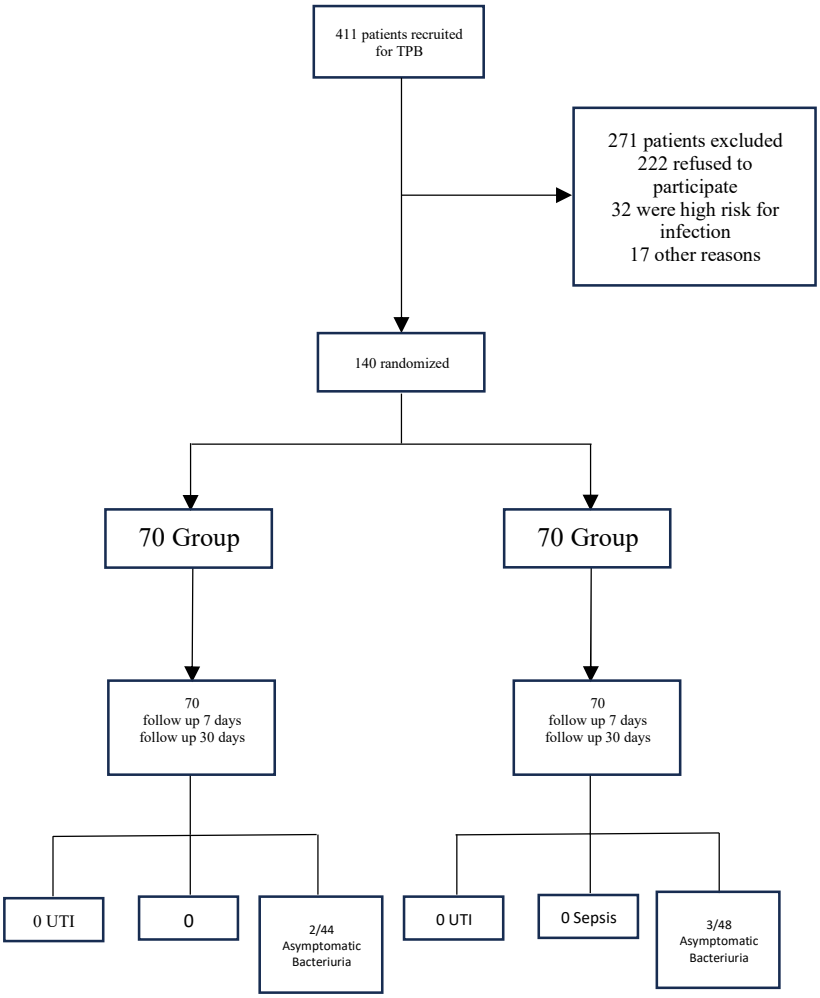
Results

Figure 1. Baseline Characteristics



From June 2024 to June 2025, 400 patients undergoing TPB were recruited. Of these, 140 were randomly assigned in a 1:1 ratio to either Group A (without prophylaxis) or Group B (with prophylaxis), with 70 patients in each group. All participants were followed for 30 days, and full adherence to both intervention and treatment protocols was maintained. Baseline characteristic **(Table 1)** were similar between both groups. Patients who received antibiotics had a median age of 67 years, a median BMI of 25.95, and were mostly Charlson score 2 (67.1%). Their median prostate volume was 42.15 mL, and the median PSA level was 9.0 ng/mL. In the non-antibiotic group, the median age was 66 years, with a median BMI of 25.25; 67.1% also had a Charlson score of 2. The median prostate volume was 44.05 mL, and the median PSA was 11.22 ng/ml. There were no significant differences in median number of biopsy cores (23.5 vs. 21) or median PIRADS score (both 4.0) between the two groups. The overall cancer detection rate was 57.1%, higher in the no-antibiotics group (62.9%) compared to the antibiotics group (51.4%). The most common Gleason score overall was 7 (3+4) at 31.4%, followed by Gleason 8 (4+4) at 10%. In the antibiotics group, Gleason 8 (4+4) was more prevalent (11.4%), while Gleason 7 (3+4) was most common (21.4%) in the non-antibiotic group.

Primary Outcome:

Table 2 shows the primary and secondary outcomes. There were no cases of UTI and sepsis, in either group. Thus, no adverse infectious events occurred in either the antibiotic (0/70) or no-antibiotic group (0/70). The absolute difference was 0%, with a 90% confidence interval (CI) of 0.00 to 4.19. As this upper bound did not exceed the non-inferiority margin of 5%, non-inferiority was demonstrated. Post hoc analysis showed bacteriuria detected in 4.5% (2/44) in Group A, and 6.25% (3/48) in Group B, all of which were asymptomatic and required no treatment.

Secondary Outcome:

There were no 30-day readmissions in either group. This supports non-inferiority, as the 90% CI (–4.19 to 4.19) did not exceed the 4.85% threshold. Urinary retention occurred in 2.1% of patients overall—2.86% in the no-antibiotic group and 4.3% in the antibiotic group. The difference was 1.43%, with a 90% CI of –3.13 to 5.99. All of which required emergency room visits and subsequent catheterization.

Table 1. Baseline Characteristics

		No Antibiotic	Antibiotic	p value
Age		66 (61 - 71.0)	67 (62.75 - 72)	0.645
BMI		25.25 (23.6 - 28.73)	25.95 (23.48 - 28.69)	0.645
Charlson				
1		6 (8.6%)	6 (8.6%)	1.000
2		47 (67.1%)	47 (67.1%)	
3		16 (22.9%)	17 (24.3%)	
4		1 (1.4%)	0 (0.0%)	
Prostate Volume		44.05 (32.0 - 62.0)	42.15 (33.75 - 57.85)	0.121
PSA		11.22 (7.05 - 17.25)	9.0 (6.27 - 17.61)	0.712
Number of Cores		23.5 (16 - 32)	21 (17.75 - 26.25)	0.251
	All	**No Antibiotic**	**Antibiotic**	**p value**
Cancer Detected				
Yes	80 (57.1)	44 (62.9)	36 (51.4)	0.1734
No	60 (42.9)	26 (37.1)	34 (48.6)	
Gleason				
Gleason 6 (3+3)	13 (9.3)	6 (8.6)	7 (10)	
Gleason 7 (3+4)	22 (31.4)	15 (21.4)	7 (10)	
Gleason 7 (4+3)	9 (6.4)	5 (7.1)	4 (5.7)	
Gleason 8 (4+4)	14 (10)	6 (8.6)	8 (11.4)	
Gleason 9 (4+5)	13 (9.3)	9 (12.9)	4 (5.7)	
Gleason 9 (5+4)	4 (2.9)	2 (2.9)	2 (2.9)	
Gleason 10 (5+5)	5 (3.6)	1 (1.4)	4 (5.7)	

Table 2. Primary and Secondary Outcomes

	All		No Antibiotic		Antibiotic		Difference		p value
	n, %	90% CI	n, %	90% CI	n, %	90% CI	Value	90% CI	
Primary Outcome									
Urinary Tract Infection [Yes]	0 (0.0)	0.0 to 2.1	0 (0.0)	0.0 to 4.19	0 (0.0)	0.0 to 4.19	0.00	-4.19 to 4.19	1.0000
Sepsis [Yes]	0 (0.0)	0.0 to 2.1	0 (0.0)	0.0 to 4.19	0 (0.0)	0.0 to 4.19	0.00	-4.19 to 4.19	1.0000
Bacteriuria	5 (5.4)	2.2 to 11.1	2 (4.5)	0.8 to 13.6	3 (6.3)	1.7 to 15.4	1.80	-9.5 to 5.9	1.000
Secondary Outcome									

30 Day readmission Rates [Yes]	0 (0.0)	0.0 to 2.1	0 (0.0)	0.0 to 4.19	0 (0.0)	0.0 to 4.19	0.00	-4.19 to 4.19	1.000
30 day Emergency Room Visits [Yes]	3 (2.1)	0.59 to 5.44	2 (2.86)	0.51 to 8.72	1 (1.43)	0.07 to 6.60	1.43	-3.13 to 5.99	1.000
Non Infectous Complications [Yes]	3 (2.1)	0.59 to 5.44	2 (2.86)	0.51 to 8.72	1 (1.43)	0.07 to 6.60	1.43	-3.13 to 5.99	1.0000

Table 3. Adverse Events

	Patient 1	Patient 2	Patient 3
Antibiotic Prophylaxis	None	None	Cefoxitin
Age	72	68	75
BMI	22.6	25.4	20.2
Charlson Score	2	3	2
Prostate Volume	53.2g	39	43g
PSA	11.8 ng/mL	8.9	23.25 ng/ml
Number of Cores	35	32	21
Biopsy Result	Gleason 6 (3+3)	BPH	Gleason 8 (4+4)
Urine Culture Result	No growth	No growth	No growth
Complication	Urinary Retention	Urinary Retention	Urinary Retention
Clavien Dindo Classification	2	2	2
Treatment	Foley Catheter Insertion	Foley Catheter Insertion	Foley Catheter Insertion
Hospital Readmission	No	No	No
Emergency Room Visit	Yes	Yes	Yes

Table 4. Bacteriuria Profile

	Patient 1	Patient 2	Patient 3	Patient 4	Patient 5
Antibiotic Prophylaxis	None	None	Cefoxitin	Cefoxitin	Cefoxitin
Age	74	75	51	52	66
BMI	28.2	31.2	25.4	29.7	22.2
Charlson Score	2	3	2	2	3
Prostate Volume	103.3g	31.3g	47.7g	287g	37g
PSA	24.4 ng/ml	14.1 ng/ml	4.44 ng/ml	229 ng/mL	54 ng/ml
Number of Cores	35	26	32	18	16
Biopsy Result	BPH	Gleason 7 (4+3)	BPH	Gleason 10 (5+5)	BPH
Urine Culture Result	S. haemolyticus 50k CFU	S. Agalactiae 10k CFU	E. Coli 10k CFU	P. Aeruginosa 40k CFU	K. Pneumonia 10k CFU
Complication	None	None	None	None	None
Treatment	None	None	None	None	None
Hospital Readmission	No	No	No	No	No
Emergency Room Visit	No	No	No	No	No