Efficacy of 1 versus 3 days of intravenous amikacin as a prophylaxis for patients undergoing transurethral resection of the prostate: A prospective randomized trial

Selvin Theodore Jayanth, J. Chandrasingh*, Rani Diana Sahni[1], Rajiv Paul Mukha, Santosh Kumar, Antony Devasia, Nitin Sudhakar Kekre

Departments of Urology and [1]Microbiology, Christian Medical College, Vellore, Tamil Nadu, India
*E-mail: chandrasingh@cmcvellore.ac.in

ABSTRACT

Introduction: There are no uniform guidelines on the duration of antibiotic prophylaxis for transurethral resection of the prostate (TURP). The objective of this study was to evaluate the efficacy of 1 day versus 3 days of intravenous amikacin as prophylaxis, before TURP.

Materials and Methods: In this prospective randomized control trial, patients with sterile preoperative urine culture were randomized to receive either 1 day (Group A) or 3 days (Group B) of intravenous (IV) amikacin. All patients had their catheter removed on the 3rd day and a midstream urine culture was obtained on the 4th day. The follow-up was scheduled at 1 week and at 1 month. The rate of bacteriuria on the 4th postoperative day was analyzed as the primary outcome. The secondary outcomes included symptomatic urinary tract infection (UTI), its risk factors, and other complications at 1 month.

Results: Of the 338 patients randomized, 314 patients were evaluable until day 7 and 307 until 1 month. Bacteriuria rate at day 4 (Group A: 8.8% [95% confidence interval (CI): 4.2–13.2]; Group B: 4.4% [95% CI: 1.2%–7.7%], $P = 0.124$, Fisher's exact test) was similar in both the groups. At 1 month, the rate of symptomatic UTI was also similar in both the groups (3.5% [95% CI: 0.8–6.9] vs. 1.7% [95% CI: 0.2–4.2], $P = 0.344$, Fisher's exact test). Bacteriuria (colony-forming unit, $>10^4$/ml) at day 4 was a significant risk factor for developing symptomatic UTI ($P = 0.006$). Antibiotic resistance was higher in Group B ($P = 0.002$) (Group A: 7.1% [95% CI: 6.3–20] vs. Group B: [71%, CI: 38–104], $P = 0.0021$, Fisher's exact test).

Conclusion: One day is possibly noninferior to 3 days of IV amikacin as prophylaxis in patients undergoing TURP with respect to bacteriuria and symptomatic UTI, with an added advantage of lower antibiotic resistance.

INTRODUCTION

Antibiotic prophylaxis is a well-accepted, evidence-based practice in patients undergoing transurethral resection of the prostate (TURP).[1-4] However, the optimal duration of prophylaxis is yet to be determined.[5] Poor adherence to the guidelines and the use of antibiotics for a longer duration, even beyond the catheter removal, is common. There is no uniformity in the protocols, and the treatment is guided by the common belief that "more is better" in preventing the infections following TURP. A multicentric study found that ~ 50% of the urologists give three or more days of perioperative antibiotics in the patients undergoing TURP.[6] Clearly,

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the antibiotic prophylaxis policy should be determined by the local resistance patterns, yet there are lacunae in the trials assessing the standard antibiotic regimens, antibiotic safety profiles, and the side effects relevant to the duration of antimicrobial prophylaxis when a mucosal breach is anticipated, as in TURP.[3,7,8]

In the present study, we hypothesized that a single preoperative antibiotic administration is noninferior to 3 days of antibiotics in the patients undergoing TURP. A 3-day course of antibiotics has cost, inconvenience, and antibiotic resistance issues. To address the above, we planned a randomized control trial comparing the outcomes of patients receiving a single day versus 3 days of intravenous (IV) amikacin as the prophylaxis for TURP.

MATERIALS AND METHODS

Study design
We conducted a single-center, noninferior, parallel-arm, randomized controlled trial with 1:1 allocation, comparing a single day versus 3 days of IV amikacin (15 mg/kg) in patients undergoing TURP with a preoperative sterile urine culture.

The study protocol was in accordance with the ethical standards of the Declaration of Helsinki. This study was approved by the Institutional Review Board (IRB min number 9884 [INTERVEN] dated January 20, 2016) and was registered with the Clinical Trial Registry of India (CTRI/2017/09/009721).

Population
All patients undergoing TURP at our center, who had a sterile preoperative urine culture, were eligible for inclusion in the study. Patients who were on a catheter preoperatively (suprapubic catheter/per-urethral catheter), patients with preoperative positive urine culture, patients who had received antibiotics in the week before the enrollment, and patients with contraindication to aminoglycoside administration, e.g., chronic kidney disease (creatinine clearance <60 ml/min/1.73 m^2, myasthenia gravis, and mitochondrial diseases) were excluded.

Interventions
Patients were admitted a day before TURP. Written informed consent was taken in the appropriate format. Randomization was done before the induction of anesthesia. As per the antibiogram published yearly by the hospital infection control committee, amikacin showed the highest sensitivity (83%) to the common uropathogens (*Escherichia coli*) and hence was the drug of choice for prophylaxis [Supplementary Figure 1]. All the patients received a dose of IV amikacin (15 mg/kg) before the induction. Group A patients did not receive any further antibiotics. Patients in Group B received injection amikacin (15 mg/day) on day 2 and 3 as well. Patients underwent TURP as per the standard protocol described previously.[9] The

urinary catheter was removed on day 3 (day 1 being the day of surgery) and the postoperative urine culture was sent on day 4. In case of any perioperative complication such as fever, clot retention requiring bladder wash, or re-exploration, the clinician in-charge was free to change the antibiotic type and duration. All such events were recorded and considered as protocol violations.

The following parameters were recorded: age, comorbidities, IPSS score (mild: 0–7. moderate: 8–19, and severe: 20–35), preoperative postvoid residue (PVR) in ml, grade of the prostate,[1-3] duration of prostatic resection in minutes, operative surgeon's experience (resident, junior consultant with <5 years of experience postresidency, and senior consultant with more than 5 years of experience postresidency), and the resected weight of the prostate.

Postoperatively, the following variables were recorded: the incidence of fever (>100°F), episodes of acute urinary retention (AUR), hematuria, reoperation, and bladder washes.

Outcome assessment
The primary outcome was the rate of bacteriuria in the urine culture sent on the 4th postoperative day. The secondary outcomes were the incidence of urinary tract infection (UTI) in the immediate postoperative period and at 1 month, incidence of AUR, hematuria, and transurethral syndrome (TUR syndrome). Risk factors for the development of UTI were also assessed (diabetes, surgeon experience, resection time, weight of the resected prostatic tissue, and significant bacteriuria).

Definitions
A colony-forming unit of ≥10^4/ml of urine was considered to be significant bacteriuria based on the available data.[10-13] UTI was defined as patients who developed fever (>100 deg F), symptoms of frequency, urgency, and burning micturition with significant bacteriuria. The first postoperative day was defined as the day of the TURP. Breach in protocol was defined as the patients who did not receive the stipulated duration or dose of antibiotics for various reasons. This included patients who required prolonged catheterization in the postoperative period or needed reintervention in the form of bladder wash/reoperation. Grade of the prostate was defined as Grade 1, 2, and 3.[14]

Follow-up
The patients were followed up during the hospital visit on day 7 and through a telephonic interview on day 30. On the first visit on day 7, the urine culture report was followed up and the patients were assessed for symptoms which were documented. At 1 month, a telephonic interview was conducted and the patients' symptoms were inquired. If they had developed a symptomatic UTI, the details of the same and the urine culture report were asked to be mailed to the principal investigator.

Statistical analysis

Block randomization was done before the induction of anesthesia. The method of allocation was sealed, opaque envelopes based on the computer-generated random tables.

Sample size calculation: Based on a study by Wagenlehner *et al.*,[11] we assumed that the incidence of postoperative bacteriuria would be 20% and the calculated sample size to show that 1 day is noninferior to 3 days of amikacin was 169 in each arm with 80% power, a noninferiority margin of 12%, and an expected dropout rate of 10%. To prove noninferiority, a total of 338 patients were to be recruited to have 305 evaluable patients.

Analysis

The data were entered using EpiData entry software, Epidata association, version 2.0, Odense, Denmark. The data were screened for outliers and extreme values using Box-Cox plot and histogram (for shape of the distribution). Analysis was performed per-protocol and as intention to treat. Summary statistics were used for reporting demographic, clinical, and laboratory characteristics. Fisher's exact test was used to calculate the association between the groups for categorical variables. Binary logistic regression was done to determine the risk factors. Number needed to treat (NNT) was calculated based on the absolute risk reduction (ARR). Differences were considered significant at $P < 0.05$. A planned interim analysis was performed after recruitment of 100 patients. The data were submitted to the Data Safety Monitoring Board of the institution and the recruitment was completed. At the end of the study, exploratory analysis was performed by assessing the antibiotic resistance pattern in both groups.

Blinding

The reporting microbiologist was blinded to the group allocation. However, as the primary outcome measure was an objective parameter and blinding would require IV administration of a placebo, the surgeon, patient, or the assessor were not blinded.

RESULTS

Between April 2016 and April 2019, 392 patients were eligible for the study. Ten patients did not consent to be a part of the study and 44 were not included, based on the exclusion criteria [Figure 1]. Of the 338 patients randomized, 169 were randomized to Group A (1 dose of injection amikacin) and 169 were randomized to Group B (injection amikacin 3 doses). Details of the patients with a breach in the protocol and loss to follow-up are shown in Figure 1.

All patients were available at day 7 for the follow-up, while seven patients were lost to follow-up at 1 month. The last follow-up was completed in May 2019. Intention-to-treat and per-protocol analysis were performed. There was no amikacin related adverse events.

Patient characteristics are summarized in Table 1. Patients were matched in both the groups with respect to age, comorbidities, preoperative IPSS, and grade of prostate gland enlargement.

Primary outcome: Rate of significant bacteriuria on postoperative day 4

Although the rate of significant bacteriuria in Group A was double than that of Group B (8.3% versus 4.1%), this was not statistically significant (confidence interval [CI]: –1.1–9.8, $P = 0.124$, Fisher's exact test) as per the intention-to-treat analysis. Per-protocol analysis also showed similar results [Table 2].

Secondary outcomes

The rate of postoperative sepsis, need for antibiotics, and readmissions were similar between both the groups. Although there were twice the number of UTIs at 1 month in Group A (6 vs. 3), this difference was not statistically significant (3.5% vs. 1.7% [95% CI: –1.9–5.6] $P = 0.344$, Fisher's exact test) [Table 3].

Risk factors for the development of postoperative significant bacteriuria/urinary tract infection

None of the risk factors studied in this trial (diabetes, surgeon experience, resection time, and weight of prostatic tissue resected) contributed to patients developing significant bacteriuria or UTI at day 4 and 1 month, respectively.

Significant bacteriuria at postoperative day 4, a risk factor for developing urinary tract infection at 1 month

Eighty three percent of the patients in Group A, who had UTI at 1 month, had significant bacteriuria, while the comparative figure was 67% for the patients in Group B. This indicates that postoperative bacteriuria is an important risk factor for developing UTI ($P = 0.006$, Fisher's exact test) [Supplementary Table 1].

The number needed to prevent bacteriuria and urinary tract infection by giving a 3-day course of injection amikacin when compared to a single dose

The NNT to prevent one episode of bacteriuria by giving 3 days of amikacin is 24 (ARR: 4.14%). The NNT to prevent one episode of UTI at 1 month was 55 (ARR: 1.8%).

Postoperative complications

Postoperative complications were comparable in both the groups [Supplementary Table 2]. The infective complications were also similar (3 [1.8%] vs. 1 [1.6%], $P = 0.31$).

Post hoc/exploratory analysis

Antimicrobial resistance pattern

Of the 14 patients in Group A with significant bacteriuria, there was only one patient in whom a resistant organism was isolated. In others, the organisms were sensitive to the first-line antibiotics (cefpodoxime and amikacin). However, in Group B, of the 7 patients with significant bacteriuria, 5
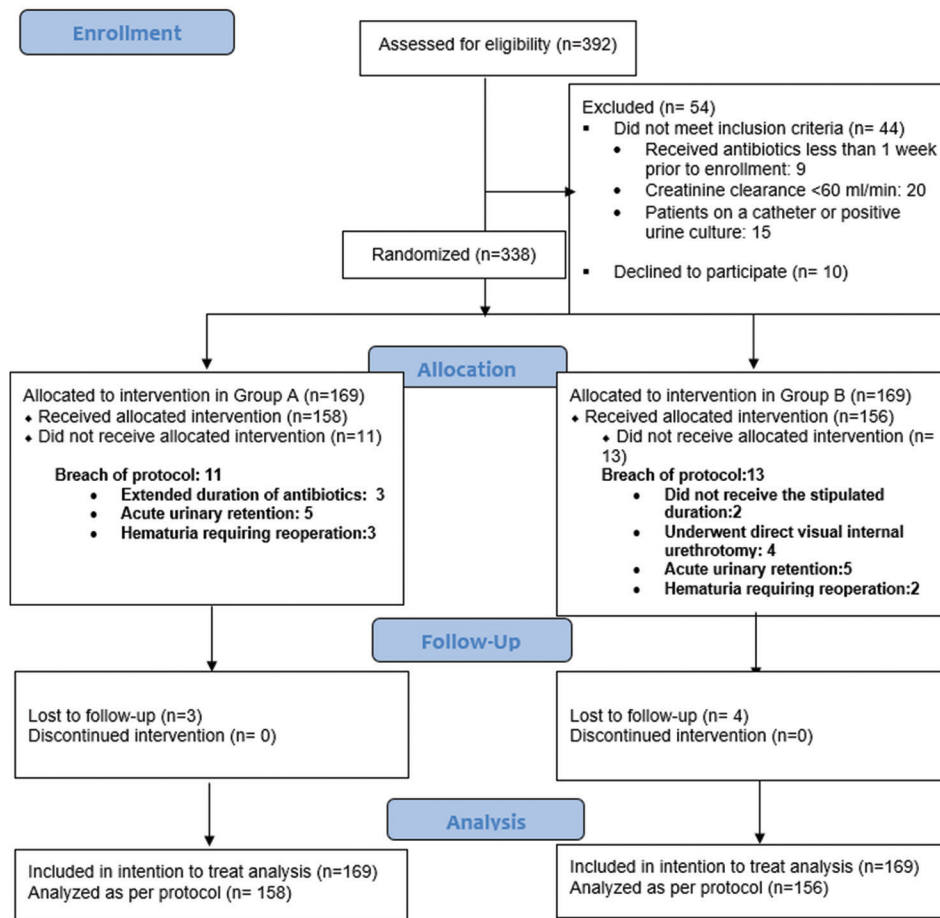
Figure 1: Consort diagram

had infection with resistant organisms (extended-spectrum beta-lactamase producing – 2, carbapenem resistant – 1, and Enterococcus resistant to ampicillin – 2). This indicates that, in the patients who received 3 days of amikacin, there was a higher incidence of drug resistance, which was statistically significant (Group A: 7.1% [95% CI: 6.3–20] vs. Group B: 71%, [CI: 38–104], $P = 0.0021$, Fisher's exact test) [Figure 2].

DISCUSSION

In patients with sterile urine, single-dose antibiotics have been shown to be comparable to a short-course of antibiotics, in terms of reducing the postoperative bacteriuria rate and complications. However, in some trials the short-course antibiotic protocols (cephalosporin based) have been found to be more effective than the single-dose regimens.[3] Although the American Urological Association, Clinical Practice Guideline for the Management of Asymptomatic Bacteriuria: 2019 Update by the Infectious Diseases Society of America, and the European Urological Association recommend the use of prophylactic antibiotics before TURP, the evidence for the duration of the prophylaxis is weak.[15-17]

Randomized controlled trials by Hall *et al.*,[18] Weiss *et al.*,[19] and Shah *et al.*[20] showed that the rate of symptomatic UTI was similar at 4–6 weeks of follow-up in the patients receiving extended duration of antibiotics when compared to a single dose. There were no episodes of sepsis or difference in the complications between the groups. However, a subgroup analysis of cephalosporin-based trials in the meta-analysis by Berry *et al.*[3] indicated that the short treatment protocols (~72 h) appeared to be more effective than the single-dose protocols. Alsaywid *et al.*[5] conducted a systematic review and concluded that antibiotic prophylaxis is required for surgeries such as TURP or TURBT, but the optimal antibiotic regimen (antibiotic class, dose, and course) still needs to be determined. The rationale given for the common practice of 3 days of antibiotic prophylaxis in the developing countries is that the incidence of postoperative bacteriuria is high (10%–20%).[21] Mohee *et al.* found an asymptomatic bacteriuria rate of 23% following TURP.[22] Experience from the West also showed similar trends. Koves *et al.*[6] found that a majority of the patients (51%) received 3 days of antibiotics (up to catheter removal) and that there were no uniform protocols. This made a compelling case of proving the noninferiority of a single dose of aminoglycoside versus 3 days of antibiotics in the Indian scenario.

Table 1: Patient characteristics at randomization by allocated treatment

Parameters	Total randomized (*n*=338)	1 day amikacin (Group A) (*n*=169)	3 days amikacin (Group B) (*n*=169)
Median age (years), range	64 (30-87)	64 (33-87)	62 (30-81)
Diabetes mellitus	94	49	45
IPSS			
Mild (≤7)	0	0	0
Moderate (8-19)	27	17	10
Severe (20-35)	311	152	159
Preoperative PVR (ml), median (range)	84 (25-250)	80 (15-250)	8025-(260)
Prostate grade			
1	69	30	39
2	263	137	126
3	6	2	4
Median duration of resection (min), *n* (range)	40 (10-120)	40 (10-120)	40 (15-120)
Operative experience			
1 (resident)	243	123	120
2 (consultant <5 years)	64	30	34
3 (consultant >5 years)	31	16	15

IPSS=International prostate symptom score, PVR=Post void residue

Table 2: Comparison of the rate of bacteriuria at post-operative day 4

Bacteriuria- Post-operative day 4	Group A (PP)	Group B (PP)	Group A (ITT)	Group B (ITT)
Absent, *n* (%)	144 (91.2)	149 (95.6)	155 (91.7)	162 (95.9)
Present, *n* (%)	14 (8.8)	7 (4.4)	14 (8.3)	7 (4.1)
Total, *n* (%)	158 (100)	156 (100)	169 (100)	169 (100)

PP=Per protocol, ITT=Intention-to-treat analysis

Table 3: Post-operative infective complications

Parameter	Total (PP*) (*n*=314)	Group A (PP) (*n*=155) LTFU-3	Group B (PP) (*n*=152) LTFU-4	Total (ITT) (*n*=338)	Group A (ITT) (*n*=169)	Group B (ITT) (*n*=169)
Immediate post-operative sepsis, *n* (%)	4 (1.2)	3 (1.9)	1 (0.6)	4 (1.2)	3 (1.8)	1 (0.6)
30-day readmission rate due to UTI, *n* (%)	1 (0.3)	1 (0.6)	0	1 (0.3)	1 (0.6)	0
Symptomatic UTI at 1-month, *n* (%)	9 (2.9)	6 (3.8)	3 (1.9)	9 (2.7)	6 (3.5)	3 (1.7)

PP=Per protocol, ITT=Intention-to-treat analysis, UTI=Urinary tract infection, LTFU=Lost to follow-up

[Group A-7.1% (95%CI:6.3-20) versus group B-71%, CI:38-104)
p= 0.0021, Fisher exact test]

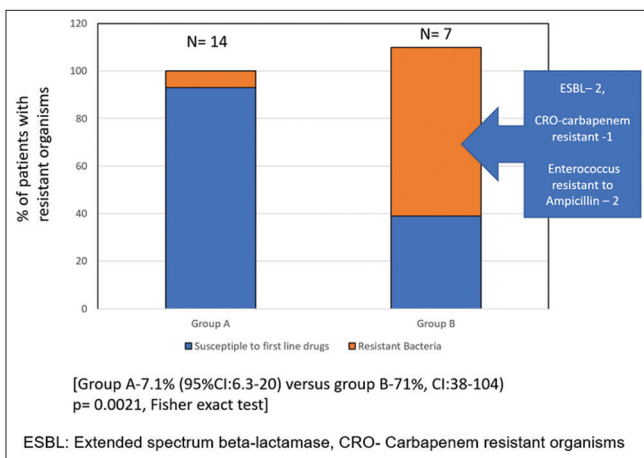ESBL: Extended spectrum beta-lactamase, CRO- Carbapenem resistant organisms

Figure 2: Antibiotic resistance pattern between Group A and B

Three other randomized controlled trials (RCTs) (as mentioned above) had oral antibiotics as the part of their protocol. There has been a change in the antibiotic resistance pattern in the past decade, especially in the Indian setting. As the efficacy of oral antibiotics in our setting is poor, with resistance to the common oral antibiotics (cotrimoxazole, quinolones, and cephalosporins), IV antibiotics such as aminoglycosides are preferred. The choice of drug is determined by the institutional microbiological profile, sensitivity, and antibiogram.

Our study states that a single-day antibiotic prophylaxis with amikacin is possibly equivalent to a 3-day course in terms of significant bacteriuria at day 4. However, the clinical significance and conclusive noninferiority has to established by a larger sample size and longer follow-up.

The study also suggests that significant bacteriuria (postoperative day 4) is the only significant predictor of developing a UTI post-TURP. Similar findings have been noted in the other RCTs on this topic.[11] The clinically relevant outcome of UTI, though numerically higher in the single dose arm, was not statistically different in both the arms. The NNT to prevent one episode of UTI with 3 days of injection amikacin as compared to 1 day was 55 in our study.

As suggested by our study, a single-day antibiotic prophylaxis may also reduce the risk of developing a drug-resistant UTI. Similar concerns have been highlighted in the recent literature. A multinational, multicentric study assessing the global prevalence of infections in urology and the use of antibiotics before TURP also showed a high incidence of antimicrobial resistance.[6] In the context of antibiotic prophylaxis before TURP, Baten *et al.*[23] have also found a greater incidence of antimicrobial resistance and have called for antibiotic stewardship. Thus, taken as a whole, a 3-day antibiotic regimen would prevent one additional UTI, for every additional 55 patients being treated with the 3-day course of antibiotics. This benefit would be at the cost of promoting antibiotic resistance. Antibiotics remove drug-sensitive competitors, leaving the resistant bacteria behind to reproduce as a result of natural selection. These resistant organisms persist in the hospital environment and get transferred to the other patients. These resistant nosocomial microbial florae pose a serious threat and thus the need for judicious use of antibiotics is the need of the hour.

Our study has a few limitations. The first limitation was the assessment of the secondary outcome of UTI was based on a telephonic interview, as it introduces a possible reporting bias. The urine culture at 1-month follow-up was performed at different laboratories and hence there may be a lack of standardized reporting.

The strength of this study includes being the first RCT evaluating TURP prophylaxis conducted in the recent times in India. This assumes importance given how the baseline antibiotic resistance has changed the outcomes of antibiotics prophylaxis in patients with vesicoureteric reflux and in patients with asymptomatic bacteriuria in pregnancy. The rigorous methodology, in accordance with the consort guidelines, gives credibility to the results presented.

CONCLUSION

A single day is possibly noninferior to 3 days of IV amikacin as prophylaxis in patients undergoing TURP with respect to bacteriuria and UTI, with the added advantage of lower antibiotic resistance.
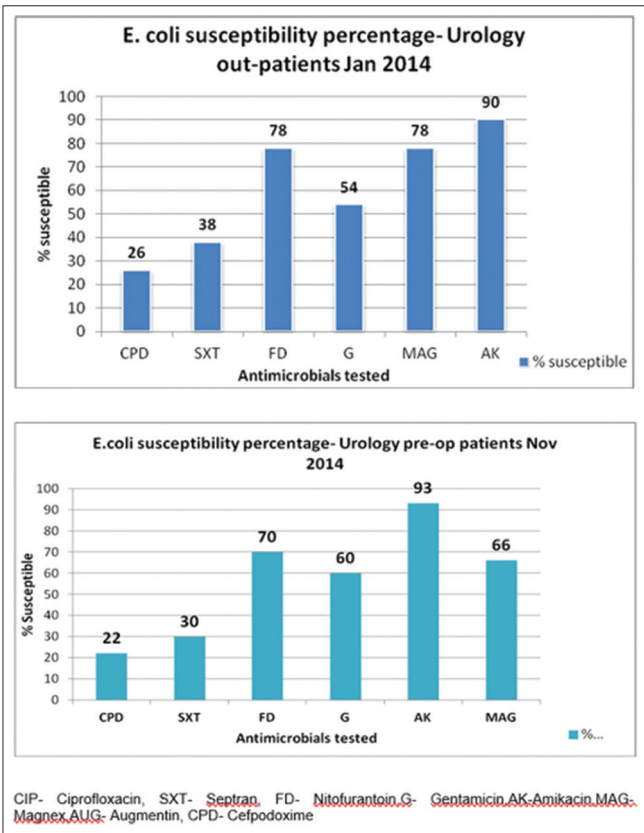
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CIP- Ciprofloxacin, SXT- Septran, FD- Nitofurantoin G- Gentamicin AK-Amikacin MAG- Magnex AUG- Augmentin, CPD- Cefpodoxime

Supplementary Figure 1: Antibiotic susceptibility testing for Urology out-patients and pre-operative patients

UTI at 1 month	Significant bacteriuria on post-operative day 4		Total (PP)	Significant bacteriuria on post-operative day 4		Total (ITT)
	No	Yes		No	Yes	
Group A (*n*=155) (PP) LTFU - 3						
UTI at 1 month						
Absent, *n* (%)	140 (94)	9 (6)	149	150 (94)	9 (6)	159 (100)
Present, *n* (%)	1 (17)	5 (83)	6 (100)	1 (14)	6 (86)	7 (100)
Total	141	14	155	151	15	166
Group B (*n*=152) (PP) LTFU-4						
UTI at 1 month						
Absent, *n* (%)	144 (96)	5 (4)	149 (100)	157 (97)	5 (3)	162 (100)
Present, *n* (%)	1 (33)	2 (67)	3 (100)	1 (33)	2 (67)	3 (100)
Total	145	7	152	158	7	165

Supplementary Table 1: Post-operative significant bacteriuria versus symptomatic urinary tract infection at 1 month

PP=Per protocol, ITT=Intention-to-treat analysis, LTFU=Lost to follow-up, UTI=Urinary tract infection

Supplementary Table 2: Early postoperative complications

Complications (Clavien-Dindo)	Total (*n*=338)	Group A (ITT) (*n*=169)	Group B (ITT) (*n*=169)
I: AUR, *n* (%)	1	5 (3)	5 (3)
III: Hematuria, *n* (%) (re exploration)	5	3 (1.8)	2 (1.1)
IV a: Sepsis, *n* (%)	4	3 (1.8)	1 (0.6)
IV b: TUR syndrome, *n* (%)	2	1 (0.6)	1 (0.6)

ITT=Intention-to-treat analysis, AUR=Acute urinary retention, TUR=Transurethral resection