



ORIGINAL RESEARCH ARTICLE

Number of risk factors versus infection after transrectal prostate biopsy: a nationwide population-based study

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ABSTRACT

Objective: It is unknown how risk factors for infection after transrectal prostate biopsy interact. We designed a study to evaluate this.

Methods: We identified biopsy procedures from 2006 to 2020 in the Swedish nationwide database PCBaSe. Primary outcome was post-biopsy infection, defined as a dispensed prescription of a urinary tract antibiotic and secondary outcome was inpatient care for infection both within 30 days. Risk factors were age, diabetes, medical treatment of lower urinary tract symptoms (LUTSs), prostate enlargement, immunosuppressives, corticosteroids, and defined antibiotic exposure during the past 1–12 months. When analysing risk in men with several risk factors clinically related factors were grouped as urinary tract infection (UTI)-antibiotics, treatment of LUTS, immunosuppressives including corticosteroids, and diabetes. Logistic regression was used to calculate odds ratios (ORs) with 95% confidence intervals (CI).

Results: A total of 139,056 transrectal prostate biopsy procedures were analysed. The grouped risk factors were significantly associated with post-biopsy infection (multivariable ORs: 1.22–1.72). Infection increased with number of risk factors; none: 4.0% (95% CI: 3.8–4.1), one: 6% (95% CI: 5.9–6.4), two: 10% (95% CI: 9.3–11), and three or four: 12% (95% CI: 9.8–14); inpatient care increased from 2.0% (95% CI: 1.9–2.1) to 3.1% (95% CI: 2.2–4.4).

Conclusion: Infection risk after transrectal prostate biopsy incrementally increases with the number of risk factors.

Clinical Implications: The transrectal biopsy route should be used with caution for patients with several risk factors for post-biopsy infections.

Patient Summary: Diabetes, urinary symptoms, previous urinary infection, and immune suppressing medication increase the risk of infection after a prostate biopsy through the rectum. Patients with many of these conditions have a particularly high risk.

What does the study add? We used nationwide register data to estimate the infection risk after transrectal prostate biopsy by the number of these risk factors: diabetes, medical treatment of lower urinary tract symptoms, immunosuppressives including corticosteroids, and use of urinary tract antibiotics the past year. The risk incrementally increased from 4.0% in men with no risk factor to 12% in those with 3 or 4.

Take Home Message: Infection after transrectal prostate biopsy increases with number of risk factors: diabetes, medical treatment of lower urinary tract symptoms, immunosuppressives including corticosteroids, and use of urinary tract antibiotics the past year, from 4.0% (none) to 12% (3 or 4).

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Introduction

A prostate biopsy is a common diagnostic procedure in urology [1]. The transrectal route has long been standard of care [2], but this route is debated mainly owing to the risk for post-biopsy infection [3, 4]. European guidelines recommend the transperineal route since 2022 [5], but the American Urological Association (AUA) guidelines consider both the transrectal and

transperineal routes 'of choice' [6]. Two randomised clinical trials showed no significant difference in post-biopsy infections between transperineal without and transrectal with antibiotic prophylaxis [7, 8]. Measures to reduce the risk of post-biopsy infection are relevant regardless of biopsy route [9].

Diabetes mellitus and previous urinary tract infection (UTI) have consistently been associated with the risk of infection after a transrectal prostate biopsy [10–12]. The importance of other

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potential risk factors is less clear. A study from a screening setting suggested that prostate enlargement is a risk factor [13]. In a previous register study, we found that medication for benign prostatic hyperplasia (BPH) and more than two previous negative urine culture, likely reflecting non-infectious lower urinary tract symptoms (LUTS), were both associated with post-biopsy infection [14]. It is thus not clear whether it is prostate enlargement as such or if it is the subsequent pathophysiological events that lead to LUTS that increase the risk of post-biopsy infection. There is also uncertainty about how different antibiotic exposures affect the risk of post-biopsy infection. In a previous study, we found that any kind of antibiotic treatment was associated with post-biopsy infection [14].

It is not known how the presence of several risk factors for infection after transrectal prostate biopsy affects the risk of infection. The primary aim of this study was therefore to explore the association between the number of risk factors and the risk of infection after transrectal prostate biopsy. We also aimed to explore whether prostate enlargement or LUTS, or both, increase the risk of infection, and how different antibiotic exposures affect this risk.

Material and methods

Study population

The National Prostate Cancer Register (NPCR) captures 98% of men with prostate cancer in Sweden compared with the Cancer Register to which reporting is mandated by law [15]. The primary aim of NPCR is to assess the adherence to national guidelines [16–18]. Our study population was obtained from the Prostate Cancer data Base Sweden (PCBaSe), in which information from the NPCR has been enriched by data from other nationwide health care registers and demographic databases [19]. In addition to data on men with prostate cancer, PCBaSe includes data on five prostate cancer-free men, matched for year of birth and region of residence [20]. PCBaSe includes data on diagnosis and procedure codes for inpatient episodes and outpatient visits in secondary care from the National Patient Register, and data from the Swedish Prescribed Drug Register on all dispensed drug prescriptions from 2006 [21].

PCBaSe 5.0 and this specific study were both approved by the Swedish Ethical Review Authority.

Definition of exposure

Biopsy procedures from 2006 to 2019 were identified by the procedure code TKE00 (prostate needle biopsy). In 2020, codes for transrectal and transperineal biopsy were introduced [22] and from the same year, procedures coded TKE10 were included in the study. As the transperineal route was rarely used in Sweden before 2020, all biopsy procedures before 2020 were considered transrectal. Men in the matched prostate cancer-free population could have more than one registered biopsy procedure. To avoid double registration, we excluded men in the matched PCBaSe population who had a biopsy procedure with a benign result but were later diagnosed with prostate cancer. The number of

procedures per individual is presented in [Supplement Table S6](#). In our previous study, a history of one or several prostate biopsy procedures was not associated with infection [14], so this variable was not included in this study. A single dose of oral 750 mg ciprofloxacin was the most common prophylactic regimen in Sweden throughout the study period [23, 24]. The Swedish guidelines did not recommend any other prophylactic measure during the study period.

Outcome measures

The primary outcome was any post-biopsy infection within 30 days from biopsy, defined as a dispensed prescription of an antibiotic indicated for UTI 1–30 days after the biopsy in outpatient or inpatient care (a prescription on the day of the biopsy was regarded as prolonged prophylaxis). The secondary outcome was inpatient care 0–30 days after biopsy with a diagnosis compatible with infectious complication. The drug treatment and diagnosis codes used for these definitions are listed in [Supplement Table S1](#) and [Table S2](#).

Investigated potential risk factors

The following potential risk factors for infection were investigated: age, previous UTI, previous fluoroquinolone treatment, previous non-UTI antibiotic treatment, diabetes mellitus, immunosuppressive treatment, systemic corticosteroid treatment, prostate enlargement, and LUTS. To capture these factors, we used the following definitions.

A *previous UTI* was defined as a dispensed prescription from 4 weeks to 1 year before biopsy of either a *fluoroquinolone* or a *non-fluoroquinolone UTI antibiotic* (see [Supplement Table S1](#) for the codes defining these antibiotics). A prescription of a UTI antibiotic within 4 weeks before biopsy may suggest that the patient was fragile or had a high risk for infection, and that the prescribed antibiotic was to provide periprocedural antibiotic prophylaxis or treatment rather than to treat a clinical UTI. We also analysed exposure to *non-UTI antibiotics* 4 weeks to 1 year before biopsy. The 4-week limit was also applied to previous non-UTI antibiotics for comparability. The 12-month limit was chosen in accordance with our previous study [14].

Diabetes mellitus was defined by ICD-10 code E11/E10 and/or a dispensed prescription of a diabetes drug within 1 year before biopsy.

To define *LUTS*, we used a dispensed prescription of treatment for BPH (*LUTS/BPH*) or for overactive bladder (*LUTS/OAB*) any time before or within 6 months after biopsy. Data on *prostate volume* were available only for men diagnosed with prostate cancer.

Systemic corticosteroid treatment was defined as ≥ 2 dispensed prescriptions within 7 months and *immunosuppressive treatment* as a dispensed prescription within 4 months, both before biopsy.

Statistical analysis

Univariable logistic regression was used to calculate odds ratios (ORs) for the outcomes with 95% confidence intervals (CIs). In

the regression models, age was analysed as a continuous variable, whereas prostate volume was categorised as <40, 40–79, and ≥ 80 cm³ because we assumed a non-linear association. The remaining variables were dichotomous. Diabetes mellitus, LUTS/OAB, LUTS/BPH, immunosuppressive treatment, and prostate volume are all associated with age and were therefore adjusted for age in a separate analysis. We adjusted for calendar year to avoid missing or misinterpreting factors with a changing prevalence over time. When we analysed the association between the number of risk factors and infection from the multivariable models, we merged closely related variables: non-fluoroquinolone antibiotic for UTI with fluoroquinolones, treatment for LUTS/OAB with treatment for LUTS/BPH, and immunosuppressives with corticosteroids. Prostate volume was not included in the multivariable model because of a strong association with BPH treatment and weak, non-consistent univariable association with the outcomes. Age was not included because a clinically insignificant association with the outcome on univariable analysis. Non-UTI antibiotics were not included in the analysis of the association between the number of risk factors and the absolute risk of infection, because of lacking association with inpatient care and poor biological underpinning as a causal risk factor.

To exclude that the association between LUTS treatment and infection was caused by the treatment as such, we performed a sensitivity analysis including only men who started LUTS treatment after the biopsy.

Although LUTS/BPH and LUTS/OAB both had a clinically relevant association with post-biopsy infection, their association with inpatient care was weak. Because of this and because a directly causal relation between treatment for LUTS and infection is unlikely, we analysed the cumulative effect of grouped risk factors both with and without LUTS to find out whether the addition of LUTS makes a clinically relevant difference.

Table 1. Patients' characteristics at the time of transrectal prostate biopsy procedure.

Investigated potential risk factors		Number (%)
Age (years)	< 60	12,321 (19.2)
	60–69	31,380 (48.9)
	70–79	16,901 (26.3)
	≥ 80	3,458 (5.4)
	Unknown	157 (0.2)
Diabetes mellitus		13,566 (9.8)
Previous UTI-antibiotics		11,036 (7.9)
Previous fluoroquinolone		15,304 (11)
Previous non-UTI antibiotic		20,316 (15)
Immunosuppressive treatment		1,734 (1.3)
Systemic corticosteroids		4,323 (3.1)
LUTS/BPH treatment*		41,931 (30)
LUTS/OAB treatment*		7,921 (5.7)
Prostate volume**	< 40 ml	30,807
	40–79.9 ml	20,971
	> 80 ml	3,009
	Unknown	9,430

*Including treatment started within 6 months after the biopsy.

**Information available only for those diagnosed with prostate cancer.

LUTS: lower urinary tract symptoms; OAB: overactive bladder; UTI: urinary tract infection; BPH: benign prostatic hyperplasia.

As the outcome measure was assessed indirectly with antibiotics prescription, we assessed the 'background prescription' of antibiotics and of inpatient care in the studied population the same calendar month one year before the prostate biopsy.

The analyses were done with R version 4.3.2. The manuscript adheres to the STROBE checklist for observational studies.

Results

The study included 139,056 prostate biopsy procedures, out of which 64,217 led to a prostate cancer diagnosis and 74,839

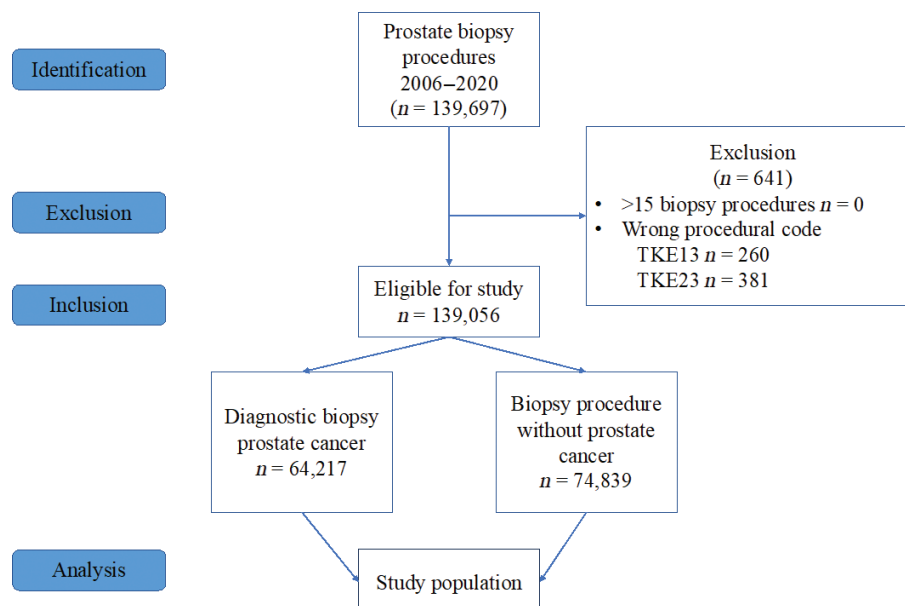


Figure 1. STROBE flow chart of study population from PCBaSe 5.0 included 2006–2020.

Table 2. Risk for any post-biopsy infection and for inpatient care for post-biopsy infection after transrectal prostate biopsy by number of risk factors.

Risk factor	Any post-biopsy infection		Inpatient care for post-biopsy infection	
	Absolute risk (%)	95% CI	Absolute risk (%)	95% CI
0	4.0	3.8–4.1	2.0	1.9–2.1
1	6.1	5.9–6.4	2.5	2.3–2.6
2	10.0	9.3–10.7	3.2	2.8–3.7
3	11.7	9.8–13.9	3.1	2.2–4.4

UTI: urinary tract infection; CI: confidence interval.

The here analysed risk factors were diabetes mellitus and grouped: immunosuppressive treatment and/or corticosteroid and non-fluoroquinolones UTI and/or fluoroquinolones. An analysis with LUTS as a fourth risk factor is presented in [Supplement Table S3](#).

did not ([Figure 1](#)). Baseline characteristics are presented in [Table 1](#). A total of 6,608 (4.8%) of the biopsy procedures resulted in a post-biopsy infection and 2,979 (2.1%) in an inpatient care episode for an infection within 30 days ([Supplement Figure 2](#)). The proportion of post-biopsy infection increased from 3.4% in 2006 to 5.9% in 2020; the corresponding increase of infections leading to inpatient care was from 1.0% to 2.7% ([Supplement Figure 1](#)).

The variables for the analysis of the association between the number of risk factors and infection were based on the results of the univariable and multivariable analyses. The analysis including diabetes mellitus, previous UTI, and immunosuppressive treatment showed that 4.0% (95% CI: 3.8–4.1%) of men with none of these risk factors had a post-biopsy infection. The proportion with infection incrementally increased with the number of risk factors up to 12% (95% CI: 9.8–14) in men with three risk factors ([Table 2](#)). The proportion of procedures that led to inpatient care increased from 2.0% (95% CI: 1.9–2.1%) in men with no risk factor to 3.1% (95% CI: 2.2–4.4%) in those with three factors ([Table 2](#)). The analysis with LUTS treatment as a fourth risk factor yielded similar results ([Supplement Table S3](#)).

LUTS/BPH and LUTS/OAB treatment were in univariable analysis both significantly associated with post-biopsy infection (ORs 1.43 and 1.61) and inpatient care (ORs 1.13 and 1.28), ([Table 3](#)), and so was the merged variable LUTS treatment in multivariable analysis (OR 1.34 for any post-biopsy infection and OR 1.11 for inpatient care) ([Table 4](#)). The sensitivity analysis of LUTS medication started after the biopsy included 30,067 men with LUTS/BPH medication and 4,475 men with LUTS/OAB medication; it gave identical results as the main analysis of the primary outcome: LUTS/BPH 5.9% versus 5.9%; LUTS/OAB 7.2% versus 7.2%.

The analyses of prostate volume gave inconsistent results: A moderate prostate enlargement (40–79 cm³) was significantly associated with both outcome measures on univariable analysis (ORs 1.16 and 1.24), but there was no significant association between a larger prostate (≥ 80 cm³) and any of the outcomes (OR 1.15 for any post-biopsy infection and OR 0.84 for in-patient care ([Table 3](#)). Adjustment for age and calendar year did not change the results ([Supplement Tables S4 and S5](#)).

Previous antibiotic treatment was associated with post-biopsy infection on univariable analysis ([Table 3](#)): non-fluoroquinolone UTI antibiotics (OR: 2.26), fluoroquinolones

Table 3. Univariable odds ratios for any infection and for infection leading to inpatient care after transrectal prostate biopsy.

	Any post-biopsy infection			Inpatient care for post-biopsy infection		
	OR	95% CI	P-value	OR	95% CI	P-value
Age at biopsy	1.01	1.00–1.01	< 0.001	0.99	0.99–1.00	0.019
Age at biopsy, groups						
<60 years	1.00	reference		1.0	reference	
60–69	1.12	0.92–1.09	0.961	0.96	0.85–1.09	0.517
70–79	1.16	1.03–1.22	0.012	0.93	0.82–1.05	0.229
80+	1.16	1.04–1.29	0.006	0.85	0.73–0.99	0.043
Diabetes mellitus	1.56	1.45–1.67	< 0.001	1.54	1.39–1.71	< 0.001
Previous non-fluoroquinolone UTI antibiotic	2.26	2.11–2.42	< 0.001	1.30	1.15–1.47	< 0.001
Previous fluoroquinolone	1.69	1.58–1.81	< 0.001	1.09	0.97–1.22	0.137
Previous non-UTI antibiotic	1.35	1.26–1.44	< 0.001	1.12	1.01–1.23	0.029
Immunosuppressive treatment	1.38	1.13–1.66	0.001	1.48	1.11–1.92	0.005
Systemic corticosteroids	1.51	1.33–1.70	< 0.001	1.38	1.14–1.64	< 0.001
LUTS/BPH treatment	1.43	1.36–1.50	< 0.001	1.13	1.05–1.22	0.001
LUTS/OAB treatment	1.61	1.47–1.76	< 0.001	1.28	1.11–1.47	< 0.001
Prostate volume*						
< 40 ml	1.00	reference		1.00	reference	
40–79.9 ml	1.16	1.07–1.26	< 0.001	1.24	1.10	< 0.001
≥ 80 ml	1.15	0.97–1.36	0.110	0.84	0.62	0.213

*Analysis restricted to biopsy procedures that led to a prostate cancer diagnosis in men with a registered prostate volume.

UTI: urinary tract infection; OR: odds ratio; CI: confidence interval; LUTS: lower urinary tract symptoms; BPH: benign prostatic hyperplasia; OAB: overactive bladder.

Table 4. Multivariable variable odds ratios for any infection and for infection leading to inpatient care after transrectal prostate biopsy.

Multivariable analysis	Any post-biopsy infection			Inpatient care for post-biopsy infection		
	OR	95% CI	P-value	OR	95% CI	P-value
LUTS/BPH and/or LUTS/OAB	1.34	1.27–1.41	< 0.001	1.11	1.03–1.20	0.006
Immunosuppressive and/or systemic corticosteroid treatment	1.27	1.13–1.42	< 0.001	1.28	1.08–1.51	0.003
FQ and/or non-FQ UTI antibiotic	1.72	1.62–1.82	< 0.001	1.10	1.00–1.21	0.057
Non-UTI antibiotic	1.22	1.14–1.30	< 0.001	1.07	0.97–1.19	0.165
Diabetes mellitus	1.45	1.35–1.55	< 0.001	1.51	1.36–1.67	< 0.001

LUTS: lower urinary tract symptoms; BPH: benign prostatic hyperplasia; OAB: overactive bladder; FQ: fluoroquinolones; UTI: urinary tract infection; OR: odds ratio; CI: confidence interval.

(OR: 1.69), and non-UTI antibiotics (OR 1.35), but only non-fluoroquinolone UTI antibiotics and non-UTI were significantly associated with inpatient care. In multivariable analysis (Table 4), the merged group UTI antibiotics was strongly associated with any post-biopsy infection (OR: 1.72) but not with inpatient care (OR 1.10). Non-UTI antibiotics had lower multivariable ORs for both outcome measures (ORs 1.22 and 1.07, Table 4). One year before the prostate biopsy 0.56% of the men had a dispensed antibiotics prescription and 0.09% had an inpatient care episode over a 30-day period.

Discussion

In this large nationwide, population-based register study, the risk of an infection after transrectal prostate biopsy increased with the number of risk factors (diabetes mellitus, previous UTI, immunosuppressive treatment, and LUTS), from 4% in men with none of these to 12% in men with three or four risk factors.

A secondary aim was to investigate how prostate enlargement and LUTS affect the risk of post-biopsy infection. Both prostate enlargement and BPH treatment have been reported to increase the risk of infection after transrectal prostate biopsy [11, 13]. Likely pathophysiological mechanisms are residual urine, bacteriuria, and bacteria in the prostate. In this study, treatment for OAB was more strongly associated with infection than treatment for BPH. This, together with the inconsistent and weak association between prostate volume and infection, suggests that the pathophysiological changes associated with LUTS are the causal link to infection, and that a prostatic enlargement per se does not increase the risk of infection.

Another secondary aim was to clarify different antibiotic exposures as risk factors. Both a previous fluoroquinolone treatment and a non-fluoroquinolone UTI treatment increased the risk of an infectious complication, but only the latter increased the risk of inpatient care. Fluoroquinolone treatment may lead to microbial resistance in the rectum [25] and thereby increase the risk of infection if a fluoroquinolone is used as prophylaxis [26], which was common practice in Sweden during the study period [14, 24]. Our observation that the ORs were consistently higher for previous non-fluoroquinolone UTI treatment than for previous fluoroquinolone treatment, suggests that a previous UTI may be a more important risk factor for post-biopsy infection than fluoroquinolone resistance, although a recent study from Sweden suggests the opposite [27].

Importantly, whereas microbial contamination from the rectal flora is overcome by using the transperineal biopsy route, the pathophysiological mechanisms behind the increased risks in men with a previous UTI and changes with LUTS are probably not.

A previous non-UTI antibiotic treatment was associated with both the primary and the secondary outcome. Although it cannot be excluded that this is related to changes in the gut bacteriome's antibiotic resistance pattern, it may also be explained by that men with previous non-UTI antibiotic treatment have a general propensity to seek medical care and thereby are more likely to receive antibiotic treatment for unspecific symptoms after a biopsy. We did, therefore, not include non-UTI antibiotic treatment as a risk factor in the analysis of how the presence of several risk factors affect the absolute risk of post-biopsy infection.

Immunosuppressive treatment, including corticosteroids, is associated with a generally increased risk of infections and infectious complications [28]. A previous Swedish register study, with a design like ours, reported a similar OR for inpatient care [11].

Age has previously been positively associated with inpatient care for infection after prostate biopsy [29]. In our study, the association between age and post-biopsy infection was statistically significantly but the OR was only 1.01 and considered clinically insignificant. There was, surprisingly, a (similarly weak) negative association with inpatient care.

The risk of an infection after a transrectal prostate biopsy doubled between 2006 and 2020. The increase is likely caused by several different factors, necessitating a reassessment of prophylactic measures. Future research, and the development of strategies to prevent infectious complications, may lead to a choice between the transrectal and transperineal route being based on the individual patient's risk factors.

The main strengths of our study include the population-based national cohort, the large number of biopsy procedures, and the accuracy of the Swedish registers. The rate of infection in this national study was similar to our previous regional study in which we validated the prescriptions and the diagnosis of admitted patients [14]. Weaknesses include the indirect definitions of previous UTI and post-biopsy infection by dispensed antibiotic prescriptions. The low 'background prescription' 1 year before biopsy does, however, suggest that misclassification does not much affect our results. Another weakness is that we could not evaluate the risk factors in a

setting with routine rectal cleansing with povidone-iodine, as now recommended in the European guidelines [5], because this preventive measure was not used in Sweden during the study period. Finally, we had no data on specific antibiotic prophylactic measures, for example, men with a previous UTI or post-biopsy infection, and those with diabetes or immunosuppressive treatment, may have received prolonged antibiotic prophylaxis or targeted treatment.

Conclusion

An increasing number of the risk factors diabetes, medical treatment of lower urinary tract symptoms, immunosuppressives including corticosteroids, and use of urinary tract antibiotics the past year, results in an incrementally increased risk of infection after transrectal prostate biopsy. Our results suggest that LUTS increases the risk of infection but that prostate enlargement per se does not. If several risk factors are present, measures such as prolonged antibiotic prophylaxis and povidone-iodine should be considered or the transperineal route chosen.

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