Office Cystoscopy and Transrectal Ultrasound-guided Prostate Biopsies Pose Minimal Risk: Prospective Evaluation of 921 Procedures

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OBJECTIVES
To examine the outcomes of 2 commonly performed urologic office procedures as a part of a process to align these with the Joint Commission standards to ensure patient safety. We determined whether cystoscopy and transrectal ultrasound-guided prostate biopsy performed in the office setting pose minimal risk to patients.

METHODS
An evaluation of urologic office procedures in the office clinic setting of an academic medical center was prospectively performed during 3 different periods to document patient and system events. The patients included those undergoing cystoscopy for workup of hematuria, history of bladder cancer, or other indicated conditions (n = 554) and patients undergoing transrectal ultrasound-guided prostate biopsy for suspicion of prostate cancer (n = 367). All consecutive patients were evaluated.

RESULTS
A total of 7 patient events (0.76%) and 101 system events (10.97%) were documented. The most significant adverse patient event was 1 case of acute bacterial prostatitis due to quinolone-resistant Escherichia coli. In most cases, the system event rate reflected a delay of >15 minutes in the initiation of the procedure. No patient experienced significant bleeding, perforation, or a major cardiopulmonary event.

CONCLUSIONS
The results of our study have shown that cystoscopy and transrectal ultrasound-guided prostate biopsy procedures performed in the office setting pose a minimal risk to patients. This information could be useful for hospitals and practices that are undergoing efforts to align their individual policies with current Joint Commission standards.

The Institute of Medicine has drawn professional and public attention to the safety of patients in our healthcare system through 2 prominent publications.1,2 The Joint Commission, formerly known as the Joint Commission for Accreditation of Healthcare Organizations (JCAHO), has responded by developing a series of National Patient Safety Goals that must be followed to achieve accreditation.3 For patients undergoing surgery and procedures, the JCAHO developed the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery, which outlines a number of essential practices designed to ensure patient safety.4 The JCAHO excluded procedures they identified as being at “minimal risk,” such as venipuncture, peripheral intravenous insertion, insertion of nasogastrian tube, and Foley catheter insertion. All other procedures are considered more than minimal risk unless proved otherwise.

As our institution implemented these and other processes for ensuring the safety of patients undergoing surgery and other invasive procedures, we began to examine the outcomes of commonly performed outpatient office procedures. In 2006, the Department of Urology was asked to provide documentation showing that urologic office procedures are safe. Cystoscopy and transrectal ultrasound-guided prostate biopsy (TRUS-PB) are the most commonly performed procedures in most academic and private urology office practices. We thus performed a prospective quality assurance evaluation to evaluate the true risk associated with these 2 commonly performed procedures to address the concern that these would be considered as more than minimal risk.

MATERIAL AND METHODS

Patients
Data were collected during 3 different periods (July to November 2006, April to June 2007, and December 2007 to March...
Data Collection
Data collection was performed by the nursing team at the point of care. Any patient identified by the nursing team as having a potentially more difficult procedure was interviewed by telephone 24-48 hours after the procedure so that any additional events could be recorded. Both patient and system events were recorded. A system event was regarded as an event that did not directly relate to patient care, such as instrument unavailability, scheduling problems, or a delay in starting a procedure for any reason. A patient event was any event directly related to the care of the patient. All documentation was prepared by the nursing team without physician involvement. Additionally, a retrospective query was performed to capture any delayed events that might not have been captured by the nursing data collection.

Cystoscopy and TRUS-PB
Patients underwent history taking, physical examination, and laboratory evaluations in accordance with standard urologic practice and were scheduled to undergo cystoscopy or TRUS-PB on the basis of the findings of these tests. Per the JCAHO requirements, the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery was also completed.

At our institution, sedation was not given when cystoscopy was administered in the office setting per hospital policy. However, anxiolysis was occasionally used. Patients who were unable to tolerate the procedure in the office setting were scheduled to undergo the procedure in the outpatient setting in accordance with hospital policy. A total of 10 mL of viscous 2% lidocaine jelly was injected intraurethrally after the perineum was prepared and draped in a sterile field. Flexible or rigid cystoscopy was then performed and, depending on the findings, stent placement or exchange, or biopsy and/or fulguration of small tumors were done. A short course of postcystoscopy antibiotics was prescribed, and patients were discharged after voiding. Patients were informed that self-limiting hematuria might occur as a side effect of cystoscopy.

We also did not administer sedation when TRUS-PB was delivered in the office setting. Patients who were unable to tolerate the procedure in the office setting were scheduled to undergo the procedure in the outpatient setting. Similar to cystoscopy, anxiolysis was occasionally used. The patient self-administered an enema and took 1 dose of ciprofloxacin (Bayer, Leverkusen, Germany) immediately before the procedure. TRUS-PB was performed by a urologist or a credentialed physician assistant under the supervision of a urologist. Once ultrasonography was initiated and the anatomy characterized, 5 mL of 1% lidocaine was infiltrated bilaterally (total 10 mL) at the seminal vesicle/prostatic junction as a local anesthetic, and 10-12 tissue cores were taken using a disposable needle guide. Patients were discharged after voiding, and an additional 2 days of ciprofloxacin was prescribed. Patients were informed that self-limiting hematuria, self-limiting rectal bleeding, and hematospermia might occur as side effects of TRUS-PB.

Data Review
After data collection was completed, the study team members from the Urology and Quality Improvement departments reviewed the data. Summary findings and descriptive analyses were prepared. A data search was performed to identify publications with relevant information about the morbidity of office cystoscopy and TRUS-PB procedures to compare our data with the published results. Institutional review board approval was obtained for publication of this quality assurance study.

RESULTS
A total of 7 patient events and 101 system events were documented (Table 1). The total patient event rate was 0.76%, and the total system event rate was 10.97%. In most cases, the system event rate reflected a delay of >15 minutes in the initiation of the procedure. The most significant adverse patient event was the development of acute bacterial prostatitis due to quinolone-resistant Escherichia coli in 1 patient. This patient was treated in the hospital with culture- and sensitivity-directed intravenous antibiotics and was discharged on hospital day 3 with oral antibiotics. No patient experienced bleeding, perforation, or a major cardiopulmonary event during the period of the audits.

In a MEDLINE search, >500 reports were found that used the terms “cystoscopy,” “prostate biopsy,” “ambulatory surgery procedures,” “complications,” and/or “adverse effects.” We found few studies that reported data specific to the complications of cystoscopies performed in the office setting, although more data were found reporting adverse events associated with TRUS-PB.

COMMENT
We systematically evaluated 554 cystoscopy and 367 TRUS-PB outpatient procedures performed at 3 different periods. Our findings have shown that cystoscopy and TRUS-PB procedures performed in the urology office
setting pose a minimal risk to patients. The risk of patient events with cystoscopy was 0.18% and with TRUS-PB was 1.64% (total risk of patient events in the office setting was 0.76%). The most common events encountered were system events secondary to overbooked schedules, likely resulting from an overrepresentation in our population of patients with bladder cancer who require surveillance cystoscopy at a rate unproportional to that of patients treated for routine urologic conditions.

The finding of a quinolone-resistant infection revealed the increasing incidence of antibiotic resistance in the community setting. In a case-control study by Colodner et al., the independent risk factors for community-acquired urinary tract infections (UTIs) due to quinolone-resistant \textit{E. coli} were a history of previous quinolone use, a previous invasive procedure, recurrent UTI, and previous hospitalization. Given this concern, we have changed our current process to further minimize the amount of antibiotics prescribed by giving a single dose of prophylaxis after cystoscopy and a single day of prophylaxis after TRUS-PB. For TRUS-PB, the published data have shown that antibiotics significantly reduce the risk of major infectious complications by threefold. However, the agreement on the duration of therapy is poor, ranging from a single dose for low-risk patients to ≤7 days of therapy. One prospective study showed no benefit of 3-day therapy vs 1 day. The use of a rectal preparation with enemas also appears to significantly lower the rate of infectious complications. Taking >6 cores increases the risk of rectal bleeding, but major complications and hospitalizations remain low. Delayed complications have been evaluated prospectively using questionnaires and telephone follow-up surveys. The incidence of these has been exceedingly low, and most expected side effects resolve by 1-2 weeks. Using a population-based screening program, the major complication rates in 5802 patients undergoing sextant biopsies were low, with an incidence of fever of 3.5%, acute urinary retention of 0.4%, and hospitalization of 0.5%. A recently published report by Sieber et al. prospectively evaluated contemporary TRUS-PB complication rates in a community-based practice. The investigators compared the historical 6-core biopsy standard to the modern standard of 10-12 cores in 1000 consecutive patients. UTIs were detected in 0.11% of patients. One febrile UTI was due to quinolone-resistant \textit{E. coli}, and another to quinolone-resistant \textit{Stenotrophomonas maltophilia}. The third infection was due to quinolone-sensitive Enterococcus. Bleeding episodes were documented in 0.27% of patients, including 1 case of hematuria and 7 of rectal bleeding. None of these findings were statistically significant between the 2 groups, although a trend was seen toward increased rectal bleeding with the 12-core biopsies. A recent report by Gillespie et al. of 4 patients hospitalized with \textit{Pseudomonas aeruginosa} infections after TRUS-PB revealed that patients were infected because of improper reprocessing of contaminated needle guides. The investigators recommended prevention of this complication by following the manufacturers’ cleaning recommendations or by the use of disposable needle guides.

Although office cystoscopy is generally accepted as being low risk, little information is available in the current environment of heightened awareness to patient safety. The use of antibiotics has been addressed most frequently and for more than half a century, with current recommendations ranging from no prophylaxis for those at low risk to a single dose or short courses for those at greater risk.

The strength of the present study was the prospectively designed evaluation performed by nursing personnel without a professional or personal stake in the generated data. Although it is still possible that some patient events were missed, it is unlikely that this would have significantly changed the resulting data. This report probably overestimated the system events, because some of the reported outcomes, such as a delay of >15 minutes, might not be considered significant by some.

**CONCLUSIONS**

We have reported the rates of adverse patient and system events occurring after cystoscopy and TRUS-PB procedures performed in the office setting, showing that both procedures pose a minimal risk to patients. This information could be useful to hospitals and practices that are undergoing efforts to align their individual policies with the current Joint Commission standards.

**References**

EDITORIAL COMMENT

Although seemingly simple and intuitively obvious, this publication is nevertheless of critical importance for urologists in both academic and private practice. The Joint Commission, as noted, has published the “Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery” to help prevent medical errors and improve accountability in both diagnostic and therapeutic procedures. These requirements are becoming increasingly onerous for many practices. In our own institution, an attending faculty urologist must be present at the start of all procedures for a “preinduction time out” for diagnostic cystoscopies and transrectal needle biopsies of the prostate. Clearly, faculty input and oversight are integral parts of all urologic procedures; however, the classification of these less-invasive procedures in the same category as major surgery causes significant problems for patient care and efficient patient flow. Although patient safety is in fact paramount, the dearth of urologists, attempts to bring efficiency, and increased patient numbers to our practices require that urologists delegate non-medical tasks to others. To this end, many office-based procedures are organized, set in motion, and initiated by allied healthcare personnel in an effort to be more responsive to patients and their time requirements. Arguments for less formal treatment of these office-based diagnostic procedures can only occur with peer-reviewed data from well-constructed studies. With these and other similar data in hand, urologists can approach the Joint Commission and their medical centers with protocols that will not only offer excellent patient safety, but also facilitate patient flow and improve patient satisfaction with urologic care.

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