Increasing Hospital Admission Rates for Urological Complications After Transrectal Ultrasound Guided Prostate Biopsy

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Purpose: Transrectal ultrasound guided prostate biopsy is widely used to confirm the diagnosis of prostate cancer. The technique has been associated with significant morbidity in a small proportion of patients.

Materials and Methods: We conducted a population based study of 75,190 men who underwent a transrectal ultrasound guided biopsy in Ontario, Canada, between 1996 and 2005. We used hospital and cancer registry administrative databases to estimate the rates of hospital admission and mortality due to urological complications associated with the procedure.

Results: Of the 75,190 men who underwent transrectal ultrasound biopsy 33,508 (44.6%) were diagnosed with prostate cancer and 41,682 (55.4%) did not have prostate cancer. The hospital admission rate for urological complications within 30 days of the procedure for men without cancer was 1.9% (781/41,482). The 30-day hospital admission rate increased from 1.0% in 1996 to 4.1% in 2005 (p for trend <0.0001). The majority of hospital admissions (72%) were for infection related reasons. The probability of being admitted to hospital within 30 days of having the procedure increased 4-fold between 1996 and 2005 (OR 3.7, 95% CI 2.0–7.0, $p<0.0001$). The overall 30-day mortality rate was 0.09% but did not change during the study period.

Conclusions: The hospital admission rates for complications following transrectal ultrasound guided prostate biopsy have increased dramatically during the last 10 years primarily due to an increasing rate of infection related complications.

Key Words: mass screening, prostatic neoplasms, biopsy, adverse effects

Abbreviations and Acronyms

CIHI = Canadian Institute of Health Information

OHIP = Ontario Health Insurance Plan

SES = socioeconomic status

TRUS = transrectal ultrasound

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TRANSRECTAL ultrasound guided prostate biopsy is the most common method to determine the presence of prostate cancer.[1] Urological side effects of the procedure include urinary tract infection, hematuria and acute urinary retention.[2] To minimize these effects patients may be offered mechanical bowel preparation and receive prophylactic antibiotics, but standards of care have not been established. Randomized clinical trials comparing prophylactic antibiotics to placebo have shown reduced rates of infection following biopsy.[3,4] Rates of serious complica-

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tions requiring hospital admission for inpatient treatment have ranged from less than 0.1% to 2.4%.[5] However, previous studies were small[5–7] or were derived from a controlled clinical trial designed to examine a different end point.[8] To our knowledge no study has estimated the morbidity and mortality from a large population based sample.

In the last decade we have witnessed increasing rates of bacterial resistance to antibiotics, an increase in the use of antiplatelet agents and a high prevalence of benign prostatic hyperplasia. These trends raise the concern that the rates of serious complications following TRUS guided prostate biopsy might also be increasing. We examined a large, population based data set to establish the incidence of morbidity and mortality associated with TRUS guided prostate biopsy.

METHODS

Study Subjects and Data Sources

We conducted a population based retrospective study of all men who underwent TRUS guided prostate biopsy between January 1, 1996 and December 31, 2005 in Ontario, Canada. All medical procedures are reimbursed by a single, government operated health insurance system (OHIP). Because the sole indication for performing a TRUS guided biopsy is for the detection of prostate cancer, we included all men older than 18 years who underwent this procedure for the first time. To ensure that none of the patients had undergone previous biopsy we excluded anyone who had a biopsy within 5 years before 1996. However, in secondary analyses we examined the subset of patients who had repeat prostate biopsy among those with an initial negative biopsy within 2 years of the initial biopsy.

OHIP fee codes J138 (transrectal ultrasound) and Z712 (prostate needle biopsy) performed on the same procedure date were used to identify patients. We linked records from the OHIP physician claims database to several other Ontario health databases including the CIHI hospital separation database, the Registered Persons database (a vital statistics registry) and the Ontario Cancer Registry. The CIHI compiles data from 22 databases and registries including all hospital admission data. We used only the Most Responsible Diagnosis designation, which is defined as the most significant contributor to the length of hospital stay or the diagnosis that contributed to the longest length of stay. We electronically searched data from the hospital discharge administrative databases of CIHI using the ICD-9 and ICD-10. From 1996 to 2001 CIHI databases used ICD-9 codes and from 2002 to 2005 they used ICD-10 codes. The study protocol was approved by the research ethics board.

Main Outcome Measures

The main outcome was hospital admission for 1 of 3 urological conditions within 30 days of TRUS guided prostate biopsy. These included infections, bleeding and obstruction of the urinary tract. Previous studies have shown that these are the most serious urological complications and occur within 30 days from the date of biopsy.[5–8] The 30-day hospital admission rate was based on 3 hospital CIHI discharge diagnoses of 1) urinary infection related, 2) urinary bleeding related and 3) urinary obstruction related. Secondary outcome was 30-day mortality from the date of biopsy. Death information was obtained from the Registered Persons database which tracks all vital status information in the province.

The ICD coding scheme changed during the period data were collected from ICD-9 to ICD-10. To validate whether the transition between ICD-9 and ICD-10 codes (2001 to 2002) identified the same group of patients from each coding version we compared for any differences in the frequency of our list of ICD-9 and ICD-10 codes for all patients within Ontario admitted for the same list of chosen codes during the study period, regardless of having prostate biopsy.

Exposure Variables

We collected information on prostate cancer diagnosis through linkage of the database with the Ontario Cancer Registry. Median annual income was estimated from the neighborhood of residence using 1996 and 2001 census data, and was categorized into community specific quintiles. For each patient we retrieved the number of prostate biopsies performed by the treating physician in the previous year. We also collected information on comorbidity using the Deyo/Charlson comorbidity index.[9]

Data Analysis

We calculated 30-day hospital admission and mortality rates following the date of biopsy between 1996 and 2005. Discharge diagnoses were assigned to 3 categories of 1) infection related, 2) bleeding related and 3) urinary obstruction related. To ensure that hospital admission rates were not due to prostate cancer related treatment, we calculated rates separately for men with and without prostate cancer (based on biopsy result). Age was categorized into 5 groups of 1) younger than 50 years, 2) 50 to 59 years, 3) 60 to 69 years, 4) 70 to 79 years and 5) older than 79 years. Income status was also categorized into quintiles. We conducted multivariate unconditional logistic regression to estimate the odds ratio for 30-day hospital admission based on year of biopsy, age, SES and individual physician volume. Also, to account for other factors of individual physicians who performed the biopsies we adjusted for physician clustering using generalized estimating equations. Because individual physician volume could vary yearly, for every biopsy we assigned the number of biopsies performed by the physician in the last year from the date of biopsy. Statistical analyses were performed using SAS® software V9.1. Tests were 2-tailed and significant for $p < 0.05$.

RESULTS

TRUS Guided Prostate Biopsy Related Morbidity

Between 1996 and 2005, 75,190 men underwent TRUS guided prostate biopsy in the Province of Ontario. Each biopsy was performed by 1 of 437 different physicians. Among the 75,190 men 33,508 (44.6%)

were diagnosed with prostate cancer and 41,682 (55.4%) were not diagnosed with prostate cancer. The hospital admission rate within 30 days from TRUS guided prostate biopsy was 1.4% (1,057/75,190) for all patients. When compared by cancer status the 30-day hospital admission rate was 1.9% for patients without cancer (781/41,482) and 0.8% for patients with cancer (276/33,508, $p = 1.2 \times 10^{-35}$).

Given this difference in rates by cancer status we examined rates of hospital admission stratified by cancer status. Among the patients without cancer the rate of hospital admission after TRUS guided prostate biopsy increased from 1.0% in 1996 to 4.1% in 2005 ($p < 0.0001$, chi-square 184.4, 9 df) (see figure and table 1). For patients diagnosed with cancer the rate of hospital admission also increased during the study period. The 30-day hospital admission rate was 0.4% in 1996 and increased to 0.9% in 2005 ($p = 0.002$).

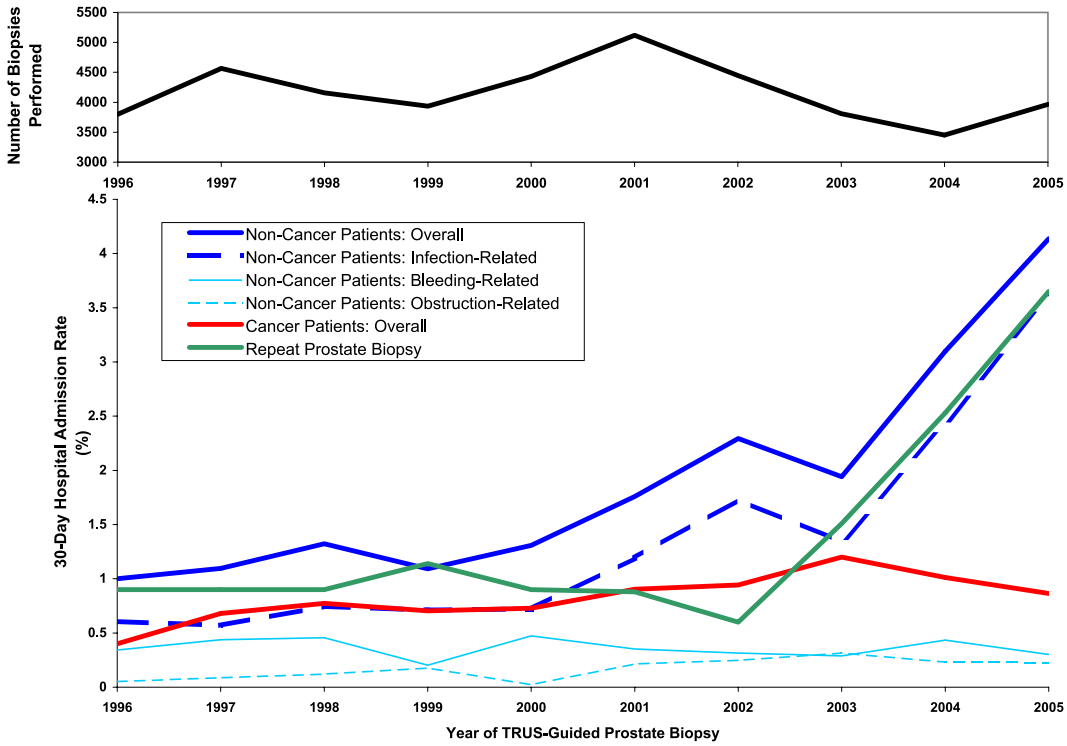
The rate was lower for patients with cancer because when those with prostate cancer were admitted to the hospital for biopsy related complications, the coders for the Most Responsible Diagnosis could have assigned it as prostate cancer rather than the complication related diagnoses. In addition, patients were likely to receive treatment for prostate cancer within 30 days of the biopsy, which also affected the accuracy of 30-day hospital admission rates. To dissociate the diagnosis of prostate cancer per se from the biopsy related morbid conditions, these analyses were restricted to the 41,682 men with no diagnosis of prostate cancer.

To determine which factors might be associated with the trend in hospital admission, we examined the crude rates of 30-day hospital admission by age and SES, and no differences were found (table 2). To address for potential factors associated with the 437 physicians performing all biopsies we also adjusted for physician clustering and procedural volume within the logistic model. The single most important factor predictive of hospital admission was year of biopsy. The adjusted odds ratio for hospital admission for patients undergoing biopsy in 2005 compared to those biopsied in 1996 was 3.74 (95% CI 2.0–7.0, $p < 0.0001$). For individual physician volume there was a negative correlation with 30-day hospital admission rates.

For the patients admitted to hospital mean time to admission from the date of TRUS guided prostate biopsy was 5.0 days (SD 7.9, median 1, range 0 to 30). Mean length of hospital stay was 1.1 days (SD 3.8, median 1, range 1 to 68). No significant differences were found for time to hospital admission or length of hospital stay when comparing by year of biopsy.

Causes for 30-Day Hospital Admission

The majority of hospital admissions were for infection related diagnoses (71.6%, 556), followed by bleeding related diagnoses (19.4%, 151) and urinary



Plots of 30-day hospital admission rate and 30-day mortality rate by year of biopsy and repeat prostate biopsy

Table 1. *Baseline patient characteristics*

	No. Study Subjects (%)
Yr of biopsy:	
1996	6,544 (8.7)
1997	7,951 (10.6)
1998	7,517 (10.0)
1999	7,200 (9.6)
2000	8,278 (11.0)
2001	9,651 (12.8)
2002	8,267 (11.0)
2003	6,725 (8.9)
2004	6,317 (8.4)
2005	6,740 (9.0)
Age category:	
Younger than 50	2,307 (3.1)
51–59	15,948 (21.2)
60–69	31,286 (41.6)
70–79	22,084 (29.4)
80 or Older	3,565 (4.7)
SES:*	
1	10,727 (14.5)
2	13,640 (18.5)
3	14,542 (19.7)
4	15,646 (21.2)
5	19,228 (26.1)

* Based on 73,783 subjects because SES could not be ascertained in 1,407. SES based on median annual income estimated from neighborhood of residence using 1996 and 2001 census data, and categorized into community specific quintiles within census regions, from 1—lowest income level to 5—highest income category. Specific income cutoffs cannot be provided because they vary within each community specific region.

obstruction related diagnoses (9.0%, 79). The rate of hospital admissions related to infection increased from 0.6% (23) in 1996 to 3.6% (143) in 2005 (see figure, table 3). Rates of obstruction increased to a smaller degree and the rates of bleeding related diagnoses did not change during the study period. The majority of the patients admitted to the hospital without a diagnosis of cancer were considered otherwise healthy. Of the 781 patients 729 (93.3%) had a Charlson index of zero and 21 (2.8%) had a Charlson index of one.

TRUS Guided Morbidity for Repeat Prostate Biopsy

Of the 41,682 patients who did not have cancer 7,869 (18.9%) underwent repeat prostate biopsy within 2 years from the first prostate biopsy. For these men the 30-day hospital admission rate was 1.3% (99). The 30-day hospital admission rate also increased from 0.9% in 1996 to 3.7% in 2005 ($p < 0.0001$, chi-square 61.6 with 9 df, see figure).

Internal Validity Assessment for ICD-9 and ICD-10 Coding

To ensure that there were no variations due to differences in ICD-9 and ICD-10 coding we examined all hospital admissions based on our selected ICD-9 and ICD-10 codes for all patients within the province. In the transition of 2001 to 2002 there was no significant change in the number of hospital admissions. In 2001 there were 73,655 patients admitted for selected ICD-9 codes in Ontario. In 2002, 72,649 patients were admitted for selected ICD-10 codes. From 1996 to 2001 total hospital admissions steadily increased from 58,409 to 73,655. From 2002 to 2005 total hospital admissions remained stable from 72,649 to 72,290.

TRUS Guided Prostate Biopsy Mortality

For all patients the 30-day mortality rate was 0.09% (64 of 75, 190). The 30-day mortality rates were similar between patients diagnosed with cancer (0.07%, 25 of 33, 508) and those without cancer (0.09%, 39 of 41, 482, $p = 0.37$). Between 1996 and 2005 there was no change in trends of 30-day hospital mortality rates among all patients. In 1996 the 30-day mortality rate was 0.09% and 0.11% in 2005 (range 0.07% to 0.13%). Specific cause of death could not be ascertained through this data linkage.

DISCUSSION

We observed an increased rate in hospital admissions for urological complications after TRUS guided biopsy from 1996 to 2005 in Ontario, Canada. The increase could be attributed to increasing rates of infection related diagnoses. The majority of hospital admissions occurred within the first week after biopsy. It would be of interest to examine whether these trends continue beyond 2005 and will be forthcoming as data linkages become available.

The principal strength of our study is that because our publicly funded health care system consists of a single payer system (OHIP), all biopsy procedures for the population could be identified within the study period. In addition, the transition from ICD-9 to ICD-10 coding versions did not appear to bias our results.

We did not perform a medical chart audit of each case to determine the exact cause of hospital admission which is an important limitation in using administrative data. Although we tried to minimize measurement error, coding idiosyncrasies may be present which could bias our results. In the future examination of these records will be conducted to confirm these findings and to identify any key trends, particularly examining the prebiopsy protocols and urinary culture results. Also, our study would have missed patients who were treated on an outpatient basis, or those who presented to an emergency department, and were treated and discharged home. Data on emergency room visits could not be obtained during the same study period. Further study in these areas would be important to conduct.

It is unclear why there is an increasing trend of hospital admission rates, particularly for infec-

Table 2. *Rates of 30-day hospital admission for complications following TRUS guided biopsy by baseline variables among patients without cancer based on biopsy result*

	No. Pts Admitted (%)	No. Pts Not Admitted	p Value	Adjusted OR*	95% CI	p Value
Yr of biopsy:						
1996	38 (1.0)	3,761	9 × 2 table	1.00		
1997	50 (1.1)	4,515	<0.0001†	1.14	0.8–1.6	0.44‡
1998	55 (1.3)	4,103		1.37	0.9–2.1	0.13
1999	43 (1.1)	3,893	For trend	1.18	0.7–1.9	0.50
2000	58 (1.3)	4,374	<0.0001‡	1.34	0.8–2.1	0.21
2001	90 (1.8)	5,028		1.66	1.0–2.7	0.04
2002	102 (2.3)	4,345		2.15	1.2–3.8	0.01
2003	74 (1.9)	3,736		1.83	1.1–3.0	0.02
2004	107 (3.1)	3,346		2.87	1.6–5.2	0.0005
2005	164 (4.1)	3,800		3.74	2.0–7.0	<0.0001
Age category:						
Younger than 50	41 (2.4)	1,645	5 × 2 table	1.00		
51–59	175 (1.8)	9,592	0.23	0.76	0.5–1.1	0.15
60–69	334 (1.9)	16,807		0.85	0.6–1.2	0.41
70–79	206 (1.8)	11,158	For trend	0.81	0.6–1.2	0.24
80 or Older	25 (1.5)	1,699	0.20‡	0.72	0.5–1.1	0.14
SES:						
1	95 (1.6)	5,765	5 × 2 table	1.00		
2	155 (2.0)	7,459	0.009	1.21	0.9–1.6	0.15
3	122 (1.5)	7,925		0.92	0.7–1.2	0.53
4	190 (2.2)	8,483	For trend	1.21	0.9–1.6	0.20
5	199 (1.9)	10,555	0.28‡	1.13	0.9–1.4	0.30
Physician vol§				0.99	0.9–0.9	0.04

* Multivariate logistic model also adjusted for physician clustering using generalized estimating equations.

† Chi-square value for 9 × 2 table 201.8,9 df.

‡ Based on logistic regression model using year of biopsy, age and SES variables as ordinal covariates.

§ OR for admission for every 10 biopsies performed per physician per year. Based on 457 physicians performing all biopsies in Ontario. Each biopsy procedure assigned a procedural volume based on the number performed for the previous year from the date of biopsy.

tions. Men with underlying prostatitis which would prompt a prostate biopsy due to falsely increased prostate specific antigen may have been predisposed to exacerbated infection requiring hospital admission. This may be a possible etiological source and further medical chart reviews would be helpful in determining this as a possible cause. Antibiotic prophylaxis is often used to prevent infection but the practice is nonstandardized. Lee et al conducted a survey in the United Kingdom of the practice patterns of prostate biopsy.[10] Of the 140 physicians surveyed 48% used a single agent antibiotic and 52% used multiple antibiotics. Only 18% of physicians used a mechanical bowel preparation,[10] although this practice remains controversial.[11] In addition, in a cohort of 30,851 subjects in 2004/5 Laupland et al reported that up to 6% of pathogens causing community onset urinary tract infections were resistant to ciprofloxacin.[12] Feliciano et al reported that of

Table 3. *Breakdown of 30-day hospital admission rates by underlying diagnosis category*

Yr of Biopsy	Infection Related Complications OR (95% CI, p value)	Bleeding Related Complications OR (95% CI, p value)	Obstruction Related Complications OR (95% CI, p value)
1996	1.00	1.00	1.00
1997	1.03 (0.8–1.4, 0.84)	1.21 (0.6–2.3, 0.57)	1.69 (0.3–9.9, 0.56)
1998	1.24 (0.9–1.8, 0.24)	1.23 (0.6–2.4, 0.54)	2.32 (0.4–12.9, 0.34)
1999	1.22 (0.8–1.9, 0.37)	0.57 (0.3–1.3, 0.17)	3.51 (0.9–12.8, 0.06)
2000	1.23 (0.8–1.9, 0.34)	1.28 (0.7–2.4, 0.44)	2.15 (0.4–11.8, 0.38)
2001	1.55 (0.9–2.4, 0.06)	0.96 (0.5–1.8, 0.91)	4.12 (0.8–20.1, 0.08)
2002	2.01 (1.2–3.3, 0.007)	0.89 (0.5–1.7, 0.74)	4.98 (0.7–33.2, 0.10)
2003	1.55 (1.0–2.4, 0.05)	0.70 (0.4–1.8, 0.70)	6.21 (1.3–29.3, 0.02)
2004	2.62 (1.4–4.8, 0.002)	1.28 (0.6–2.6, 0.48)	4.50 (0.9–23.0, 0.07)
2005	3.57 (1.9–4.8, <0.0001)	0.89 (0.4–1.9, 0.89)	4.33 (1.3–14.5, 0.02)

Odds ratios (adjusting for physician clustering) based on all patients undergoing biopsy using infection, bleeding and obstruction as primary outcome variable, and year of biopsy as ordinal variable in the logistic regression model with 1996 as the baseline model. Tests for trend for infection related diagnosis p <0.0001, chi-square 183.2; for bleeding related diagnosis p = 0.48 and for obstruction related diagnosis p = 0.0009.

1,273 patients undergoing prostate biopsy in whom an infection developed the prevalence of resistant organisms increased.[7]

Another possibility is that there may have been an increase in the average number of needle core samples obtained over time. Currently up to 21 needle core samples are examined (extended pattern).[13] We did not have detailed information on how the biopsy was performed in terms of the needle core number and pattern, or the type of anesthesia used. However, when we examined the hospital admission rates for patients who underwent repeat prostate biopsy, the admission rates were not higher and also showed a similar increasing trend. Generally patients undergoing repeat prostate biopsy have more needle cores obtained. Thus, increasing number of needle cores may not be the sole reason for the increase in hospital admission rates. Also, studies that compare the sextant pattern and the extended pattern of biopsies showed no significant increase in morbidity rates.[13,14] However, these studies had small sample sizes and were underpowered to examine for differences. Further medical audits of our subjects will be required to examine these details. It is also important to note that mortality rates did not increase during the same study period and that specific medical chart audits will be required to examine the specific causes of death. It is unclear why mortality rates did not increase similarly, but treatment methods for sepsis in hospital may have averted this.

It is also important to consider noninfectious complications. We saw a small increase in complications related to urinary obstruction, although the number of patients was small. This may be a result of a higher prevalence of benign prostatic hyperplasia due to the aging population.[15] A steady rate of bleeding related complications is consistent with previous findings that showed men taking low dose aspirin did not have increased rates of bleeding.[16]

Patients of physicians who performed a high number of biopsy procedures experienced relatively low 30-day hospital admission rates. This has not been seen for TRUS biopsies before, but physician volume has been associated with patient outcome for other urological procedures such as radical prostatectomy.[17]

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EDITORIAL COMMENTS

This population based study conducted on more than 75,000 men in Canada analyzed hospitalization due to prostate biopsy complications between 1996 and 2005. The Canadian health care system is nationally run and has the advantage of compiling data on all patients into 1 file.

Interestingly the study demonstrated that patients with prostate cancer had a lower incidence of complications than those without prostate cancer. The majority of complications were for infections. Preexisting infection (eg prostatitis) may explain higher rates in patients without prostate cancer.

The study also demonstrated that complication rates increased from 1% to 4% during the 10-year period. In addition, it would be valuable to know if outpatient complications also increased.

This study adds to the growing body of evidence supporting the need for the development of standardized prostate biopsy prophylaxis protocols, with overall goals of decreasing post-biopsy infectious complications (reference 3 in article). Moreover this reinforces the need for urologists to treat urinary tract infections before performing prostate biopsy (reference 8 in article).[1]

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1. Djavan B, Waldert M, Zlotta A et al: Safety and morbidity of first and repeat transrectal ultrasound guided prostate needle biopsies: results of a prospective European prostate cancer detection study. J Urol 2001; **166:** 856.

Nam et al present an insightful and careful assessment of complications related to transrectal ultrasound guided prostate biopsies. During a study period of 1 decade postoperative (30-day) hospital admission rates and admission diagnoses were determined from ICD-9 and ICD-10 codes as applied to a data set of more than 75,000 men from a single, government operated health insurance system in Ontario, Canada. The authors found a statistically significant yet concerning trend toward increasing infection related admissions within 30 days of the biopsy, increasing from 1.0% in 1996 to 4.1% in 2005. All cause mortality rates within 30 days from the date of biopsy and admission rates for urinary obstruction or bleeding complications remained steady, or did not change significantly during the study period.

Why did infection related admissions increase over time? Hopefully the answer to this important question is forthcoming. The authors acknowledge potential study biases that medical records were not reviewed, emergency room visits were not evaluated, outpatient management of complications (infections, episodes of obstruction requiring catheterization) was undetermined and the number of cores obtained per biopsy session was unknown. Essentially the prostate biopsy practice patterns of urologists in the Ontario province (ie bowel/rectal cleansing preparations, antibiotic use and duration, and number of biopsy cores) and arguably the practice patterns of urologists across the world vary greatly (reference 10 in article).

During the last decade there has been a general decrease in antibiotic use and rectal cleansing (ie enemas or other forms of bowel preparation) simultaneous with the recognition that extended biopsy schemes increase the diagnostic yield of the procedure for detecting prostate cancer.[1] The ongoing work by this collaborative group of physicians should facilitate the establishment of best practice statements related to the performance of prostate biopsies.

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