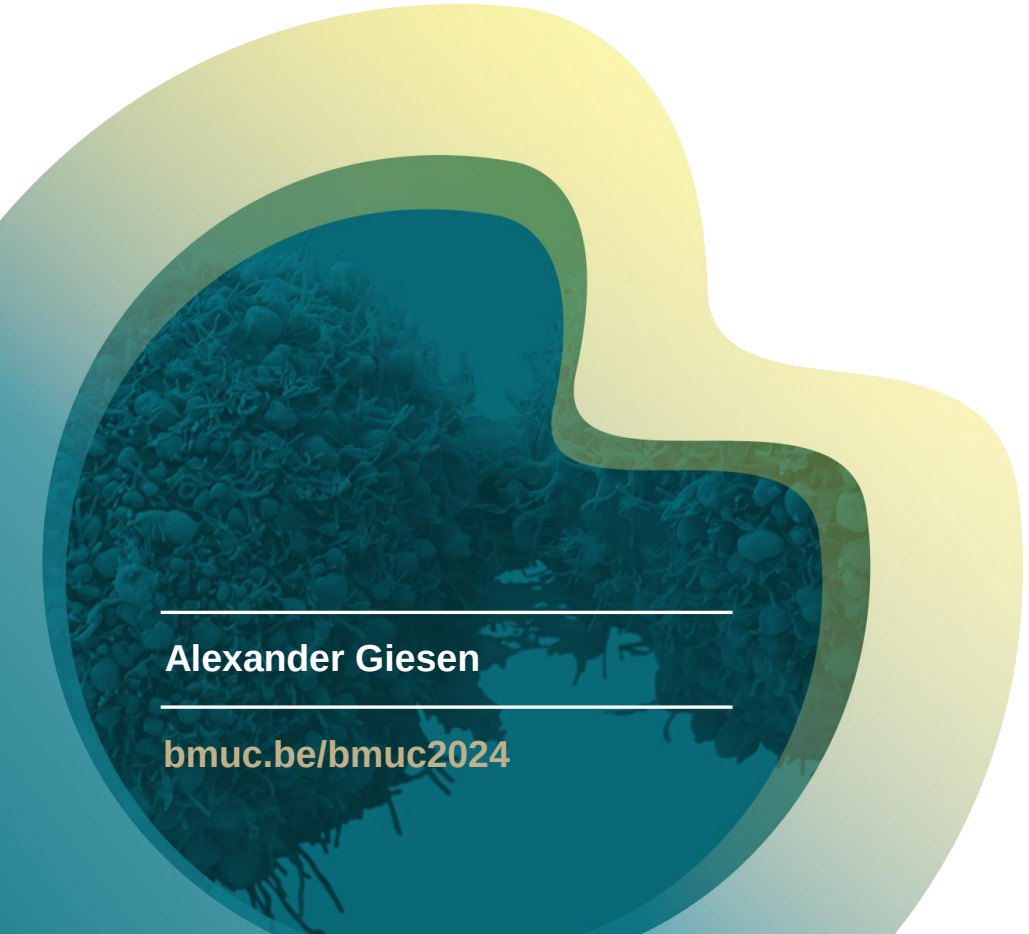
Late breaking session on uro-oncology

PREVENT Trial

Alexander Giesen



Alexander Giesen

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How do you perform a prostate biopsy?

- Transrectal
- Transperineal with general anesthesia
- Transperineal with local anesthesia
- Transrectal or transperineal (depending on the situation)

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Transperineal Versus Transrectal Magnetic Resonance Imaging–targeted and Systematic Prostate Biopsy to Prevent Infectious Complications: The PREVENT Randomized Trial

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Conflicts of interest

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- I have no potential conflict of interest to report

Setting the scene

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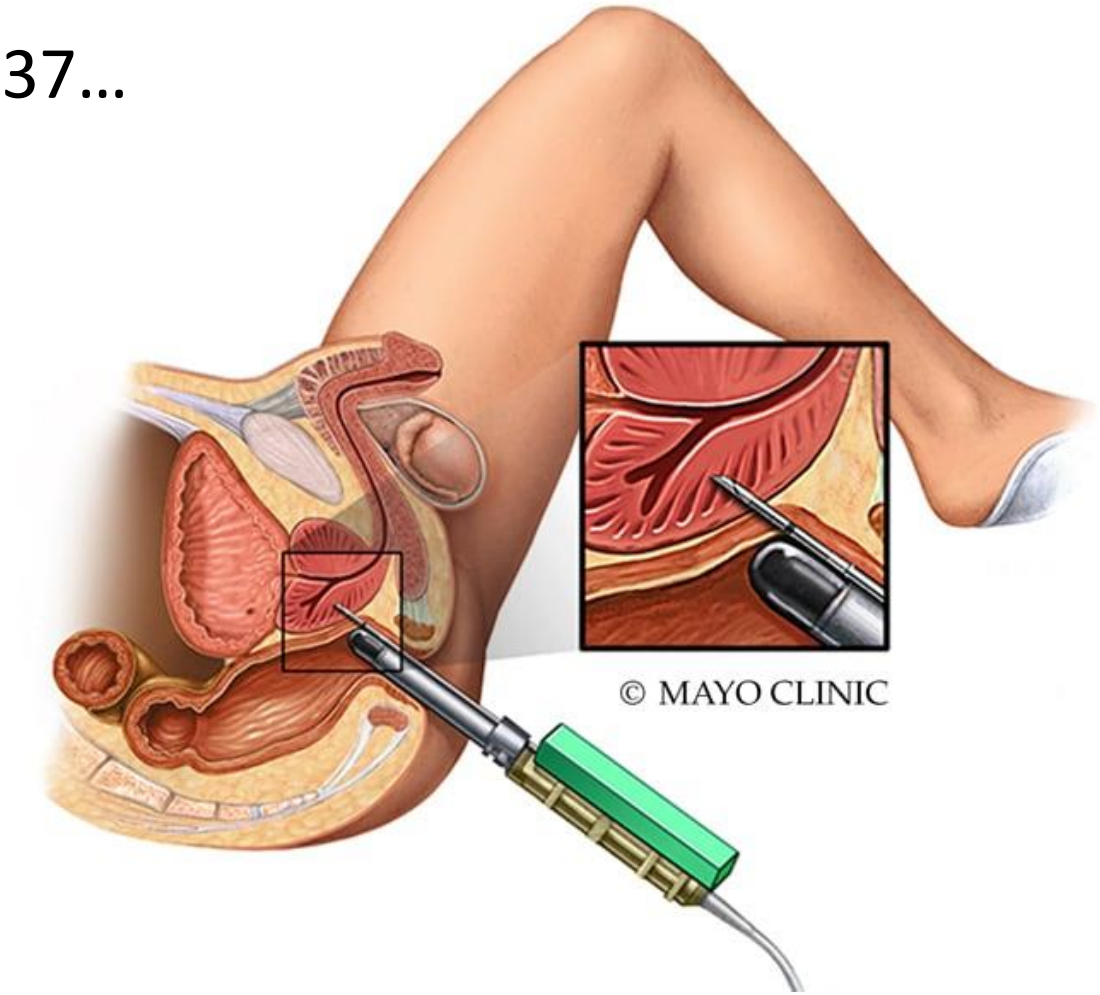


Transrectal

Setting the scene

- >2 million prostate biopsies each year (Europe + USA)[1]
- 2015: 99% was transrectal in USA[2]
- Transrectal: infectious complications in up to 7%[3]

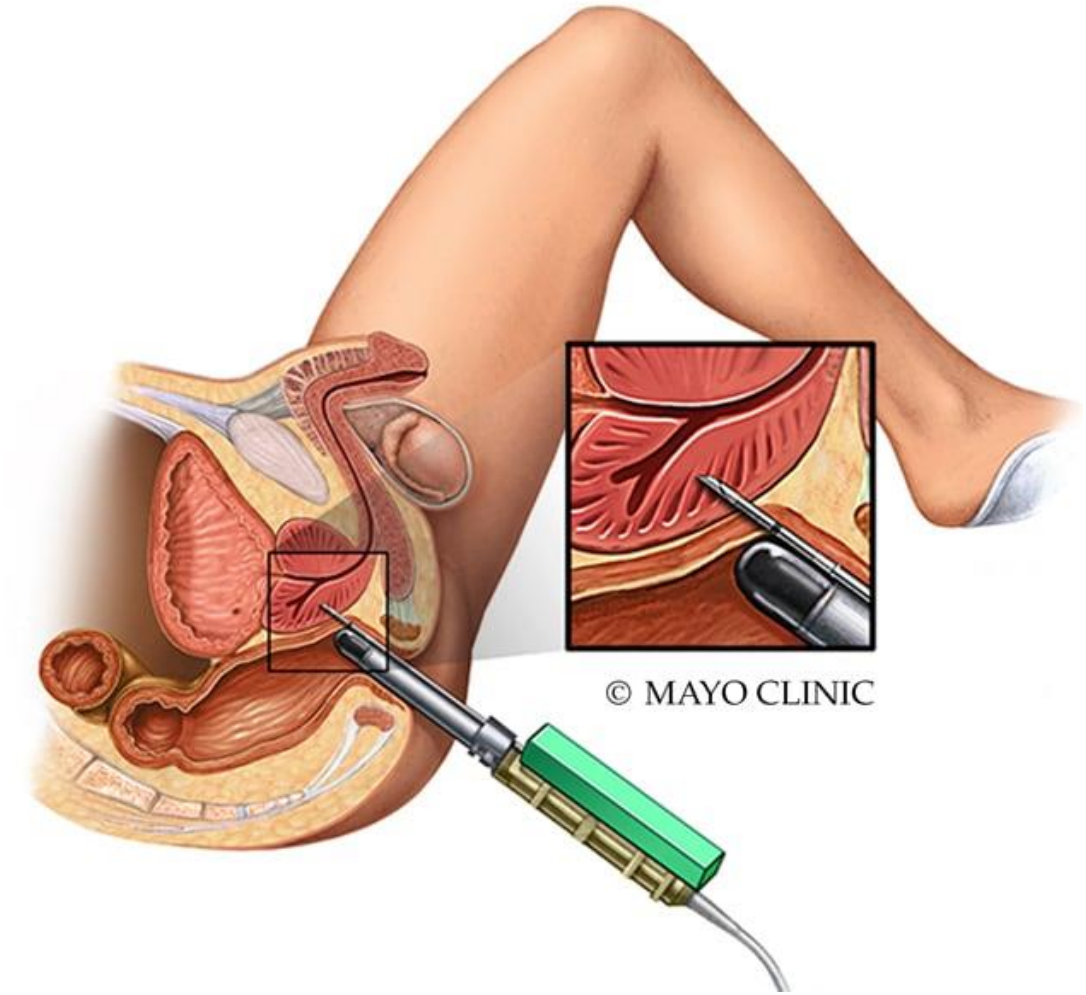
Antibiotic prophylaxis: usually fluoroquinolone

→ Increased antimicrobial resistance

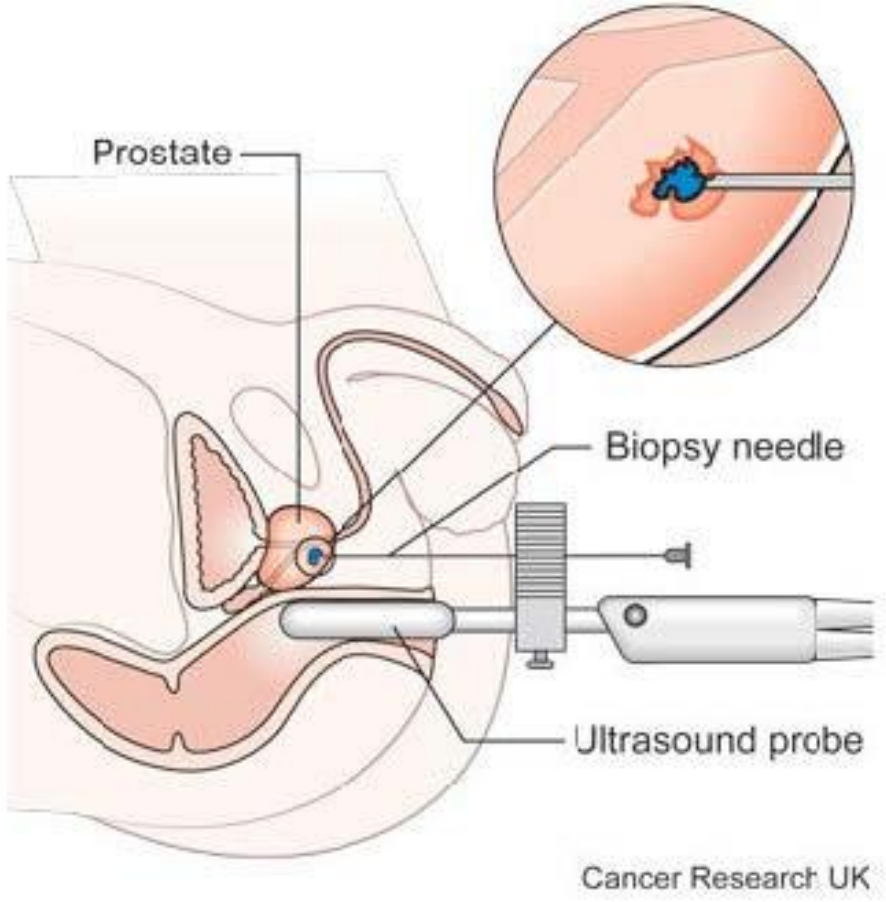
→ Increased postbiopsy infections

1. Loeb S, Vellekoop A, Ahmed HU, et al. Systematic review of complications of prostate biopsy. Eur Urol 2013;64:876-92.
2. Halpern JA, Sedrakyan A, Dinerman B, Hsu WC, Mao J, Hu JC. Indications, utilization and complications following prostate biopsy: New York State analysis. J Urol 2017;197:1020-5.
3. Shoag JE, Gafney C, Pantuck M, et al. Risk factors for infection after prostate biopsy in the United States. Urology 2020;138:113-8.

Setting the scene



Transrectal



Transperineal

Setting the scene

What do the EAU guidelines tell us about this?

Recommendations	Strength rating
When performing systematic biopsy only, at least 12 cores are recommended.	Strong
Systematic transperineal biopsies are preferred over systematic transrectal biopsies for detection of clinically significant PCa.	Strong
Where magnetic resonance imaging (MRI) has shown a suspicious lesion, MR-targeted biopsy can be obtained through cognitive guidance, US/MR fusion software or direct in-bore guidance.	Weak

Setting the scene

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What do the EAU guidelines tell us about this?

Summary of evidence	LE
A meta-analysis of eight studies including 1,596 patients showed significantly reduced infectious complications in patients undergoing transperineal biopsy as compared to transrectal biopsy.	1a
A meta-analysis of eight non-RCTS reported comparable rates of post-biopsy infections in patients undergoing transperineal biopsy irrespective if antibiotic prophylaxis was given or not.	1a
A meta-analysis of eleven RCTs including 2,036 men showed that use of a rectal povidone-iodine preparation before transrectal biopsy, in addition to antimicrobial prophylaxis, resulted in a significantly lower rate of infectious complications.	1a
A meta-analysis on eleven studies with 1,753 patients showed significantly reduced infections after transrectal biopsy when using antimicrobial prophylaxis as compared to placebo/control.	1a

Setting the scene

What do the EAU guidelines tell us about this?

Recommendations	Strength rating*
Perform prostate biopsy using the transperineal approach due to the lower risk of infectious complications.	Strong
Use routine surgical disinfection of the perineal skin for transperineal biopsy.	Strong
Use rectal cleansing with povidone-iodine prior to transrectal prostate biopsy.	Strong
Do not use fluoroquinolones for prostate biopsy in line with the European Commission final decision on EMEA/H/A-31/1452.	Strong
Use either target prophylaxis based on rectal swab or stool culture; augmented prophylaxis (two or more different classes of antibiotics); or alternative antibiotics (e.g., fosfomycin trometamol**, cephalosporin, aminoglycoside) for antibiotic prophylaxis for transrectal biopsy.	Weak
Ensure that prostate core biopsies from different sites are submitted separately for processing and pathology reporting.	Strong

Setting the scene

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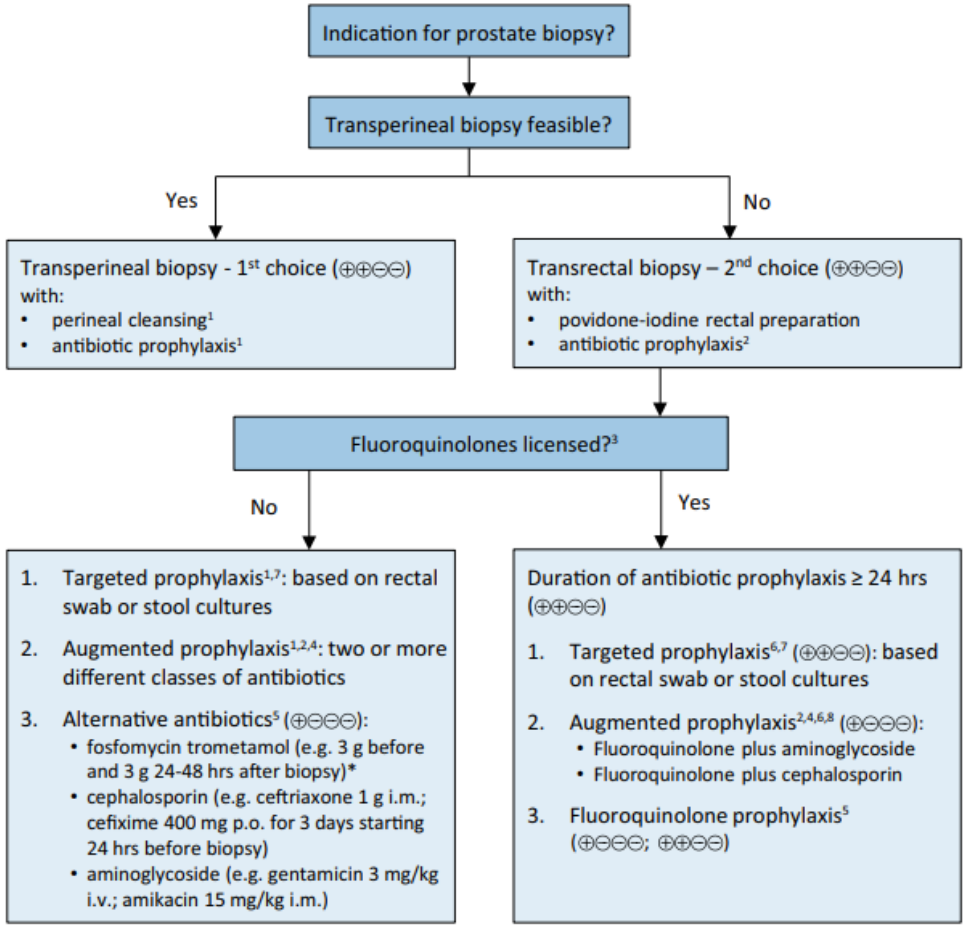
What do the EAU guidelines tell us about this?

Recommendations	Strength rating*
Perfo…state biopsy using the transperineal approach due to the lower risk of infectious com…	Strong
Us… …f the perineal skin for transperineal biopsy.	Strong
Use rectal … …er to transrectal prostate biopsy.	Strong
Do not use fluoroquino… …th the European Commission final decision on EMEA/H/A-31/1452.	Strong
Use either target prophylaxis based on rectal … …rophylaxis (two or more different classes of antibiotics); or alternative … trometamol**, cephalosporin, aminoglycoside) for antibiotic prophyla… biopsy.	Weak
Ensure that prostate core biopsies from different sites are submitted separately for processing and pathology reporting.	…ong

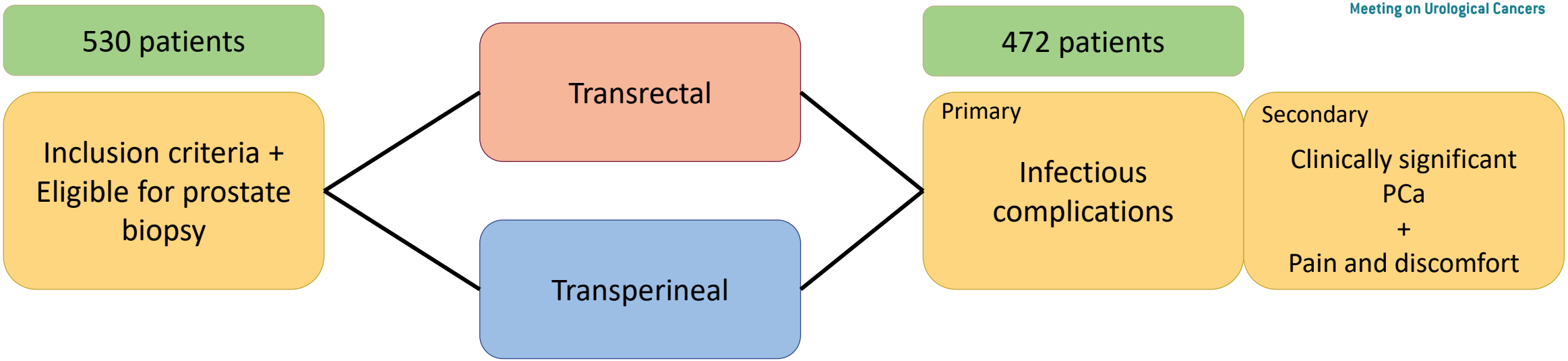
No RCT available

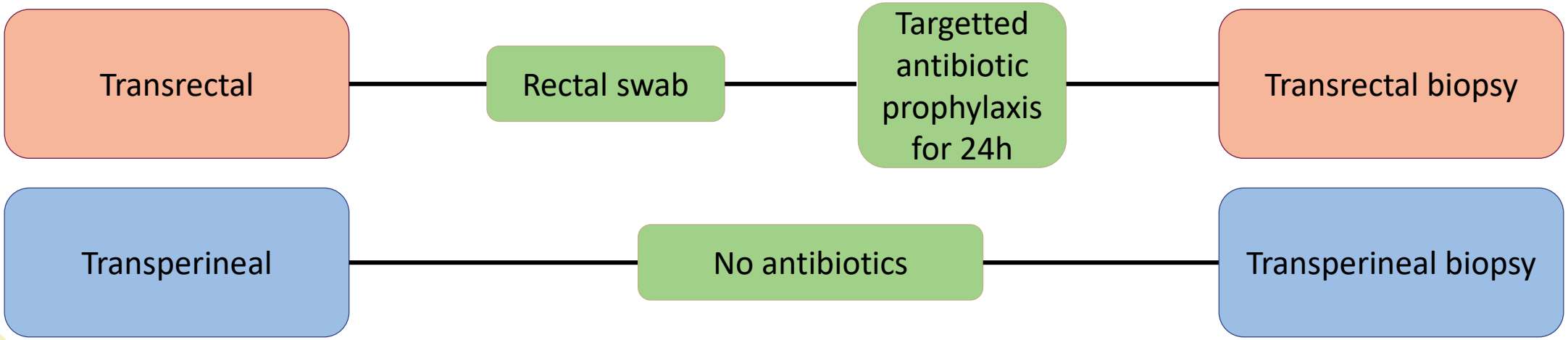
Setting the scene

Figure 5.1: Prostate biopsy workflow to reduce infectious complications*



Study design





Results

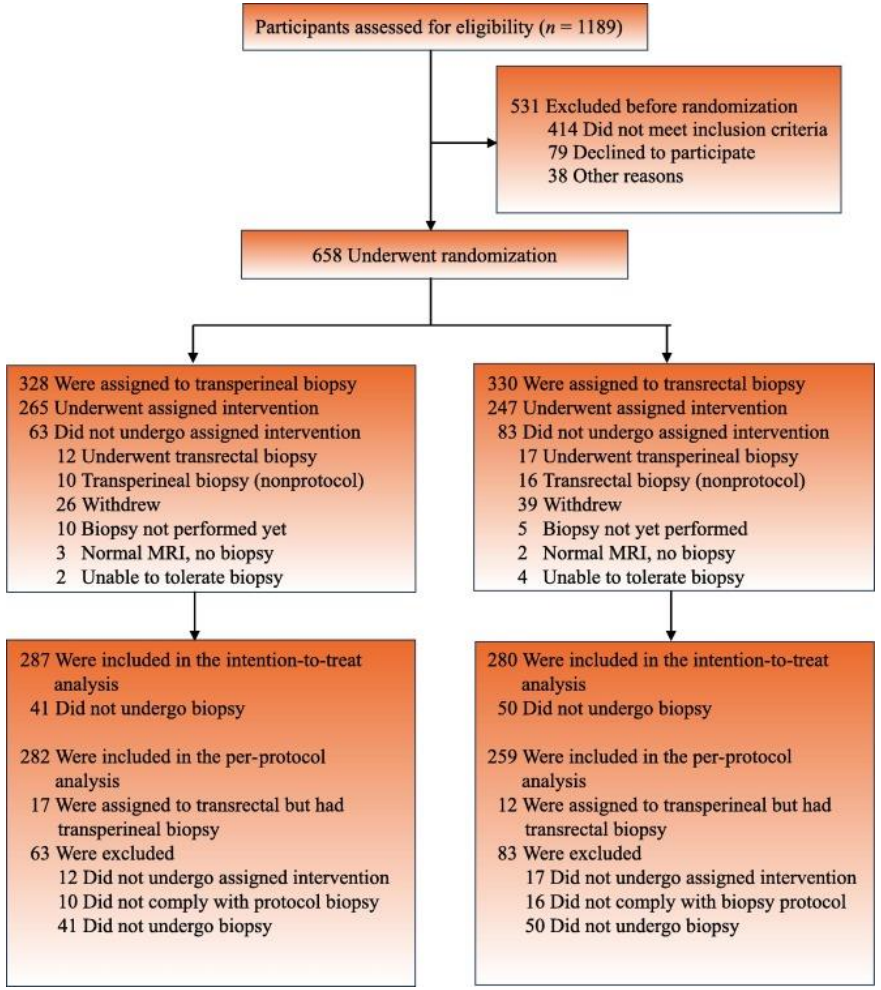


Table 1 – Characteristics by randomization arm

Characteristic	Transperineal (*N* = 287), *n* (%)	Transrectal (*N* = 280), *n* (%)
Type of biopsy		
Transperineal	272 (95)	19 (6.8)
Transrectal	15 (5.2)	261 (93)
Age	66 (61, 71)	66 (61, 70)
Race		
Asian	12 (4.2)	16 (5.7)
Black or African American	32 (11)	44 (16)
Other	17 (5.9)	15 (5.4)
Unknown	37 (13)	37 (13)
White	189 (66)	168 (60)
Hispanic ethnicity	11 (4.7)	10 (4.3)
Unknown	51	49
BMI	27 (25, 30)	27 (24, 31)
Unknown	1	0
History of smoking	66 (23)	68 (24)
Unknown	1	1
Family history of prostate cancer	69 (24)	65 (23)
Unknown	2	3
Indication		
Abnormal digital rectal exam	6 (2.1)	10 (3.6)
Elevated PSA	279 (98)	269 (96)
None of the above	1 (0.3)	1 (0.4)
Unknown	1	0
PSA	5.8 (4.4, 8.0)	5.8 (4.6, 8.3)
Prostate volume	41 (32, 57)	43 (32, 59)
Unknown	2	4
MRI	286 (100)	278 (99)
MRI PI-RADS score		
1	7 (2.5)	6 (2.2)
2	22 (7.7)	27 (9.8)
3	67 (24)	52 (19)
4	119 (42)	123 (45)
5	69 (24)	68 (25)
No MRI performed	1 (0.3)	2 (0.6)
Unknown	2	2
Number of systematic cores	12 (12, 12)	12 (12, 12)
Number of targeted cores	3 (2, 5)	3 (2, 5)
Unknown	3	1

BMI = body mass index; MRI = magnetic resonance imaging; PI-RADS = Prostate Imaging Reporting and Data System; PSA = prostate-specific antigen.
Data are presented as *n* (%) and median (quartile 1, quartile 3).

Results

Table 2 – Adverse events by randomization arm where differences are calculated as the difference in the transrectal arm subtracted from the transperineal arm

Characteristic	Transperineal (*N* = 287), *n* (%)	Transrectal (*N* = 280), *n* (%)	Difference (%)	95% Confidence interval (%)	*p* value
Infection	0 (0)	4 (1.4)	−1.4	−3.6, 0.2	0.059
Urinary retention	1 (0.3)	3 (1.1)	−0.7	−2.8, 1.0	
Bleeding requiring intervention	0 (0)	1 (0.4)	−0.4	−2.0, 1.0	
Gleason grade group 2–5	151 (53)	141 (50)	2.0	−6.0, 10	
Gleason grade group 1	49 (17)	62 (22)	−5.1	−12, 1.7	

CI = confidence interval.
Values are presented as *n* (%); differences along with Newcombe hybrid score 95% confidence intervals and *p* values were calculated using Fisher's exact test for the primary outcome of infection. For cancer detection outcomes, Gleason grade group differences adjusted for site along with 95% confidence intervals were calculated using the logistic regression least-squares adjusted mean difference (95% CI).

Primary outcome: post-biopsy infection captured by a prospective medical review and patient report on a 7-d survey

Secondary outcome: cancer detection

Results

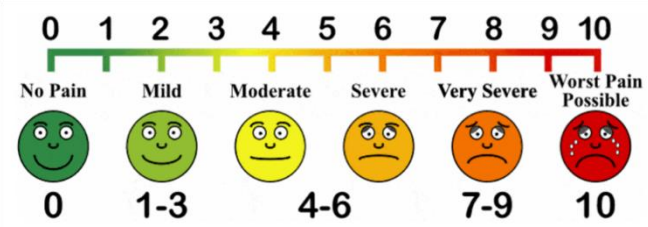


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Table 3 – Patient-reported outcomes by randomization arm where differences are calculated as the difference in the transrectal arm subtracted from the transperineal arm adjusted for study site

Characteristic	*N*	Transperineal (*N* = 287)	Transrectal (*N* = 280)	Adjusted difference	95% Confidence interval
Biopsy pain	548	3.6 (2.3)	3.0 (2.1)	0.6	0.2, 0.9
Unknown		10	9		
Biopsy pain ≥7 (severe)	548	33 (12%)	19 (7.0%)	5.0%	–0.1%, 10%
Unknown		10	9		
Biopsy discomfort	554	4.2 (2.5)	3.8 (2.3)	0.4	0.0, 0.8
Unknown		9	4		
Biopsy anxiety	565	3.9 (3.0)	4.2 (2.9)	–0.3	–0.8, 0.1
Unknown		1	1		
7-d survey discomfort	448	2.1 (2.4)	1.7 (2.2)	0.3	–0.1, 0.7
Unknown		61	58		
7-d survey pain present	449	22 (9.7%)	32 (14%)	–5.2%	–12%, 1.5%
Unknown		61	57		
7-d survey pain score >3	444	15 (6.6%)	13 (6.0%)	0.8%	–4.6%, 6.3%
Unknown		61	62		

ANCOVA = analysis of covariance.
For continuous variables, values are presented as mean (standard deviation); ANCOVA was used to generate the differences adjusted for site. For categorical variables, values are presented as *n* (%); differences were adjusted for site along with 95% confidence intervals calculated using the logistic regression least-squares adjusted mean difference.

Secondary outcome: numerical rating scale (0–10) for biopsy-related pain and discomfort during and 7-d after biopsy

Conclusion from the authors

- Transperineal
  - Safe and infection free
  - Similar detection rate of significant prostate cancer
  - More pain and discomfort → resolved by 7d
- Transrectal
  - Similar infection rates with targeted prophylaxis (after rectal cultures)

Conclusion from the authors

- Transperineal
  - Safe and infection free
  - Similar detection rate of significant prostate cancer
  - More pain and discomfort → resolved by 7d
- Transrectal
  - Similar infection rates with targeted prophylaxis (after rectal cultures)

Both are feasible options

Does this information change your clinical practice?

- No
- Yes, I'll do more transperineal
- Yes, I'll do more transrectal
- Yes, when doing transrectal, I'll perform a rectal swab for targetted antibiotics

Thank you for your attention