia, overactive bladder, lower urinary tract symptoms, spinal cord injury, kidney stones and asymptomatic bacteriuria. Our clinic followed the 2008 AUA Best Practice Policy Statement on Urological Surgery Antimicrobial Prophylaxis, which recommended fluoroquinolone antibiotic prophylaxis for a wide range of patient risk characteristics.[6]

Patients were excluded from study entry for reasons including previous or postcystoscopy catheter placement within 1 month, bacillus Calmette-Guérin within the previous 6 weeks, suprapubic tube placement within the previous 6 weeks, stents removed within the previous 6 weeks, kidney stone procedure or tubes within the previous 6 weeks, any bladder or urethral fistulas, neobladder augment, active UTI or recently treated UTI within 30 days, clean intermittent catheterization within 7 days of cystoscopy, artificial urinary sphincter in place, and any urethral dilation. Our primary outcome was any reported or treated UTI within 30 days of cystoscopy. Secondary outcome was any unplanned clinic or emergency department visit within 30 days of cystoscopy regardless of its relationship to cystoscopy procedure.

Cost

For each condition we broke cost into procedural and reprocessing costs. Procedural costs were based on the materials needed for preparation and completion of 1 procedure. These included the transport kits, table drain bag, solidifier fluid, gowns, iodine, prep trays, gloves and drapes. Reprocessing costs were based on the sterilant and maintenance costs of the respective machines as well as the cost of labor. This total monthly cost was averaged over the number of scopes reprocessed to yield an estimated cost of reprocessing per scope. Of note, sterile reprocessing includes the cost of HLD reprocessing (done per disinfection protocols) as well as the cost of sterilization.

Statistical Analysis

Prestudy sample size calculations were based on an expected UTI rate of 5% and reduction of UTI by 2% between experimental and control groups. Using a standardized

Table 1.
Demographics, comorbid conditions and cystoscopy indications/antibiotics

	Overall		2007–2010		2012–2015	
Total No.	1,888		905		983	
Demographics:						
Mean age (SD)	68.16	(10.6)	68.02	(11.0)	68.29	(10.2)
No. male gender (%)	1,823	(96.6)	867	(95.8)	956	(97.3)
No. race (%):						
White	1,559	(82.6)	752	(83.1)	807	(82.1)
Black	153	(8.1)	57	(6.3)	96	(9.8)
Other	145	(7.7)	96	(10.6)	80	(8.1)
No. comorbid conditions (%)						
Cancer	1,135	(60.1)	534	(62.9)	601	(61.4)
Type 2 diabetes mellitus	651	(34.5)	302	(35.5)	349	(35.7)
Tobacco history	445	(23.6)	201	(23.7)	244	(24.9)
Benign prostatic hyperplasia	343	(18.2)	140	(16.5)	203	(20.7)
Kidney stones	246	(13.0)	94	(11.1)	152	(15.5)
Lower urinary tract symptoms	138	(7.3)	69	(8.1)	69	(7.1)
Transplant	73	(3.9)	60	(6.6)	13	(1.3)
Recurrent UTI	51	(2.7)	23	(2.7)	28	(2.9)
No. cystoscopy indications (%)						
Urothelial cancer surveillance	941	(49.8)	442	(48.8)	499	(50.8)
Microhematuria	395	(20.9)	156	(17.2)	239	(24.3)
Gross hematuria	255	(13,5)	101	(11.2)	154	(15.7)
Lower urinary tract symptoms	168	(8.9)	98	(10.8)	70	(7.1)
Bladder mass by imaging	53	(2.8)	28	(3.1)	25	(2.5)
No. prophylactic antibiotic administered (%):						
Any antibiotic given	1,799	(95.3)	833	(92)	966	(98.3)
Quinolone	1,721	(91.2)	795	(87.9)	926	(94.2)
Gentamycin	54	(2.9)	38	(4.2)	16	(1.6)
Bactrim	24	(1.3)	0	(0.0)	24	(2.4)

difference of 60%, power of 0.8 and 2-tailed hypothesis, the number of cystoscopy encounters required to see a difference was estimated to be around 1,750. Patient demographics, indication for cystoscopy, and comorbidities are reported as mean±SD, and data were compared using a paired sample t-test. Rates of reported or treated UTI after cystoscopy are compared across treatment groups using a Fisher's exact test. Analysis was performed using SAS® and statistical significance was defined by $p < 0.05$. Cost was calculated per cystoscopy and projected through a year to determine approximate difference in annual clinic expense under each of the conditions.

Results

A total of 1,888 unique GU cystoscopy encounters were recorded with 905 in the sterile treatment group and 983 in the highly disinfected treatment group. The 2 groups were similar demographically when considering age, sex and race (table 1). The groups were also comparable in terms of procedural indications and comorbidities. Roughly half of flexible cystoscopies in our cohort were performed for bladder cancer surveillance followed closely by hematuria workup (table 1). Almost 60% of each group had a cancer history, about a third had type 2 diabetes and a quarter were active smokers. About 95% of our patients were administered a prophylactic antibiotic, most commonly either an oral dose of quinolone (91.2%) or an intramuscular dose of gentamycin (2.9%). Across the entire cohort we had a 1.43% complication rate following cystoscopy (see figure). Sterile and HLD groups had symptomatic UTI rates less than 1% with no

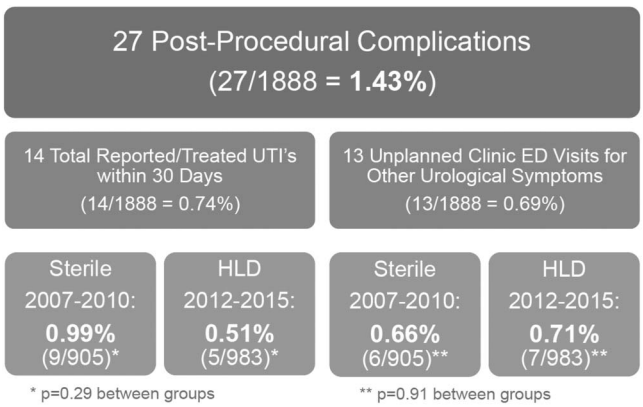

Figure. Postprocedural complications following simple office cystoscopy. Treated symptomatic UTI rates shown (left panels) with no difference between sterile and HLD (p=0.29). Unplanned visits shown (right panels) with no difference between sterile and HLD (p=0.91).

Table 2.
Cystoscopy procedural item cost with totals stratified by common, sterile or HLD.

Procedural Items	$ Single Item Cost
Items in common:	
Transport kit	3.35
Drainbag table	8.00
Solidifier fluid	18.00
Iodine	0.93
GU prep tray	14.26
Disinfection reprocessing	6.20
Total common cost	50.74
Sterile-only items:	
Surgical gown	4.19
Sterile gloves	2.94
Sterile drape	1.17
Sterilization costs	75.00
Sterile added cost	83.30
Total sterile cost	134.04
HLD-only items:	
Isolation gown	0.82
Nitrile gloves (1 pair)	0.16
HLD added cost	0.98
Total HLD cost	51.72

statistically significant difference between groups (p=0.29). Rate of unexpected ED or clinic visits for other urological complaints (hematuria, urinary frequency etc) were also low (less than 1%) and not statistically different (p=0.91, see figure).

Costs associated with sterile and HLD protocols are illustrated in table 2. GU prep trays ($14.26) and solidifier solution ($18) contributed to 28% and 36% of total common costs, respectively. HLD isolation gown and 1 pair of nitrile gloves added $0.98 to the total common procedural costs. Sterile preparation added $83.30 to total common costs, with 10% of this ($8.30) coming from procedural items and 90% ($75) coming from sterile reprocessing costs (labor, materials). HLD protocols amounted to a total cost savings of $82.32 per procedure. Based on the approximate number of simple cystoscopies carried out at our facility per year, we estimated HLD protocols have saved our clinic about $101,000 annually.

Discussion

Modern sterilization protocols stratify infection risk based on how and where the surgical instrument is used.[7] "Critical" items (entering sterile tissue, bloodstream etc) require full sterilization with chemicals and steam or if heat sensitive very high concentrations of liquid chemical sterilants such as ethanol or hydrogen peroxide gas plasma. "Semi-critical" items (contacting mucous membranes) can undergo high level disinfection.[7] To meet the U.S. Food and Drug Administration requirements, these items are first cleaned then briefly exposed to lower concentrations of chemical disinfectants (combinations of glutaraldehyde, hydrogen peroxide, orthophthalaldehyde, peracetic acid etc) without steam, eliminating enough pathogens to prevent transmission of infection. In 2010 the joint AUA/SUNA white paper reinforced that either HLD or sterilization of a cystoscope is appropriate, depending upon available resources and institutional standards of practice.[5] However, due to a paucity of UTI information in this area this publication was based on mechanical aspects unique to flexible cystoscope instrument reprocessing and not on published infection data. Therefore, this study is the first to report clinical data that directly compares sterile to HLD procedures.

Based on results from our population 27 patients (1.43%) had some type of urological symptom after procedure, but only 14 (0.74%) of these were truly symptomatic UTIs. Of these we saw no significant difference in UTI rate between patients who received a simple, office based cystoscopy under sterile vs HLD conditions. Most of the controversy surrounding flexible cystoscopy safety is in regard to use of prophylactic antibiotics. Since almost all of our patients received prophylactic ciprofloxacin orally we can best compare our findings against treatment groups from other studies who received prophylactic antibiotics.

In 2008 the AUA updated its Best Practice Policy Statement on use of prophylactic antibiotics in urological procedures. It concluded that prophylaxis for office based cystoscopy was only necessary for patients at greater infection risk including advanced age, poor nutritional status, immunodeficiency and smoking, to name a few.[6] Although many of these risks seem discretionary, almost all of our patients met at least 1 if not more of these criteria, particularly if one considers 65 years as an age cutoff.[6] The committee's position on office cystoscopy was based primarily on 3 clinical studies. The best evidence against prophylaxis was a 2005 randomized trial of norfloxacin vs placebo in normal risk individuals undergoing diagnostic cystoscopy.[8] In a setting where urine was collected before and after cystoscopy (day 3, 7) for culture, the trial was stopped early due to limited sample size and low infection rate of 0.89% (1/112) norfloxacin group compared to 0.82% (1/122) placebo.[8] Notably, the scopes in this study were processed using a glutaraldehyde based sterilization system, not HLD.

The best evidence in favor of antibiotic prophylaxis for cystoscopy, as referenced by AUA statement committee, was from 2 prospective clinical trials. In 2001 using HLD scopes Rané et al randomized a small group of individuals undergoing bladder cancer surveillance to either 120 mg intramuscular gentamycin (82) or no prophylaxis (80) with before and after cystoscopy urine collected for culture.[9] Although they did not quantify patient symptoms and had a very high rate of patients excluded for positive precystoscopy urine

cultures (23%), they reported that intramuscular gentamicin reduced positive culture rate (defined by 10^5 CFU/ml or greater and 10 white blood cells/mm^3 or greater) from 21.3% (17/80 patients) without antibiotics to 3.7% (3/82 patients) with gentamycin ($p=0.004$).[9] Similarly, in a group of 2,083 patients randomized to a 3-arm placebo controlled trial, Johnson et al found a decrease in post-cystoscopy bacteriuria from 9.1% controls (62/684) to 4.6% trimethoprim prophylaxis group (33/712) and 2.8% ciprofloxacin prophylaxis group (19/687).[10] Only a third of individuals with positive cultures had symptoms, leading to a total post-cystoscopy symptomatic UTI rate ranging from 0.9% to 3%, depending on the group studied.[10] The findings of this study led the AUA panel to recommend quinolone antibiotic prophylaxis in higher risk groups, a recommendation that has since been redacted due to potential severe side effects of quinolone antibiotics.[11] The reported rates of symptomatic UTI in each of these studies compare favorably with our findings and substantiate our results.

This study is not without limitations. Due to its retrospective design we relied on patient report of symptoms to provider followed by documentation (note and/or prescription) into the electronic chart. It is possible that we underreported our UTI rate as some patients may not have reported their symptoms, may have self-treated or may have sought treatment from an outside provider. This is less likely in our population as veterans are financially incentivized to seek medical attention within system due to cost-free cares and services. Moreover, since our objective was to compare outcomes between sterile and HLD conditions we would expect this potential loss of followup to have affected groups evenly. Second, our symptomatic UTI rate of 0.74% is well below the 5% expected rate we used for power calculation. Therefore, it is possible that this trial is significantly underpowered to see a difference between groups. If symptomatic UTI rate is truly less than 1%, then thousands of cystoscopies in each group would be needed to see a statistically significant difference. Even then, one could argue that the clinically relevant difference between groups would be very small.

Regarding cost, we found HLD to be associated with a sizable cost savings at our institution of $101,000 annually. Most of the cost disparity came from the additional labor and machinery necessary for sterilization. Procedural costs (gloves, drapes, gowns) were able to be precisely calculated by reviewing invoices. However, reprocessing costs were based on our best estimation of chemical cost in sterilization, of hourly salaries of two additional employees involved in reprocessing, and of the annual costs for maintaining reprocessing machinery (not purchasing). These costs are estimates, and the actual cost will vary by institution.

Although the aggregate cost savings are impressive, there are more nuanced improvements seen with HLD that are harder to quantify. First, sterile scopes previously arrived wet from central processing inside a sterilized container. These scopes were returned and reprocessed if they were not used on the same day. HLD scopes are significantly easier to house and access than sterile scopes, as they can be stored dry in a ventilated cabinet for up to 10 days.[12,13] The savings from this cabinet extends further than just reduced reprocessing cycles and disinfectants. Less toxic waste has a positive environmental impact. Transporting scopes in bulk cabinets allows for easier clinic workflow planning compared to individual scope delivery, particularly in facilities with very high demand or with limited endoscope availability. Less patient preparation in the endoscopy suite minimizes procedural time and improves efficiency. Finally, in an era of limited resources, the reduced use of personal protective equipment under HLD conditions leaves more gowns and materials available for other hospital providers. Our overall impression is that HLD protocols yielded comparable clinical outcomes to sterile protocols with the benefit of reduced cost and enhanced clinic efficiencies.

Conclusions

In our older, morbid veteran population receiving centralized care and prophylactic antibiotics, there was no difference in UTI rate (0.74%) or other urological complications (0.69%) between sterile or HLD technique. The data presented are some of the first to compare clinical outcomes stratified by scope processing and clean vs sterile technique during simple office cystoscopy. Along with a number of subjective clinic procedural improvements, HLD technique was associated with a sizable cost savings. In conclusion, urologists should follow best practice guidelines for prophylactic antibiotic administration[11] and should consider HLD processing with clean technique for simple office based flexible cystoscopy procedures, depending on available resources and institutional standards of practice.

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Editorial Commentaries

Flexible cystourethroscopy is one of the most commonly performed office genitourinary procedures allowing urologists key access to diagnosing lower urinary tract pathology. In 2010 the AUA/SUNA issued a white paper endorsing high level disinfection with clean technique as an alternative to traditional sterilization should the modification align with institutional principles and available resources (reference 5 in article). One might reasonably assume that a relaxation of sterilization standards would result in increased postprocedural infection rates, yet there has been a paucity of clinical data correlating the relative risk of symptomatic UTI to reprocessing methods. The authors herein rightly identified the need for evidence-based analysis and have contributed the first paper addressing the impact of the recommendation on symptomatic infection rates as well as the economies resulting from aligning with the new guidelines.

Data on sterile, simple cystoscopy encounters were collected from 2007 to 2010 and HLD encounters from 2012 to 2015 for a total of 1,888 unique patients. The wholesale transition from one technique to the other precluded randomization and contemporaneity, but the authors convincingly show that the groups were quite similar. Both groups enjoyed excellent outcomes as the rate of symptomatic UTI was less than 1% across cohorts. Notably, the groups were indistinguishable on this parameter. What did separate the groups was total cost. HLD proved to be $82 cheaper per procedure for a total institutional benefit exceeding $100,000 annually. The authors have shown convincingly that switching to HLD does not compromise safety but importantly allows substantial cost savings and better workflow. As medical practices are increasingly pressed to do more with less, the authors make a strong case for the continued adoption of HLD guidelines.

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This manuscript helps to answer the question of whether migration from a sterile to high level disinfection flexible cystoscope reprocessing and from sterile to clean handling practices result in a higher rate of symptomatic UTIs. Not only was the infection rate comparable, but there is a significant cost savings. This study is retrospective. However, the authors have clearly taken great care to compare patient outcomes and costs of the 2 practices. Although it may not have been appropriately powered to see a difference, the data look extremely promising. My practice has been doing this for at least a decade with similar (slightly lower risk of UTI) and significant cost savings as well. Our cohort is similar, but we do not use antibiotic prophylaxis as used in this trial. The AUA best practice statement "Routine cystoscopy and urodynamic studies do NOT require antimicrobial prophylaxis in healthy adults in the absence of infectious signs and symptoms" (reference 11 in article). In 2019 we performed

over 34,000 diagnostic cystoscopies with a reported rate of infection of 0.32% with a prophylaxis rate of less than 2%. Additionally, we have taken this further and eliminated prep kits, using just betadine, sterile gauze sponge, a disposable under pad (chux) and nonsterile gloves, providing further cost savings. Historically, endoscopic sheaths showed promise in increasing efficiency and reducing cost of cleaning and repairs.[1] Now disposable scopes are available and the impact on infection and cost should be carefully reviewed. This study may move us forward to a more efficient, cost-effective method of cystoscopy.

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