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Complications of Prostate Biopsy: A Prospective, Single-institution Study

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Authors' contributions

This work was carried out in collaboration among all authors. Author CMA designed the study, acquired funding, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Author BFM with methodology, project administration, supervision, reviewing and editing and author MEB managed supervision; reviewing and editing. All authors read and approved the final manuscript.

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ABSTRACT

Aims: This study aimed to determine the prevalence rates of transrectal ultrasound-guided prostate biopsy-related complications among patients receiving treatment at the large tertiary-care urology clinic of Kingston Public Hospital (KPH), Jamaica.
Study Design: Prospective cohort study.
Place and Duration of Study: Kingston Public Hospital (KPH), Jamaica from July 2018 to April 2019.
Methodology: Our study population included men who underwent prostate biopsy at KPH. Data on demographics and clinical characteristics were collected using purpose-designed questionnaires from consenting patients who underwent prostate biopsy during the stated period. Patients were then followed up for complications 30 days post biopsy. Details regarding hospitalization due to biopsy-related complications were obtained from the medical records.

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Results: Data from 185 men were included in the final analysis. Among the patients biopsied, 49% were diagnosed with prostate cancer, while 72% experienced at least one complication, mainly non-infectious complications such as hematuria (46%), lower urinary tract symptoms (24%), rectal bleeding (23%), hematospermia (9%), and urinary retention (16%). Overall, a 15% risk of developing infectious complications was observed, with 9% experiencing fever and 3% experiencing both urinary tract infection and epididymo-orchitis. Our data showed a 6% hospitalization rate within 30 days, with all available records suggesting infectious complications. One death from a prostatic abscess was noted. The present study showed that most prostate biopsy complications were minor. Moreover, although bleeding and infectious complications as well as hospitalization rates were consistent with those reported in larger series, our population experienced a slightly higher mortality and urinary retention rate.

Conclusion: Overall, our results showed that prostate biopsies performed within our institution are generally safe and well tolerated. Nonetheless, further studies are needed to determine whether morbidity of the procedure remains acceptable.

Keywords: Prostate cancer; prostate biopsy; complications; hospitalization; infection; mortality; Jamaica.

1. INTRODUCTION

Prostate cancer, which has seen a 3.7-fold increase in global incidence from 1990 to 2015 [1], accounts for approximately one-quarter of all male cancer deaths in the Caribbean, making it the leading cause of male cancer deaths and the third leading cause of male deaths overall [2]. Moreover, estimates have shown that the age-standardized mortality rate from prostate cancer among Caribbean men was 50 per 100,000 individuals in 2015, over twice that observed in the United States and the United Kingdom [2]. Prostate cancer has been the leading type of cancer in Jamaica, with an age-specific incidence rate of 78.1 per 100,000 men [3]. One study showed that prostate cancer accounted for 443 deaths in 1999, making it the leading cause of cancer-related death at that time [4]. Furthermore, data from the International Agency for Research on Cancer showed that the prostate cancer mortality rate in Jamaica was 41.7 per 100,000 individuals in 2018 [5].

A prostate biopsy, which is often performed in appropriately selected patients with abnormal prostate-specific antigen (PSA) levels or after detecting an abnormality during digital rectal examination (DRE), is key in the diagnosis and subsequent management of prostate cancer [6]. Ultrasound-guided biopsy has now become the standard of care and can be performed using either the transrectal or transperineal approach [7]. Over 1 million prostate biopsies are performed annually in Europe and the United States [8]. Kingston Public Hospital (KPH) is one of two tertiary centers in Jamaica that offer transrectal ultrasound-guided (TRUS) prostate biopsies, but is the only institution offering the service in a fully public setting, with an average of 400 procedures per year. TRUS biopsies are generally well-tolerated outpatient procedures performed under local anesthesia. Typically, 12–18 cores are obtained from multiple prostate gland zones under ultrasound guidance with a rectal probe.

Prostate biopsy complications can be largely characterized as non-infectious and infectious. Accordingly, most men may experience one or more non-infectious complications, including hematuria (10%–84%), hematospermia (1%–93%), rectal bleeding (1.3%–45%), lower urinary tract symptoms (LUTS) (25%), and urinary retention (2%) [8]. Nam et al. had reported increasing rates of 30-day infectious complications from 1% in 1996 to 4.4% in 2002, with 72% of the cases being related to sepsis [9]. Other studies have reported global increases in prostate biopsy-related complications, particularly infectious complications [10], with some studies showing that black and non-white ethnicities exhibit higher rates of infectious complications [11,12]. Unfortunately, data regarding prostate biopsy complications, hospitalizations, and mortality rates in Jamaica are not available.

The current study aimed to determine the prevalence of post-biopsy complications, hospitalizations, and mortality in Jamaica; identify predictive factors for post-biopsy complications; and ascertain commonly implicated organisms in post-biopsy sepsis.

2. METHODOLOGY

This study was conducted at the Urology Outpatient Department of KPH, Jamaica from January 2018 to April 2019. Eligible patients included consecutive men with suspected prostate cancer who visited the KPH urology clinic and had already satisfied the requirements for prostate biopsy, namely, abnormalities during DRE and/or abnormal PSA levels. No exclusion criteria had been established. Thereafter, baseline demographics and other variables around the time of the trans-rectal biopsy were recorded. Based on a projected population of 347 men, 5% margin of error, 95% confidence interval, and 50% prevalence rate, our calculated sample size was 183 men. Allowing for a priori dropout rate of 25%, we aimed to enrol a minimum of 229 men.

Type of anesthesia, preprocedural antibiotic choice, and post-procedure medications were recorded and were left to the discretion of the provider (i.e., consultants/attendings and residents in the Urology Department) considering the absence of a standard protocol guiding anesthesia and antibiotic use for prostate biopsies at KPH. However, typical regimes comprise the following: Either periprostatic or intraprostatic 2% lidocaine injection for anesthesia together with oral ciprofloxacin (500 mg) administered 1 h or 1 day before the procedure and/or gentamicin (80 mg) administered 1 h before the procedure for prophylaxis. Post-procedure medications typically consisted of analgesics, such as paracetamol and/or the alpha-blocker tamsulosin, and were usually prescribed for 5–7 days for patients with LUTS. In addition, a few physicians prescribed oral antibiotics, typically ciprofloxacin, for up to 72 h following the procedure.

Patients were reviewed 30 days later using a non-validated questionnaire on biopsy-related complications and hospitalization, either by telephone or face-to-face visits. More detailed information had been obtained from the medical records of hospitalized patients, including diagnosis, treatment, blood and urine culture reports, and outcomes, if needed.

Data were summarized using frequency tabulations, means, and ranges as appropriate. Bivariate associations between patients' clinical characteristics and the study outcomes were determined using chi-square tests of association and t-tests as appropriate. Multivariate regression models were used to determine factors independently associated with increased risk for developing infectious or non-infectious complications or hospitalization following biopsy. All statistical analyses were performed using STATA version 12.

3. RESULTS AND DISCUSSION

3.1 Results

A total of 408 men presented for biopsy during the study period, among whom 250 consented to participation and were subsequently enrolled. Only 185 patients had complete follow-up data and were included in the final analysis.

Table 1 summarizes the patient demographics and clinical characteristics. Accordingly, mean patient age was 68years (standard deviation 15.03).Among the included sample, 95 (51%) had comorbidities, with 61(33%), 29 (16%), and 5 (3%) patients having one, two, and three comorbidities, respectively. The most common comorbidities were hypertension and diabetes mellitus observed in 76 (41%) and 35 (19%) patients, respectively. PSA levels at presentation ranged from 1.7–13,520 ng/mL (median17.2 ng/mL).

Complete records on periprocedural anesthesia were available for 174 patients, a majority of whom [124 (71%)] received intraprostatic anesthesia (Table 2). Antibiotic prophylaxis was provided to 103 (56%) patients, among whom 86 (46%) received ciprofloxacin, while 17 (9%) received gentamicin. All prophylactic antibiotics were provided orally as a single oral dose or intravenously or intramuscularly, as with gentamicin, at least one hour prior to the procedure. After the procedure, most patients received ciprofloxacin either alone or in combination with an alpha-blocker typically for over 3–7 days, with 71 (39%) receiving only ciprofloxacin, 87 (47%) receiving ciprofloxacin in combination with tamsulosin, and 26 (14%) receiving a completely different medication regime.

Minimal discomfort associated with the procedure was observed, with patients having a mean discomfort rating of 3.7 on a visual analog scale from 0–10. Over 65% of the patients expressed willingness to undergo the procedure again.

Approximately half (48%) of the patients were diagnosed with adenocarcinoma of the prostate. Histology was available for 141 patients (76%),

with majority of the patients [31 (46%)] having an unfavorable Gleason Score of 4+3 disease (see Table 3 for the histology profile).

Table 4 profiles the complications experienced by the men included herein. Accordingly, 134 (72%) patients reported complications. Patients had between 0 and 7 complications, with an average of between 1 and 2 complications. The most common complication reported was hematuria, followed by LUTS, pain, and rectal bleeding. Overall, 78% and 15% of all complications were related to bleeding and infections, respectively. Within 30 days of the procedure, 12 patients were hospitalized. Moreover, 18 (10%) patients died during the follow-up period, with only one death found to be associated with the biopsy, indicating a mortality rate of 0.5%.

Although 22 patients sought treatment at a medical facility, data was available only for three patients who received treatment at KPH because of urinary catheter leakage (two patients) and hematuria and LUTS (one patient). Among the included patients, 12 (6%) were hospitalized, with records available only for six of them (Table 5). Accordingly, all six patients were admitted for infectious complications, with one autopsy-confirmed death from a prostatic abscess.

No associations were observed between the presence of complications and patient age, PSA, or comorbidities ($p>0.05$). Complications were significantly less frequent among patients with cancer diagnosis than among those without cancer (67% vs. 82%; $p=0.038$). Antibiotic administration after the procedure tended to be associated with the presence of complications, albeit not significantly, with patients receiving a ciprofloxacin-only regimen reporting more complications, most of which were LUTS and urinary retention, than those receiving other regimens (82% vs. 65%; $p=0.068$).

Table 1. Demographics and clinical characteristics of men undergoing prostate biopsies at KPH, Jamaica (January 2018 – April 2019)

Characteristic (n = 185)	n (%)
Age	47–93 (68)*
Number of comorbidities	
None	90 (49%)
1	61 (33%)
2	29 (16%)
3	5 (3%)
Comorbidities	
Diabetes	35 (19%)
Hypertension	76 (41%)
Heart disease	8 (4%)
Prostatitis	1 (1%)
Other	14 (8%)
Prostate-specific antigen (ng/mL)	1.7–13,520 (286)*
	9.8–72.1 (17.2)**

**Min–max (mean). **Inter–quartile range (median).*

Table 2. Type of anesthesia and antibiotic prophylaxis used in men who underwent prostate biopsies (January 2018 – April 2019)

Characteristic	n (%)
Type of anesthesia (n = 174)	
Intraprostatic	124 (71%)
Periprostatic	40 (23%)
Both	10 (6%)
Received antibiotic prophylaxis	103 (56%)
Antibiotic prophylaxis agent	
None	82 (44%)
Ciprofloxacin	86 (46%)
Gentamicin	17 (9%)

Table 3. Histology profile of men who underwent prostate biopsies at KPH (January 2018 – April 2019)

Characteristic	n (%)
Histology data available (n = 144)	141 (76%)
Cancer diagnosis	67 (48%)
Gleason grade group (n = 67)	
1	11 (16.4%)
2	9 (13.4%)
3	31 (46.2%)
4	11 (16.4%)
5	5 (7.5%)

Given the unavailability of several culture reports, organisms most commonly associated with post-biopsy sepsis could, unfortunately, not be determined.

3.2 Discussion

Knowledge regarding complications, morbidity, and mortality associated with prostate biopsy can assist clinical decision making among those requiring biopsy. Our results found that most men (72%) experienced at least one complication due to biopsy. In addition, the present study showed that most complications were related to bleeding (i.e., hematuria, rectal bleeding, and hematospermia). The prevalence rates of hematospermia obtained herein were significantly lower than those previously reported by Rosario (9% vs. 92.6%, respectively) [13]. However, given that the percentage of sexually active men remains unknown, only limited conclusions can be established herein. While the degree of bleeding was not recorded, most were assumed to be self-limiting, with only one patient, who was not admitted, presenting to the hospital for hematuria during the follow-up period.

Although LUTS rates obtained herein (24%) were consistent with those presented in other published studies, we noted an unusually high rate of urinary retention (16% vs. 1.7%) [8], with Bhorgessi quoting an upper limit of 6% [6]. Prostate biopsy has been known to have a transient effect on voiding symptoms. Accordingly, increased transition zone volume and prebiopsy International Prostate Symptom Scores (IPSSs) >20 have been identified as independent risk factors for subjective voiding impairment and acute urinary retention [14]. Unfortunately, the current study assessed neither IPSS nor prostate volume. As such, our cohort of men could have had larger prostate sizes or higher prebiopsy IPSSs, accounting for the higher urinary retention rates. Interestingly, our results showed that men who received the ciprofloxacin-only regimen had more LUTS/retention compared with those who received ciprofloxacin with an alpha-blocker, in accordance with previous data suggesting that tamsulosin reduces LUTS rates and retention risk [15].

Admission rates for infections have varied worldwide, with studies reporting an overall rate of 0–6.3% [8]. Accordingly, the readmission rate for infections in the UK was 3.6%, with North America and Brazil having lower rates of sepsis (0.6% and 1.7%, respectively) [8]. Another study showed that men undergoing prostate biopsy had a 2.65-fold higher risk of admission within the 30-day follow-up period compared with controls [11]. Our findings revealed that infections accounted for 15% of complications, with a 6% hospitalization rate. Unfortunately, we were unable to assess commonly implicated organisms and/or sensitivities given the limited culture data. Therefore, an appropriate antibiotic regime could not be extrapolated.

One patient died of sepsis secondary to an autopsy-confirmed prostatic abscess, resulting in a biopsy complication-related mortality rate of 0.5%. Published mortality rates for prostate biopsies have ranged from 0.09% to 0.31%, with the European Randomized Study of Screening for Prostate Cancer Rotterdam Section and Prostate Lung Colorectal Ovarian cancer Screening Trial reporting no deaths [9,16].

The current study found that age, PSA, and the presence and number of comorbidities were not associated with the presence of infectious or non-infectious complications or hospitalization. In contrast, Anastasiadis found that age >85 years was associated with increased complication rates [17]. Although a study by Loeb found no significant findings for age, it did

Table 4. Complications, hospitalization, and mortality rates in men undergoing prostate biopsies at KPH (January 2018 – April 2019)

Outcome	n (%)
Complication	134 (72%)
Number of complications	0–7 (1.6)*
Complication	
Hematuria	86 (46%)
Hematospermia	17 (9%)
Rectal bleeding	42 (23%)
Fever	16 (9%)
Urinary tract infection (UTI)	6 (3%)
Epididymitis	5 (3%)
Lower urinary tract symptoms (LUTS)	45 (24%)
Retention	30 (16%)
Pain	43 (23%)
Hospitalized within 30 days	12 (6%)
Sought treatment	22 (12%)
Died during follow-up	18 (10%)
Biopsy-related death	1 (0.5%)

**Min–max (mean)*

Table 5. Diagnosis, treatment, and outcomes of study participants hospitalized after prostate biopsy at KPH (January 2018 – April 2019)

Diagnosis	Culture availability	Treatment	Outcomes
Epididymo-orchitis	Yes: urine Enterobacter spp.	Ceftriaxone	Discharged alive
Epididymo-orchitis and lower respiratory tract infection	No	Levofloxacin	Discharged alive
Epididymo-orchitis	No	Ciprofloxacin	Discharged alive
Urosepsis	No	Ceftriaxone	Discharged alive
Urosepsis	No	Ceftriaxone	Discharged alive
Urosepsis	Blood and urine no growth	Ciprofloxacin and co-amoxiclav	Died: autopsy report indicating prostatic abscess

reveal that a later year of biopsy, higher Charlson Comorbidity score, and non-white ethnicity was associated with an increased risk for infectious but not non-infectious complications [11].

Studies have shown that men who undergo TRUS prostate biopsies without antibiotic prophylaxis have a significantly increased risk for infectious complications [18]. As such, several associations have currently advocated for routine antibiotic prophylaxis. The Global Prevalence Study of Infections in Urology (GPIU), which included 84 participating centers worldwide, reported that although 98.2% of men received antibiotic prophylaxis prior to biopsy, with 92.5% predominantly receiving fluoroquinolone [19], 5% of men still developed infectious complications. In the present study, only 56% of men were recorded to have received antibiotic prophylaxis, mostly with the fluoroquinolone ciprofloxacin. Nonetheless, the rate of symptomatic urinary tract infections observed herein was lower than that presented in the GPIU study. Therefore, our seemingly lower rate of prophylactic antibiotic administration could have likely been due to underreporting given that nurses routinely provide prophylactic antibiotics to patients on arrival at the clinic, allowing sufficient time between administration and the procedure.

The present study has some limitations worth noting. Given that this study had been conducted in a single institution within Jamaica, our results cannot be generalized to other populations. While we assume that most non-infectious complications were self-limiting and

minor, we did not determine the exact degree of severity or variations over time. Moreover, the biopsy protocol for anaesthesia and antibiotic therapy had not been standardized throughout the study. Furthermore, admission criteria can often vary depending on different management strategies by the emergency physician, possibly accounting for differences in the perceived hospitalization rate. Obtaining reports for several patients was also difficult because of the lack of an electronic medical record system, limiting our conclusions regarding commonly implicated organisms, ideal antibiotic management strategies, and hospitalization. As previously mentioned, this study did not evaluate the role of prostate size and IPSS, which can potentially increase the risk of hospitalization [11,16].

This study employed no standardization on the use of post-procedure medications, which also limited our analysis. This is noteworthy considering that the use of ciprofloxacin alone following the procedure has been associated, albeit not significantly, with a higher risk of complications. Therefore, we suggest standardizing not only prophylactic antibiotic regimens but also the post-procedure medications offered to patients in Jamaica. The American Urological Association's white paper on reducing complications in prostate biopsies recommends the use of fluoroquinolone for prophylaxis. Moreover, the duration of antimicrobial prophylaxis should be no more than 24 h with a single dose of antibiotics being sufficient. Accordingly, a study by Kalkanli proved that a single preoperative dose of oral ciprofloxacin resulted in similar infectious complication outcomes compared with 7 days of prolonged treatment among patients undergoing transrectal ultrasonography-guided prostate biopsy [20]. This suggests that our practice of prescribing longer antibiotic courses may be unnecessary and may not only increase monetary costs but also contribute to the worsening global antibiotic resistance pandemic. If resources permit, consideration can also be made for adopting the transperineal approach, as it is associated with a lower rate of infectious complications, albeit at the expense of a higher urinary retention rate when compared to the transrectal approach [21, 22].

More local studies are therefore needed to determine whether our complication, morbidity, and mortality rates increase over time. Moreover, closer attention should be given to our local antibiogram to determine resistance patterns and further guide antibiotic choices. In addition, developing a standardized prostate biopsy protocol will have numerous benefits, including ensuring a standard of care among all patients.

4. CONCLUSION

The present study showed that most prostate biopsy complications were minor. Moreover, although bleeding and infectious complications as well as hospitalization were consistent with those reported in larger series, our population experienced a slightly higher mortality and urinary retention rate. Overall, our results showed that prostate biopsies performed within our institution are generally safe and well tolerated. Nonetheless, further studies are needed to determine whether morbidity remains acceptable.

CONSENT

All participants provided written informed consent prior to participation.

ETHICAL APPROVAL

Ethical approval (ECP61 17/18) was obtained from the University of the West Indies Faculty of Medical Sciences and the South East Regional Health Authority Ethics Committee prior to commencing the study.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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