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Impact of COVID-19 vaccination on lower urinary tract (LUTS) in benign prostatic hyperplasia (BPH) patients

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Purpose: Benign prostatic hyperplasia (BPH) is a common condition in men that can impact quality of life, especially in older age. BPH is nonmalignant prostate enlargement associated with lower urinary tract symptoms (LUTS). Various factors like aging, hormonal imbalance, and inflammation contribute to BPH, with androgen dysregulation playing a key role. The coronavirus disease 2019 (COVID-19) pandemic raised concerns about vaccine side effects, particularly in BPH patients experiencing LUTS. Research is ongoing to understand the impact of COVID-19 vaccination on LUTS in BPH patients.

Materials and Methods: This prospective longitudinal study conducted at Sina Hospital in Tehran, Iran, from September 2022 to March 2023 enrolled 106 BPH patients receiving COVID-19 vaccines. Ultrasonography, total and free prostate specific antigen (PSA) test, and urine analysis were performed, and International Prostate Symptom Score questionnaires were completed before the vaccination. Vaccines included Oxford University/AstraZeneca, Sinopharm, or Sputnik-V, with booster doses administered per manufacturer protocol. Three months post-booster shot, patients were re-evaluated with the same questionnaire. Data was analyzed using SPSS software.

Results: Out of 3,591 individuals receiving COVID-19 vaccine, 106 were eligible for analysis. The mean ± standard deviation age on vaccination day was 65.4±11.74 years. Individuals receiving COVID-19 vaccines found no significant changes in PSA levels or prostate volume post-vaccination. Among urinary symptoms, urgency, dysuria, frequency, and hematuria rates increased significantly (p-value<0.05). Other symptoms showed no statistical differences.

Conclusion: Our findings elucidate that urgency, dysuria, frequency, and hematuria may be exacerbated after COVID-19 vaccination in BPH patients.

Keywords: COVID-19; BPH; Lower urinary tract symptoms (LUTS); Vaccination; Hematuria

INTRODUCTION

Benign prostatic hyperplasia (BPH) is a worldwide problem that affects the quality of life of many men in middle age and elderly. BPH is defined as nonmalignant hyperplasia of the prostate. BPH is associated with lower urinary tract symptoms (LUTS). Disease prevalence of BPH has been increased by aging, with histological prevalence of 50% to 60% in their 60s, and 80% to 90% of older than 70 years males at autopsy [1]. Various factors such as age, hormonal imbalance, the presence of chronic inflammation, and oxidative stress have been addressed for the underlying pathogenesis of BPH remains unclear [2]. Many studies showed that androgen dysregulation is the main factor in the progression of prostate diseases. Inflammation of prostate tissue, which is regulated by androgens and metabolic imbalance, regulates cell proliferation by inducing oxidative stress and is observed especially in symptomatic patients [3].

LUTS is general term describing symptoms caused by various pathologic conditions, such as bladder storage symptoms, voiding dysfunction, urinary urgency, frequent urination, weakness in urinary stream, and urine leakage [4]. Previous studies reported the incidence of LUTS in men to be approximately 30% in their 50s and 56% in their 70s. These studies also showed that histological BPH is not always associated with LUTS [5]. Early diagnosis of BPH is essential for effective management of complications. Acceptable and routine treatments for LUTS/BPH are alpha-1 adrenergic receptors antagonists, 5-alpha reductase inhibitors, and phytotherapy [6,7].

Emerging the pandemic of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), many efforts were taken to invent an effective vaccine [8]. Fortunately, various vaccines were introduced to overcome the coronavirus disease 2019 (COVID-19), including BNT162b2 mRNA (Pfizer–BioNTech), mRNA-1273 (Moderna), AZD1222 (Oxford University/AstraZeneca), BBIBP-CorV (Sinopharm), and Sputnik-V [9-11].

From the beginning of the vaccination program, worldwide concerns and arguments have been generated about the safety and probable adverse effects of vaccines on the general population. As mentioned before, BPH is mostly accompanied by LUTS which are distressing and significantly detract from patient productivity, adversely affecting health-related quality of life and social functioning. A significant proportion of men indicated that their daily routines were disrupted due to the necessity of restricting fluid intake before bedtime or travel, avoiding locations lacking restroom facilities, limiting participation in outdoor sports, and experiencing a deterioration in their occupational circumstances. Factors such as embarrassment, apprehensions regarding treatment expenses, and the perception that LUTS are an unavoidable consequence of aging contribute to the reluctance of many patients to discuss their symptoms with their physicians [6,12,13]. To document the adverse effects of vaccination, several studies on self-reported side effects in the healthcare system have demonstrated a broad spectrum of symptoms. Some studies reported urological adverse effects which most of them were LUTS [8,10,14,15].

However previous studies did not evaluate the baseline status of these symptoms. Additionally, as patients with BPH independently showed LUTS, because of the nature of the disease, before the vaccination, we hypothesized that the deterioration of LUTS after COVID-19 vaccination may be different among BPH patients. Our study could provide a better insight to potential urologic adverse events after COVID-19 vaccination in BPH patients. BPH patients suffer from LUTS more than others, so the possible worsening of these symptoms after vaccination mainly affects the quality of life of these patients. This study examines LUTS before and after vaccination to give us a better insight into LUTS status in our targeted group and help the physician to manage the symptoms properly before interfering with the patients' routine life.

MATERIALS AND METHODS

This prospective longitudinal study was conducted at Sina Hospital in Tehran, Iran, from September 2022 to March 2023. Prior to the initiation of the study, all patients provided written informed consent, and the study protocol received approval from the Ethics Committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1401.122). The study adhered to the principles outlined in the Helsinki Declaration.

A total of 106 patients' diagnosis with BPH who attended to the Sina Hospital in order to receiving COVID-19 vaccine were enrolled in the trial. Inclusion criteria comprised an age range of 40 to 85 years, BPH patients diagnosed by signs and symptoms and confirmed with ultrasonography and prostate specific antigen (PSA), patients under treatment with alpha-1 adrenergic receptors antagonists, 5-alpha reductase inhibitors, and willingness to participate in the research. Exclusion criteria included a history of genitourinary surgery, history of urinary tract infection (UTI) within the last month, anatomical or functional disorders of the genitourinary system, ureteral stricture, previous radiotherapy or chemotherapy, simultaneous urolithiasis, neurologic disorders, suspected presence of genitourinary

malignancies, chronic kidney disease, previous documented history of COVID-19, uncontrolled systemic diseases, and documented COVID-19 infection, UTIs, and genitourinary interventions during the study (**Fig. 1**). All patients underwent a complete physical examination. Characteristics data including age, body mas index, and medical history were collected prior to the vaccination. PSA level and prostate volume were recorded for all patients before the first dose of vaccination. Hematuria was also assessed by urine analysis test. The severity of LUTS is assessed by a self-reported questionnaire. The International Prostate Symptom Score (IPSS) is a validate questionnaire commonly used in order to assess the severity of LUTS. The questionnaire includes seven questions covering frequency, nocturia, weak urinary stream, hesitancy, intermittence, incomplete emptying and urgency [16]. Patients also asked about dysuria before and after vaccination. All patients were provided with a modified version of IPSS questionnaire (with yes/no options) translated into Persian language before vaccination. Urine analysis parameters including white blood cell (WBC) and red blood cell (RBC) were also documented. All participants were vaccinated with Oxford University/AstraZeneca, Sinopharm, or Sputnik-V. The booster doses were injected based on the manufacturer protocol. Three months after booster shot, participants were followed by PSA test, ultrasonography, urine analysis test, and questionnaires again.

The data were analyzed using IBM SPSS Statistics (Version 26; IBM Corp., Armonk, NY, USA). The results were expressed as mean ± standard deviation (SD) or numbers (percentage) and paired samples t-test or McNemar test were used as appropriate. Non-normal distributions of continuous variables were also described with medians and interquartile ranges and the Kruskal-Wallis test or Wilcoxon test were utilized for analysis. Statistical comparisons were made using the p-value<0.05 was considered significant.

RESULTS

Analysis was done on 106 participants. The mean ± SD age was 65.4±11.74 years on the vaccination day. Characteristic data is demonstrated in **Table 1**. There were no differences in PSA (total and free) levels and prostate volume before and after the vaccination. Analysis of WBC and RBC (urine analysis parameters) showed significant differences before and after the vaccination among participants.

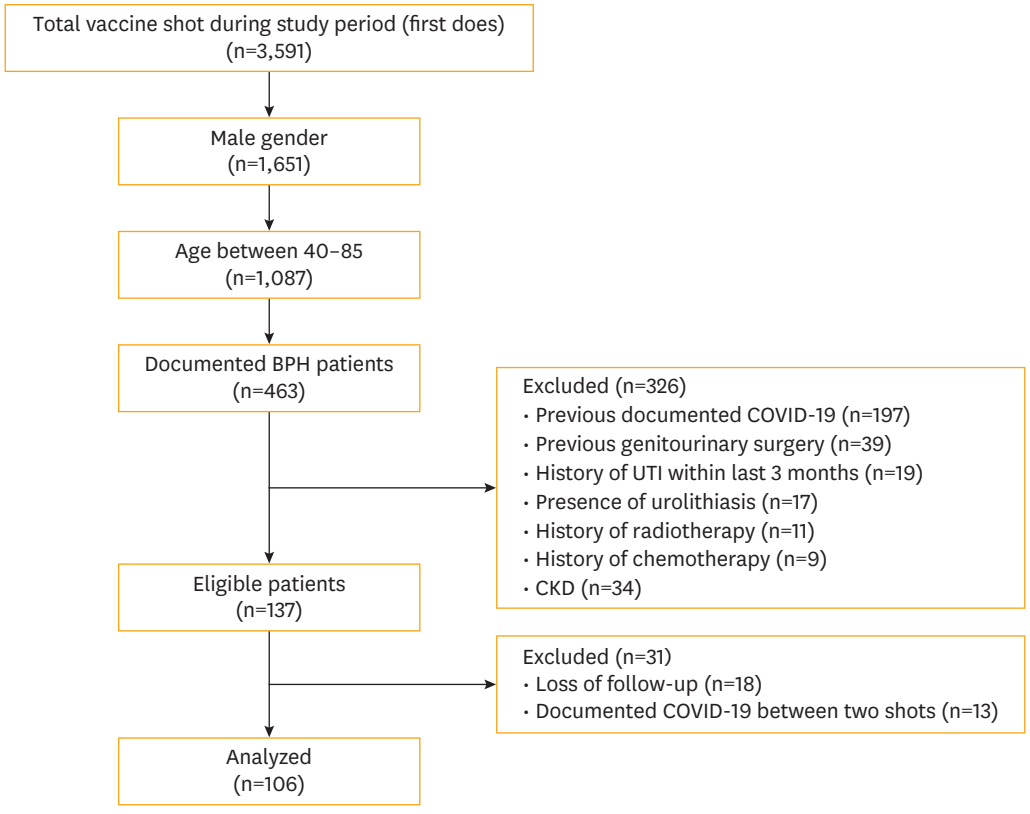

Fig. 1. Study design flowchart.
BPH, benign prostatic hyperplasia; COVID-19, coronavirus disease 2019; UTI, urinary tract infection; CKD, chronic kidney disease.

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Table 1. Participants characteristic data

Variables	Descriptive statistics	p-value
Age (yr)	65.40±11.74	-
BMI (kg/m^2)	25.90±2.72	-
Type of vaccine		-
Sinopharm	62 (58.5)	
Oxford University/AstraZeneca	25 (23.5)	
Sputnik-V	19 (18)	
Treatment		-
Tamsulosin	53 (50)	
Finasteride	34 (32)	
Tamsulosin + Finasteride	19 (18)	
Prostate volume (mL)		0.109[a]
Before vaccination	51.40±22.93	
After vaccination	51.80±23.71	
Total PSA (ng/mL)		0.137[a]
Before vaccination	4.20±2.80	
After vaccination	4.30±2.59	
Free PSA (ng/mL)		0.875[a]
Before vaccination	1.10±1.03	
After vaccination	1.10±0.78	
WBC		0.029[b]
Before vaccination	3.0 (2–5)	
After vaccination	3.5 (2–5)	
RBC		<0.001[b]
Before vaccination	3.0 (2–3)	
After vaccination	3.0 (3–10)	

Values are presented as mean ± standard deviation, number (%), or median (interquartile range).
BMI, body mass index; PSA, prostate specific antigen; WBC, white blood cell; RBC, red blood cell.
[a]Paired samples t-test; [b]Wilcoxon test.

Table 2. Comparison of lower urinary tract symptoms before and after vaccination

Variables of interest	Before vaccination	After vaccination		p-value[a]
		Yes	No	
Dysuria	Yes	46 (43)	10 (9)	<0.001
	No	34 (32)	16 (15)	
Nocturia	Yes	53 (50)	12 (11)	0.121
	No	22 (20)	19 (17)	
Urgency	Yes	45 (42)	10 (9)	0.002
	No	30 (28)	21 (19)	
Hesitancy	Yes	39 (36)	8 (7)	0.076
	No	18 (16)	41 (38)	
Intermittency	Yes	66 (62)	11 (10)	0.265
	No	18 (16)	18 (16)	
Weak stream	Yes	81 (76)	4 (3)	0.754
	No	6 (5)	15 (14)	
Frequency	Yes	46 (43)	12 (11)	0.024
	No	27 (25)	21 (19)	
Hematuria	Yes	9 (8)	9 (8)	0.001
	No	30 (28)	58 (54)	
Incomplete emptying	Yes	57 (53)	4 (3)	0.180
	No	10 (9)	35 (33)	

Values are presented as number (%).
[a]McNemar test, colored cells represent the discordant, i.e., those items that are positive before, but not after vaccination and vice versa.

A comparison of variables of interest before and after vaccination is demonstrated in **Table 2**. The rate of urgency, dysuria, frequency, and hematuria were significantly higher after vaccination (p-value=0.002, <0.001, 0.024 and 0.001, respectively). While other symptoms such as nocturia, hesitancy, intermittency, week stream, and incomplete emptying showed no statistical differences (p-value>0.05).

Comparison of WBC and RBC changes between each group of patients (based on their symptoms) are demonstrated in **Table 3**. Analysis revealed that WBC and RBC changes are significant among patients who experienced worsening of hematuria.

Table 3. Comparison of the differences of urine analysis parameters among variables that were different before and after vaccination

Variables	Before (yes)/After (yes)	Before (yes)/After (no)	Before (no)/After (yes)	Before (no)/After (no)	p-value[a]
Dysuria					
WBC (difference)	1.0 (–1, 2)	0.0 (–2, 1)	1.0 (–1.5, 3)	0.5 (–2, 3)	0.740
RBC (difference)	1.0 (0, 8)	1.0 (–1, 5)	0.0 (0, 7)	0.0 (–1, 1)	0.159
Urgency					
WBC (difference)	1.0 (–1, 2)	1.0 (–3, 4)	0.5 (–1, 2)	0.0 (–3, 4)	0.181
RBC (difference)	1.0 (0, 8)	1.0 (0, 8)	0.0 (–1, 1)	0.0 (0, 7.5)	0.923
Frequency					
WBC (difference)	1.5 (–1, 3)	2.0 (–1, 4)	0.0 (–1, 1)	1.0 (–2, 3)	0.242
RBC (difference)	2.5 (0, 8)	1.0 (–6, 10)	0.0 (0, 1)	0.0 (–1, 1)	0.087
Hematuria					
WBC (difference)	2.0 (–0.5, 3)	2.0 (1.5, 3)	2.0 (–1, 4)	0.0 (–3, 2)	0.008
RBC (difference)	1.0 (–1, 4)	–6.0 (–10, –3)	9.5 (6, 13)	0.0 (0, 1)	<0.001

Values are presented as median (interquartile range).
WBC, white blood cell; RBC, red blood cell.
[a]Kruskal-Wallis test.

DISCUSSION

The emergence of SARS-CoV-2 led to the devastating consequences globally. Many efforts have been taken to limit the transmission including using face masks, social distancing, and isolation. However, these actions have shown to be not enough in stop the spread of SARS-CoV-2. Vaccines are essential to reduce the morbidity and mortality caused by COVID-19 [17]. It should be considered that no medicinal products, including drugs and vaccines, are risk-free. When deciding to use a drug or receive a specific vaccine, pros and cons should always be considered. As soon as vaccination started, common and serious adverse events for each vaccination were widely reported. However, there is a lack of data on organ-specific adverse events [18-21].

Our findings showed that urgency, dysuria, frequency, and hematuria are significantly higher after vaccination in BPH patients, while nocturia, hesitancy, intermittency, week stream, and incomplete emptying showed no statistical differences. Considering the similar PSA and prostate volume before and after the vaccination, increased rate of dysuria, frequency, and hematuria would attribute to the vaccination. These findings suggest that irritative symptoms are more likely to be exacerbated by vaccination compared to obstructive symptoms. In a study by Zhao et al. [22], COVID-19 Vaccine adverse effects were collected by the FDA Adverse Event Reporting System (VAERS) until February 2021. The 15,785 adverse events were recorded but only about 1% included urologic symptoms. Out of these, 34 individuals reported LUTS, 14 reported hematuria, and 41 reported UTI. In another study, Chen et al. [8] conducted a cross-sectional study on 889 overactive bladder patients to investigate LUTS before and after the first dose of the COVID-19 vaccine. Up to 13.4% of patients experienced worsening of irritative LUTS after the first dose of vaccination including urinary urgency (p-value=0.030), and frequency (p-value=0.027). Results showed that irritative LUTS may be exacerbated after vaccination.

Aoki et al. [23] analyzed the laboratory data of 127 patients presenting with gross hematuria after COVID-19 vaccination at the first presentation, 3 months, and 6 months after. They also analyzed the histopathological changes in patients' kidney biopsies. Gross hematuria was mostly observed after booster doses. Thirty-seven patients previously underwent kidney biopsy, and 36 had been diagnosed with IgA nephropathy or IgA vasculitis. Out of 90 remaining patients, 70 underwent kidney biopsy after vaccination, and surprisingly 69 patients were diagnosed with IgA nephropathy. Findings suggest gross hematuria is more likely to happen after the booster dose in IgA nephropathy or IgA vasculitis patients, but renal function showed no exacerbation. Matsuzaki et al. [24] conducted a study to find a possible relationship between hematuria and COVID-19 vaccine. Twenty-seven cases reported hematuria after vaccination, out of which 19 (70.4%) were previously diagnosed with IgA nephropathy. Four cases underwent kidney biopsy and all of them were diagnosed with IgA nephropathy. Our findings also showed that hematuria was significantly higher after vaccination, however, there is no available data about the presence of IgA nephropathy in our patients.

Although urological complications after COVID-19 vaccination are rare, unfortunately few studies evaluate the COVID-19 vaccine-related urological adverse events [22]. Yet there is no convincing evidence to suggest that COVID-19 vaccinations are associated with serious urological adverse events. Our study exclusively focused in BPH patients and has shown worsening of irritative symptoms after vaccination. The underlying etiology of worsening LUTS after vaccination remains unclear, however, these results may be explained by triggering the immune response by the vaccine and reflected in the urinary system by secreting nitric oxide, acetylcholine, and ATP from urothelium. Previous studies have shown positive associations between inflammatory markers, such as C-reactive protein or neutrophil/lymphocyte ratio, and the incidence of LUTS, which can suggest that inflammation may contribute to the development of LUTS [25-27]. In an interesting study by Pan et al. [25], as urinary protein reflects the overall immune response, immune-related proteins were evaluated after COVID-19 vaccination. The results demonstrated that urinary protein varies obviously before and after vaccination, and the significant proteins belong to regulated exocytosis and immune response, confirming the role and necessity of the COVID-19 vaccine. Our study findings also revealed that WBC and RBC were significantly increased after vaccination (p-value=0.029 and <0.001, respectively) and suggested that worsening of LUTS may attributed to immunologic reactions after vaccination, especially among patients experiencing worsening hematuria.

One of our limitations was the lack of further follow-up to determine whether these complications were transient or permanent. Studies should carry out to evaluate LUTS after a reasonable period to identify whether the exacerbation of symptoms is temporary or needs intervention. Lack of control group, considering the nature of the COVID-19 and the importance of vaccination, was another limitation.

In conclusion, our findings elucidate that urgency, dysuria, frequency, and hematuria may be exacerbated after COVID-19 vaccination in BPH patients. Close monitoring of BPH patients should remain ongoing after vaccination and appropriate efforts should be taken to minimize the symptoms.

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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