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Was a Change to a Urologist Owned Pathology Laboratory Associated with a Change in Prostate Biopsy Use?

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Abstract

Introduction: We assessed the impact of self-referral to urologist owned pathology facilities on prostate biopsy practice patterns, clinical decision making and pathology service use.

Methods: We reviewed a transrectal ultrasound guided prostate biopsy database during 2 periods, including 1) August 5, 2008 to April 10, 2010 (613 days) when pathology samples were sent to an independent service laboratory, and 2) June 11, 2010 to February 13, 2012 when samples were assessed at a urologist owned pathology laboratory. We also examined data on independent service laboratories during 3 preceding periods of equal length immediately before August 5, 2008 to determine baseline transrectal ultrasound guided prostate biopsy rates. Billing databases were used to identify the number of new patient visits for increased and/or abnormal digital rectal examination. The Student t-test, and Wilcoxon rank sum and chi-square tests were used for statistical comparisons.

Results: All biopsies were obtained using a standard transrectal ultrasound guided prostate biopsy protocol. The biopsy rate in patients with increased or abnormal digital rectal examination was 39% during the urologist owned pathology laboratory era, and 35%, 40%, 35% and 40% during the 4 preceding independent service laboratory periods of equal length. There was no statistically significant difference in patient age, digital rectal examination, abnormal digital rectal examination or indications triggering repeat transrectal ultrasound guided prostate biopsy among the periods. The prostate cancer detection rate was 45% in the independent service laboratory era and 46% in the urologist owned pathology laboratory era.

Conclusions: Self-referral of transrectal ultrasound guided prostate biopsy specimens to urologist owned pathology facilities was not associated with a significant variation in the biopsy rate, the repeat biopsy rate, indications triggering biopsy or the cancer detection rate.

Key Words: prostate, biopsy, pathology, laboratories, conflict of interest

Abbreviations and Acronyms

DRE = digital rectal examination

ISL = independent service laboratory

PSA = prostate specific antigen

UOL = urologist owned pathology laboratory

Physician use of medical facilities in which they have a financial holding is a controversial topic and a focus of discussion regarding current health care reforms. The federal government enacted legislation, including the Social Security Amendments Acts of 1989 and 1993, to define the legal circumstances under which physicians may refer patients to clinical services in which they hold a financial interest and thereby regulate the practice of self-referral.[1] However, whether the enforcement of such policies has been effective in reducing health care costs while maintaining high levels of clinical care is unclear.

Previous studies of self-referral showed increased use when physicians held a financial interest in the health care facilities and equipment.[2–4] Kapoor and Penson recently addressed urologist ownership of pathology laboratories for which questions have been raised regarding potential overuse of prostate biopsy and lower cancer detection rates.[5]

A change in ownership and operating procedures governing the processing of clinical samples at our large urban urology

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practice provided an opportunity to assess whether self-referral to a urologist owned pathology facility influenced the number of prostate biopsies performed, cancer detection rate and clinical decision making. We report comparisons between prostate biopsy rates and indications triggering prostate biopsy during sequential and equivalent length periods when clinical samples were exclusively sent to an independent, unaffiliated pathology laboratory or to a pathology facility in which our practice physicians held a financial interest. Our null hypothesis was that UOL use was not associated with a significant increase in the biopsy rate in our clinical practice.

Materials and Methods

Our urology group prospectively maintains detailed records of patients who undergo prostate needle biopsy, including age, PSA, DRE and transrectal ultrasound findings, and pathological results. These clinical indexes were queried for 2 equal length periods for comparison, including 1) August 5, 2008 to April 10, 2010 (613 days) when pathology samples were exclusively sent to an unaffiliated ISL, and 2) June 11, 2010 to February 13, 2012 (613 days) when samples were assessed only at a UOL. A 2-month interval between periods was included to control for transitional changes in practice and referral patterns. Data on additional ISL periods of equal length dating back to 2003 before implementation of self-referral to a UOL laboratory were also analyzed to determine baseline variance in biopsy rates.

A physician from elsewhere was responsible for patient referral and patients were scheduled for consultation at the next available date. Proceeding with prostate biopsy was based on evaluation by a urologist. The patient was scheduled to undergo prostate biopsy at the next available biopsy slot with a urologist in the practice. During the study period 8 urologists remained stable in the practice, 1 joined and left, 1 left, 2 retired and 3 were newly hired. Thus, we had a steady state of urologists. Nurse practitioners did not see new patients. In the UOL and ISL eras this patient flow pattern was consistent.

In the ISL periods all urologists were compensated on a fee for service basis for the prostate biopsy procedure but they received no financial benefit from pathology laboratory processing and interpretation. During the UOL period all urologists were compensated on a fee for service basis for the prostate biopsy procedure and they received a share of profits from pathology laboratory processing as ancillary revenue. Two subspecialty trained urological pathologists salaried by the urology group were responsible for processing and interpreting specimens. One of these pathologists, who had been previously employed at the ISL, maintained the specimen processing protocol consistent between the ISL and UOL periods. The UOL did not own immunohistochemistry equipment and these tests were performed elsewhere at a commercial laboratory.

Billing databases for the eras were queried to quantify the number of new patient visits for increased PSA (ICD-9 code 790.3), nodular prostate without obstruction (600.10) and nodular prostate with obstruction (600.11). The number of prostate biopsies performed in each era was determined from the prostate biopsy database, which included new and established patients. Tabulated prostate biopsy related variables included the total number of biopsies performed and the number of repeat biopsies. For the 2 most recent periods additional variables examined included patient demographic data, serum PSA at biopsy, indications for repeat biopsy and pathology results.

Prostate biopsies were uniformly performed using ultrasound guidance in the office and inpatient settings. All specimens in the ISL and UOL periods were submitted according to a standard operating procedure, which specified the collection of 12 biopsy cores with each core submitted in separate jars. Pathology reports were reviewed to determine cancer detection rates and Gleason scores.

Normally distributed demographic indexes were analyzed using the Student t-test. PSA values were compared using the Wilcoxon rank sum test. DRE findings at biopsy and biopsy results were compared with chi-square analysis. To compare biopsy rates the difference between the 2 incidence rates was compared to a 95% CI based on the Poisson distribution. Using an overall α of 0.05 the Bonferroni correction was applied with an α level for each test of $p = 0.01$. Statistical analysis was done with MedCalc, version 13.1.1 (http://www.medcalc.com/).

Results

Initial Biopsies

During the UOL period 3,224 men were diagnosed with increased PSA and/or abnormal DRE, of whom 1,260 (39.1%) underwent initial prostate biopsy. During a similar period when samples were sent exclusively to unaffiliated ISLs 3,497 patients were diagnosed with increased PSA and/or abnormal DRE, of whom 1,205 (34.5%) underwent prostate biopsy. During the 3 preceding and consecutive periods when samples were referred to an unaffiliated independent laboratory the initial biopsy rates were 40.0% (1,350 of 3,368 men diagnosed with increased PSA and/or abnormal DRE from November 2006 to August 2008), 34.6% (1,057 of 3,051 diagnosed from March 2005 to November 2006) and 40.0% (1,080 of 2,695 diagnosed from July 2003 to March 2005, table 1 and fig. 1).

The aggregate initial biopsy rate for all ISL periods was 37.2%, which was not statistically significant compared to the 39.1% biopsy rate in the UOL period ($p = 0.12$). To examine

Table 1.
Biopsy rates during equivalent periods when samples were sent exclusively to unaffiliated ISL or UOL

Biopsy Referral Site (period)	No. Pt Visits/No. Biopsied (%)
UOL (6/11/10–2/13/12)	3,224/1,260 (39.1)
ISL:	
8/5/08–4/10/10	3,497/1,205 (34.5)
11/30/06–8/4/08	3,368/1,350 (40.0)
3/26/05–11/29/06	3,051/1,057 (34.6)
7/21/03–3/25/05	2,695/1,080 (40.0)