Original Article

A Randomized Controlled Trial to Study the Rationale of Antibiotic Prophylaxis in Diagnostic Rigid Cystoscopy: A Relook in The Era of Antibiotic Stewardship

Abstract

Background: In the era of widespread antibiotic (AB) resistance, the role of prophylaxis in diagnostic cystoscopy is controversial. **Aim:** This study aimed to compare the incidence of postcystoscopy positive urinary culture (PC-PUC) and urinary tract infection (UTI) in patients undergoing diagnostic rigid cystoscopy with and without prophylaxis with preprocedural single-dose intravenous AB. **Materials and Methods:** This prospective study was done in patients with preprocedural sterile urine undergoing elective diagnostic rigid cystoscopy. Patients were randomized into two groups, with one group receiving preprocedure single dose of intravenous cefuroxime sodium as prophylaxis half to 1 h before the procedure (Group AB prophylaxis) and the other group receiving no antibiotic prophylaxis (Group NAB). All patients were followed up till 1-month postprocedure, for any symptoms of urinary infection, mandatory urine microscopy and culture at 24–48 h, 1 week and 4 weeks post procedure, and addition sample in case of any urinary symptoms or fever. **Results:** A total of 225 patients were studied, with 110 in AB prophylaxis and 115 in NAB groups. The use of prophylaxis did not decrease the incidence of PC-PUC (8.7%–3.6%; $P = 0.167$) or UTI (6.1%–1.8%; $P = 0.102$). Females and diabetics had significantly higher risk of PC-PUC, on univariate and multivariate analysis, not affected by prophylaxis. **Conclusion:** Preprocedural AB prophylaxis does not decrease the incidence of postcystoscopy bacteriuria significantly. Females and diabetics have significantly increased risk, but prophylaxis has no role in them either.

Keywords: *Antibiotic prophylaxis, diagnostic rigid cystoscopy, post cystoscopy positive urinary culture, urinary tract infection*

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Introduction

Urology is unique among surgical subspecialties in having mostly endourological and minimally invasive procedures with no or minimum incisions and breach of natural protections. Diagnostic cystoscopy is the most common elective endourological procedure, usually done to monitor tumor progression and recurrence in patients with superficial bladder tumors[1] and is the mainstay diagnostic tool in the evaluation of various other conditions including hematuria, bladder outlet obstruction, interstitial cystitis, and stress incontinence.[2] There is a definitive risk of bacterial seeding during cystoscopic procedures, with suspected sources being flora residing in the urethra, prostatic ducts, and glands or through the instruments used, but the routine use of antibiotic (AB) prophylaxis is debatable.[2]

The incidence of postcystoscopy-positive urinary culture (PC-PUC) has been reported to be as high as 22%.[3] Prophylaxis with parenteral ABs such as ceftriaxone[4] and gentamycin[5] has been shown to reduce the incidence significantly; however, oral prophylaxis with fluoroquinolone and fosfomycin has shown conflicting results.[6-9] A recent large review has shown a decrease in symptomatic urinary tract infection (UTI) but no difference in systemic UTIs.[10] In the current era of widespread AB resistance, especially plaguing the developing nations,[11,12] the effectiveness and rationale of prophylactic use of ABs are questionable.

This prospective randomized study aimed to compare the incidence of UTI in patients with preoperatively sterile urine undergoing diagnostic rigid cystoscopy with and without preoperative AB prophylaxis with single-dose intravenous cephalosporin.

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Materials and Methods

This prospective study was done in a large tertiary care center in North India. The study included patients with preoperatively sterile urine undergoing diagnostic rigid cystoscopy. Other inclusion criteria were no additional therapeutic intervention at the time of cystoscopy such as transurethral resection or fulguration of tumor, no urinary stents, renal stones or chronic kidney disease, no rectourinary tract fistula or congenital urinary tract anomalies, no indwelling per-urethral catheter, no antibiotics (NAB) received for any indication in 7 days duration before cystoscopy, no allergy to penicillin or cephalosporin group of drugs, no history of corticosteroids or immunosuppressive therapy, no cardiac or orthopedic prosthesis, rheumatic heart disease, infective endocarditis, or congenital heart disease. The study was approved by the institutional and medical university ethical committee, and a written informed consent was taken from each patient before inclusion in the study.

Each patient with preplanned (elective) diagnostic rigid cystoscopy was instructed to give a preoperative midstream sample of urine for microscopy and culture, 72 h before the procedure, and only patients with sterile urine were considered for inclusion. The patients were divided into two Groups A and B of 125 each, (later labeled as AB [receiving AB prophylaxis] and NAB [not receiving AB prophylaxis]). Randomization was done by computer-generated list: the study was partially blinded. The patient did not know the group to which he was allocated. Only one of the researchers knew whether the prophylaxis has been given or not. The surgeon, data collecting team, and data analyzing team did not know the group of the patients.

Group AB was given single dose of intravenous cefuroxime sodium (1.5 g injection, supacef [Glaxo]), 30–60 min before the procedure, and group NAB was not given any AB prophylaxis. The choice of AB (second-generation cephalosporin) was as per our hospital AB policy for prophylaxis in low-risk urological endoscopic surgeries.

All cystoscopies were performed using 23Fr rigid urethroscope, either under local or regional anesthesia. Patients assumed lithotomy position, the external genitalia were cleaned with topical betadine solution (Povidone-iodine), and parts were draped with sterile coverings. Topical urethral analgesia and lubrication were done with lignocaine jelly (2%), injected into the urethra 5 min before cystoscopy. Standard sterile techniques were adopted during each procedure.

All patients were followed up till 1-month postprocedure, with urine microscopy and culture at 24–48 h postprocedure and at 1 week and 4 weeks. Patients were enquired at these visits for any symptoms suggestive of UTI (fever, chills and rigors, dysuria, and increased frequency of micturition), and in such event, at any time during their follow-up, another sample was sent for urine culture before starting empirical ABs. The urine microbiological culture with more than 10^5 colony-forming unit per milliliter of urine was considered positive. In case of positive urine culture with symptoms of UTI, the patient was given ABs according to sensitivity.

Two previously published studies had reported a reduction of incidence from 21% to 5%[5] and 10.2% to 2.5%[4] with single dose of parenteral AB, and their average was taken for calculating the sample size for this study. The expected reduction with prophylaxis was presumed as 15.6% to 3.75%, which could be detected with 80% power, at two-sided 5% of significance level, with two groups of 97 patients each.[13] Allowing for a possible loss to follow by at least 10% of patients, 240 patients were recruited for the study.

The primary outcome was to study the decrease in the incidence of PC-PUC and symptomatic UTI by preprocedural prophylaxis with single dose of intravenous AB. The secondary outcomes were to study the various risk factors affecting this incidence.

Statistical analysis

Data were described in terms of mean ± standard deviation, frequencies (number of cases), and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the groups was done using Student's *t*-test. For comparing categorical data, Chi-square test was performed, and exact test was used when the expected frequency was <5. For multivariate analysis, logistic regression was performed. A $P < 0.05$ was considered statistically significant. All statistical calculations were done using SPSS 21 version (Statistical Package for the Social Science - SPSS Inc., Chicago, IL, USA). version statistical program for Microsoft Windows.

Results

A total of 369 diagnostic cystoscopies were performed in the study period (March 2014 to March 2018), 250 patients that met the inclusion criteria were included in the study and divided into the two groups AB and NAB of 125 patients each. Fifteen patients in AB and 10 patients in NAB defaulted on follow-up and only 110 AB patients and 115 NAB patients were included in final analysis.

Demographic parameters such as age, gender, and premorbidities in the two groups were comparable, with males outnumbering females in both the groups. Mean age in Group AB and NAB was 56.52 ± 14.8 and 52.37 ± 19.4 years, respectively. The most common indication was check cystoscopy for follow-up of bladder tumor, followed by need for the evaluation of microscopic/macroscopic hematuria [Table 1].

Total 14 patients had PC-PUC, and AB prophylaxis did not decrease its incidence significantly (8.7%–3.6%; $P = 0.167$), neither did it decrease symptomatic UTI (6.1%–1.8%; $P = 0.102$), asymptomatic bacteriuria ($P = 0.688$), or sterile pyuria ($P = 0.350$). No patient had bacteremia [Table 2]. There was no difference in baseline characteristics and symptomatic presentation in patients suffering from PC-PUC [Table 3] or UTI [Table 4] in the AB prophylaxis (AB) and the no prophylaxis group (NAB).

On comparing patients with PC-PUC from No-PC-PUC [Table 5], irrespective of the use of prophylaxis, females and diabetic patients were found to have significantly higher risk of post cystoscopy bacteriuria both in univariate and multivariate analysis. There was no effect of history of previous UTI or radiation therapy.

Out of the 14 PC-PUC, seven had *Escherichia coli*, two - *Klebsiella pneumoniae*, three - *Pseudomonas aeruginosa, and* two - *Enterococcus faecium*. Except for two *E. coli* isolates, none was sensitive to cefuroxime. The patients were treated with the ABs according to sensitivity.

Discussion

In wake of increasing global concern for superbugs and medical fraternity worldwide struggling with highly resistant bacterial and fungal species, the unnecessary use of subtherapeutic doses of ABs is akin to vaccination of microbes further. Thus, there is a dire need to rationalize AB use for preventing the situation from worsening even further.

Data dating two to three decades back had shown the risk of postcystoscopy bacteriuria to be as high as 22%[3] and supported the routine use of prophylaxis, with reported risk reduction from 21% to 5% with single-dose intramuscular Gentamicin[5] and 10.2%–2.5% with single-dose preprocedural intravenous ceftriaxone.[4] However, studies in the last decade, majority using oral fluoroquinolone prophylaxis, had yielded conflicting results.[6-8] Studies from developing world again have divided opinion, with a Cambodian study[8] finding decreased asymptomatic bacteriuria (14.5%–5.8%; $P = 0.01$), but no significant decrease in UTI (3%–0.7%; $P = 0.17$) with levofloxacin,[8]

Table 1: Baseline parameters of the two study Groups: Antibiotic group and no antibiotic group

	Group AB (n_{AB}=110), *n* (%)	Group NAB (n_{NAB}=115), *n* (%)	χ^2	*P*
Age, mean±SD	56.52±14.8	52.37±19.4	1.795	0.074
Male	70 (63.6)	79 (68.7)	0.643	0.422
Female	40 (36.4)	36 (31.3)		
Co-morbidities				
Diabetes	18 (16.4)	21 (18.3)	0.141	0.707
Hypertension	13 (11.8)	10 (8.7)	0.597	0.440
Ischemic heart disease	7 (6.4)	5 (4.3)	0.452	0.501
Chronic liver disease	3 (2.7)	1 (0.9)	1.111	0.292
Past history of malignancy	4 (3.6)	0	4.258	0.039
Indications				
FUBT	56 (50.9)	65 (56.5)	0.713	0.424
Hematuria	23 (20.9)	18 (15.7)	1.043	0.388
BOO	8 (7.3)	5 (4.3)	0.884	0.401
CPPS	6 (5.5)	12 (10.4)	1.895	0.221
VVF	6 (5.5)	2 (1.7)	2.263	0.164
Radiation cystitis	5 (4.5)	2 (1.7)	1.469	0.272
Incontinence	4 (3.6)	4 (3.5)	0.004	1.000
Interstitial cystitis	2 (1.8)	4 (3.5)	0.597	0.684
PUV	0	3 (2.6)	2.908	0.247

BOO: Bladder outlet obstruction, CPPS: Chronic pelvic pain syndrome, VVF: Vesicovaginal fistula, PUV: Posterior urethral valves, AB: Antibiotic, NAB: No antibiotic, SD: Standard deviation, CC-FUBT: Check cystoscopy for follow-up of bladder tumor

Table 2: Incidence of postoperative urinary complication in the two groups: Antibiotic group and no antibiotic group

Results	Group AB (n_{AB}=110), *n* (%)	Group NAB (n_{NAB}=115), *n* (%)	χ^2	*P*
PC-PUC	4 (3.6)	10 (8.7)	2.466	0.167
UTI	2 (1.8)	7 (6.1)	2.668	0.102
Asymptomatic bacteriuria	2 (1.8)	3 (2.6)	0.162	0.688
Sterile pyuria	16 (14.5)	12 (10.4)	0.872	0.350
Bacteremia	0	0		

PC-PUC: Post cystoscopy positive urine culture, UTI: Urinary tract infection, AB: Antibiotic, NAB: No antibiotic

Table 3: Impact of baseline characteristics and differences in symptomatology in patients suffering from post cystoscopy positive urinary culture in the antibiotic and the no-antibiotic group

Group	Group AB patients with PUC		Group NAB with PUC		χ^2	*P*
Impact of baseline characteristics on incidence of PUC in AB and NAB						
Group	**PUC, *n* (%)**	**Total patients**	**PUC, *n* (%)**	**Total patients**	χ^2	***P***
Male	2 (2.9)	70	3 (3.8)	79	0.498	0.58
Female	2 (5.0)	40	7 (19.4)	36		
Diabetes	2 (11.1)	18	5 (23.8)	21	0.000	1.000
Previous UTI	0	7	0	5		
Radiation	0	5	0	2		
Incidence of postoperative symptoms in the two groups						
Group	**PUC, *n* (%)**	**Total patients**	**PUC, *n* (%)**	**Total patients**	χ^2	***P***
Dysuria	2 (28.6)	7	4 (36.4)	11	0.117	0.733
Frequency	0	6	1 (20.0)	5	0.431	0.512
Fever	2 (100.0)	2	3 (100.0)	3	0.498	0.580
Chills/rigors	0	0	2 (100.0)	2	0.933	0.334

AB: Antibiotic, NAB: No antibiotic, PUC: Positive urine culture, UTI: Urinary tract infection

Table 4: Impact of baseline characteristics and differences in symptomatology in patients suffering from urinary tract infection in the antibiotic and no-antibiotic group

Group	Group AB patients with UTI		Group NAB with UTI		χ^2	*P*
Impact of baseline characteristics on incidence of UTI in AB and NAB						
Group	**UTI**	**Total patients**	**UTI**	**Total patients**	χ^2	***P***
Male	2 (2.9)	70	2 (2.5)	79	3.214	0.167
Female	0	40	5 (13.9)	36		
Diabetes	2 (11.1)	18	4 (19.0)	21	1.286	0.257
Previous UTI	0	7	0	5		
Radiation	0	5	0	2		
Incidence of postoperative symptoms in the two groups						
Group	**UTI**	**Total patients**	**UTI**	**Total patients**	χ^2	***P***
Dysuria	2 (28.6)	7	4 (36.4)	11	1.286	0.500
Frequency	0	6	1 (20.0)	5	0.321	0.571
Fever	2 (100.0)	2	3 (100.0)	3	2.057	0.444
Chills/rigors	0	0	2 (100.0)	2	0.735	0.391

AB: Antibiotic, NAB: No antibiotic, UTI: Urinary tract infection

and a Turkish study finding no use of prophylaxis with third-generation cephalosporin.[14] Our data too somewhat collaborate with the developing nations' scenario with no significant decrease in the incidence of PC-PUC ($P = 0.167$) and UTI ($P = 0.102$) with AB prophylaxis. The data discrepancy over these decades, and between developed to developing world, can be correlated to the ever-increasing AB resistance, the situation of which is worse in developing nations due to over-the-counter availability and rampart self-medication.[11,13-17]

Most of the patients in our study were late middle age to older males, constituting the age group needing diagnostic cystoscopy for follow-up of bladder tumors, a scenario correlating with the epidemiology of bladder malignancies in India.[18] However, we found females to have a significantly increased risk of bacteriuria ($P = 0.019$ univariate; $P = 0.035$ multivariate), which could not be decreased by the AB prophylaxis ($P = 0.58$). Some previous studies have also reported higher UTI in women (9.3 vs. 2.6% in men, average 4.5% for the group studied), but no recommendations regarding chemoprophylaxis were made.[19]

Diabetes too was an independent risk factor for PC-PUC in our study ($P = 0.004$ univariate; $P = 0.005$ multivariate), although no benefit of AB prophylaxis was found ($P = 1.000$) in preventing the same.

Our study did not show any increased proneness to infection in patients with the previous history of UTI ($P = 0.359$) or radiation therapy ($P = 0.489$), contrary to Clark and Higgs's[20] observation of increased infection following cystoscopy in patients with previous UTI.

The most common pathogens implicated in postcystoscopy UTIs in the literature are *E. coli*, *Proteus*, *Klebsiella*, and

Table 5: Comparison of patients suffering post cystoscopy positive urinary culture from those with sterile post cystoscopy urine culture with respect to various risk factors

Group	PC-PUC (*n*=14), *n* (%)	No PC-PUC (*n*=211), *n* (%)	χ^2	*P*
Univariate analysis				
AB	4 (3.6)	106 (96.4)	2.466	0.167
NAB	10 (8.7)	105 (91.3)		
Male	5 (3.4)	144 (96.6)	6.212	0.019
Female	9 (11.8)	67 (88.2)		
Diabetics	7 (17.9)	32 (82.1)	11.118	0.004
Nondiabetic	7 (3.8)	179 (96.2)		
Previous UTI	0	12 (100.0)	0.841	0.359
No history of prior UTI	14 (6.6)	199 (93.4)		
History of radiation	0	7 (100.0)	0.479	0.489
No past radiation history	14 (6.4)	204 (93.6)		
Multivariate analysis				
	Exp (*B*)	**95% CI for EXP (*B*)**		***P***
		Lower	**Upper**	
Sex-female	3.46	1.09	11.01	0.035
DM	5.05	1.62	15.72	0.005

AB: Antibiotic, NAB: No antibiotic, UTI: Urinary tract infection, CI: Confidence interval, PC-PUC: Post cystoscopy positive urine culture, DM: Diabetes mellitus

Enterococcus.[21] *E. coli* was the most common isolate in our patients too (seven patients; 50%), followed by *Pseudomonas, Klebsiella,* and *Enterococcus*. Most of the isolates were resistant to second and even third-generation cephalosporins, besides high rate of multidrug resistance. Some other studies from India and other developing countries have also proved the worsening scenario of resistance in uropathogens.[22-25]

Although the study population was small and the rigid cystoscopy was the only procedure studied, this study confers a significant clinical understanding about the use of AB prophylaxis in patients with preprocedural sterile urine undergoing elective diagnostic endourological procedure.

We advocate against the routine use of AB prophylaxis in diagnostic rigid cystoscopy, which not only proves futile but may actually be contributing to worsening scenario of AB resistance, besides adding to cost implications for the patient and the health-care system. However, high-risk populations such as females and diabetics may be closely followed up for any postprocedure symptoms of urinary infection and positive urine culture and treated wherever required. Larger multicentric and multinational studies may be required to make specific recommendation in this regard.

Conclusion

This study shows that prophylactic ABs is not effective in decreasing the incidence of postprocedure bacteriuria in patients with previously sterile urine undergoing elective diagnostic rigid cystoscopy. Females and diabetics have higher propensity for new-onset bacteriuria which too cannot be prevented by AB prophylaxis.

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Ethical clearance

The study was approved by the ethical committee of Dayanand Medical College and Hospital, Ludhiana, and Baba Farid University of Health Sciences, Faridkot, Punjab, India, vide approval no. BFUHS/2k14/P-Th/9005.

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Conflicts of interest

There are no conflicts of interest.

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