



XIII congresso nazionale

simeu

GENOVA 30 MAG - 1 GIU 2024



I.MEU

I.MEU

Xpert® bladder cancer detection in Emergency Setting Assessment (XESA PROJECT): a prospective, monocentric trial

Antonio Desai, MD
Emergency Medicine Specialist
IRCCS Humanitas Research Hospital



XIII congresso nazionale

simeu

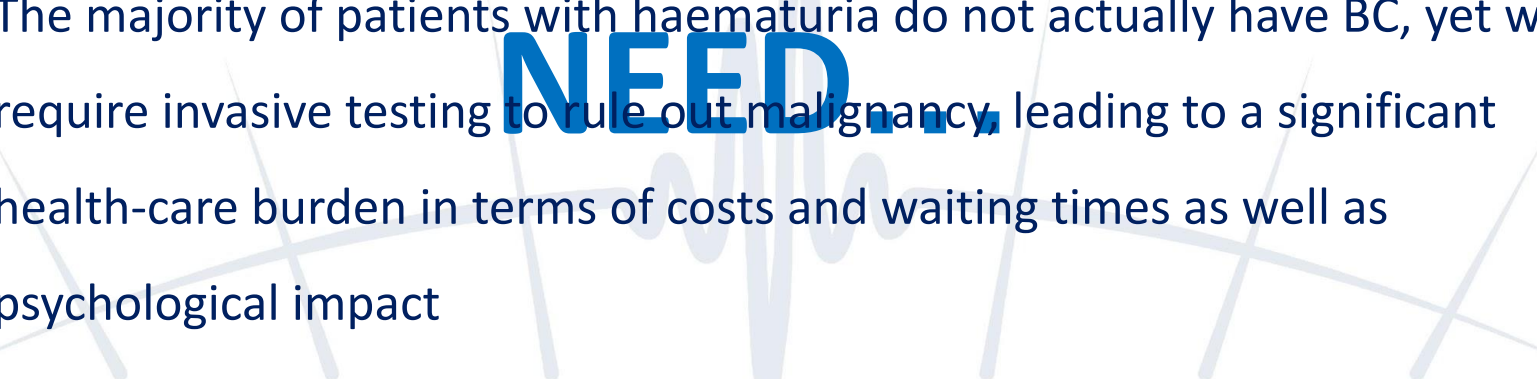
GENOVA 30 MAG - 1 GIU 2024



BACKGROUND

- Bladder cancer (BC) is a globally significant health concern, ranking as the 10th most frequently diagnosed cancer worldwide
- Frequently diagnosed during evaluations for gross hematuria, a common presentation at Emergency Departments (ED)
- The majority of patients with haematuria do not actually have BC, yet will require invasive testing to rule out malignancy
- The current gold standard methods for identifying BC are white light cystoscopy (WLC) and urine cytology (UC)
- Xpert® Bladder Cancer Detection (Xpert BC Detection) is a novel mRNA-marker test for BC diagnosis

UNMET CLINICAL

- 
- The majority of patients with haematuria do not actually have BC, yet will require invasive testing to rule out malignancy, leading to a significant health-care burden in terms of costs and waiting times as well as psychological impact
 - **NEED...**
AVOID UN-NECESSARY PROCEDURES AND SAVE RESOURCES



AIM OF THE STUDY

In our study, we aimed to assess the clinical performance of Xpert® BC Detection in patients presenting to the Emergency Department with hematuria.



Specifically, we sought to determine its diagnostic accuracy compared to the gold standard diagnostic work-up involving UC and WLC

AND

... to evaluate the economic resource utilization associated with an Xpert[®] BC Detection-led diagnostic pathway.



MATERIALS AND METHODS



STUDY DESIGN

- Prospective
- Single center
- Single arm
- Observational
- Started in February 2022

- approved by the institution's ethical committee (ICH-015- n. 3065)
- **all participants provided informed consent for the clinical trial**

POPULATION

Inclusion criteria:

- patients aged ≥ 18 years presenting at the ED with gross hematuria within 48 hours
- triage priority code of 4 or 5
- provide informed consent and agree to undergo the study protocol



POPULATION

Exclusion criteria:

- known bladder cancer lesions under active surveillance
- history of bladder chemotherapy
- in situ urinary stent or
- any condition that could interfere with the study protocol





Xpert® Bladder Cancer Detection

Xpert® BC Detection (Cepheid, Sunnyvale, CA, USA) is an mRNA-based urinary biomarker test developed for BC diagnosis. It is based on RT-PCR to quantitatively measure levels of five mRNAs associated with cell proliferation and survival (IGF2); cell growth, division and signal transduction (ANXA10, ABL1); epigenetic dysregulation (UPK1B); and response to neuroendocrine stress, immunity, and inflammation (CRH) from a voided urine sample.



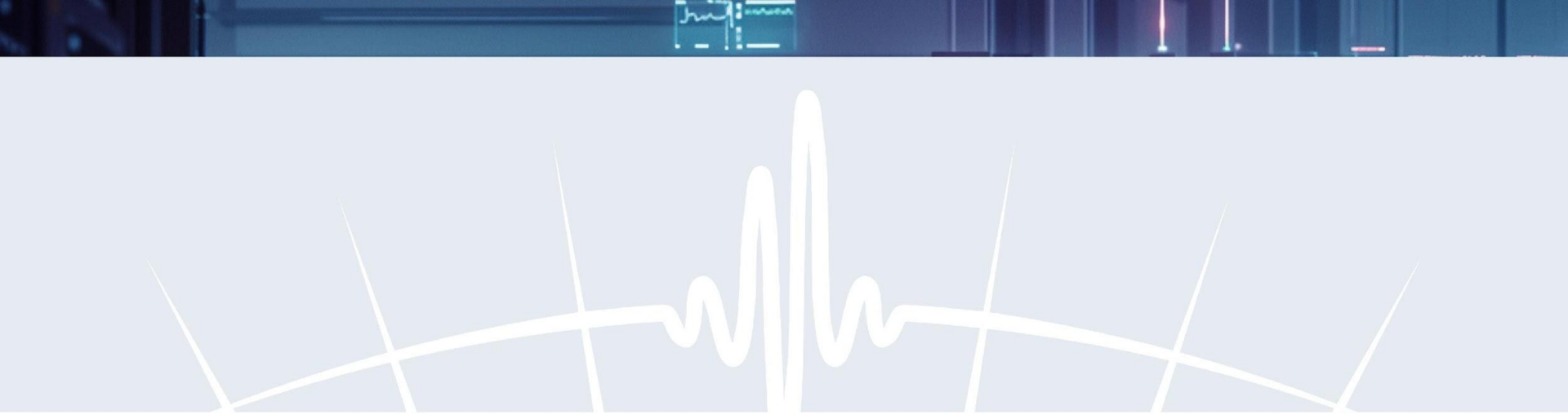
OUTCOMES

Primary Outcome

- To evaluate Xpert® BC Detection's diagnostic performance in identifying bladder cancer in ED patients with gross hematuria
- We also assessed Xpert®, UC, WLC, and UC + WLC in identifying pT $\geq$ 1 and/or HG BC

Secondary Outcome

- Assessing test feasibility in the ED
- Identifying avoided unnecessary cystoscopies/TURBs with Xpert® BC Detection
- Comparing its diagnostic accuracy with UC for TURB screening using WLC as the control
- **A cost-analysis compared resource consumption between Xpert® BC Detection and the standard pathway**



RESULTS

Patients presented with
haematuria = **110**

Excluded:

- **15** patients withdrew
their informed consent

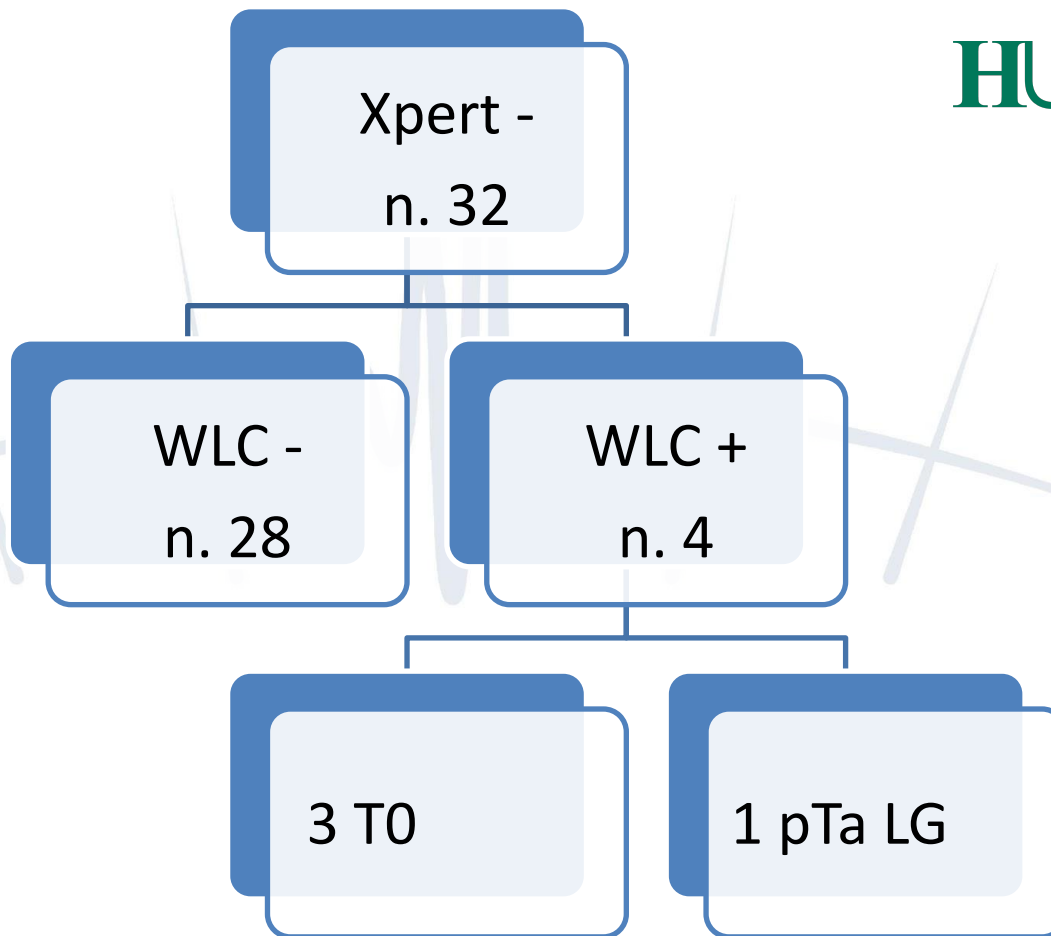
- **13** patients did not
undergo either UC or WLC

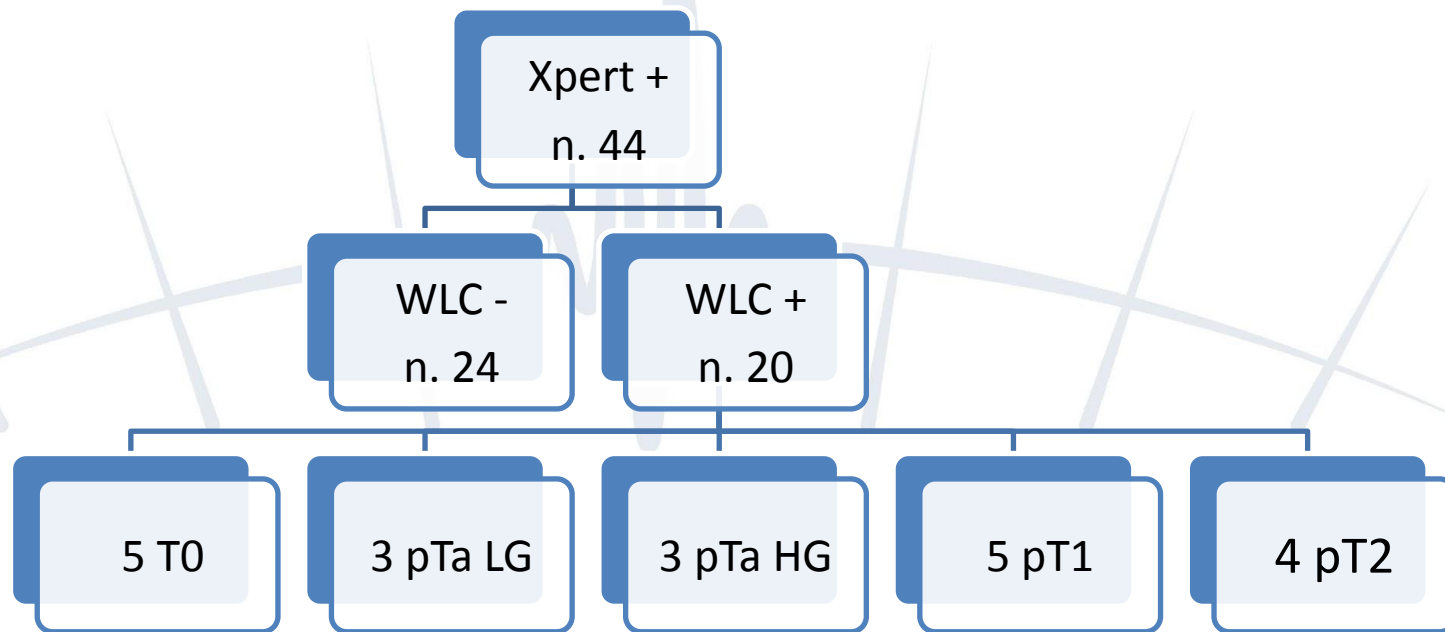
Later excluded:

- **6** patients had
invalid Xpert test

Valid Xpert test = n. **76**

Age at surgery, years, median (IQR)	66 (22, 89)
Gender, n (%)	
Male	64/76 (84.2%)
Body Mass Index (kg/m2)	26.5 (18.7, 38.5)
Family History of Urothelial Cancer, n (%)	2/76 (2.6%)
Men with Benign Prostatic Hyperplasia, n (%)	21 (27.6%)
Patients with Hypertension, n (%)	44/76 (57.9%)
Patients on anticoagulant or antiplatelet therapy, n (%)	33 (43.4%)
Smoking history, n (%)	
Current smokers	7/76 (9.2%)
Former smokers	17/76 (22.4%)





	TEST	SN	SP	PPV	NPV
Any BC	Xpert® BC Detection	93.8%	51%	39.5%	96%
	UC	28.6%	100%	100%	83.3%
	WLC	100%	89.5%	72.3%	100%
	UC+WLC	100%	89.5%	72.3%	100%
pTa HG – pT≥1	Xpert® BC Detection	100%	49%	31.6%	100%
	UC	40%	100%	100%	88.9%
	WLC	100%	83.6%	54.5%	100%
	UC+WLC	100%	83.6%	54.5%	100%

	TEST	SN	SP	PPV	NPV
Any BC	Xpert®	93.8%	50%	75%	75%
	UC	25%	100%	100%	40%
pT≥1 - HG	Xpert®	100%	33.3%	60%	100%
	UC	33.3%	100%	100%	65%

	Standard Pathway (€)	Xpert NEG Pathway (€)	Xpert POS Pathway (€)
Procedure	cost per patient		
Urine microscopy	€ 2.30	€ 2.30	€ 2.30
Abdominal Ultrasound	€ 71.79	€ 71.79	€ 71.79
Urologic consultation	€ 70.00	€ 70.00	€ 70.00
Xpert BC Detection	€ -	€ 104.46	€ 104.46
Urine Cytology (UC)	€ 15.65	€ -	€ -
WLC	€ 211.12	€ -	€ 211.12
total cost per patient in pathway	€ 370.86	€ 248.55	€ 459.67
Number patients	400	184	216
Cost SOC pathway (400 pts)	€ 148,344.00		
Cost of each Xpert Pathway (184 and 216 pts)		€ 45,733.20	€ 99,288.72
Cost Xpert Pathways (400 Patients)	€ 145,021.92		
Savings (400 patients)	€ 3,322.08		

Annual patient estimate	400
Negative result	46%
Xpert® Neg pathway in (n of patients)	184
Direct costs in €	- €22,505.04
Released resources in €	- 41.726,00
Possibility of optimization in €	- €64,260.72

Procedure	Cost (€)	Standard Pathway	Xpert NEG Pathway	Xpert POS Pathway
Urine microscopy	2,30	x	x	x
Abdominal Ultrasound	71,79	x	x	x
Urologic consultation	70,00	x	x	x
Urine Cytology (UC)	15,65	x		
Xpert® BC Detection	~ 24,00		X	x
WLC	211,12	x		x
Total Sum		370,86	168,09	379,21

Annual patient estimate	400
Negative result	46%
Xpert® Neg pathway in (nof patients)	184 pts
Direct costs in €	- €37.309,00
Released resources in €	- 41.726,00
Possibility of optimization in €	- €79.035,00



CONCLUSIONS

Conclusions

- Xpert® BC Detection test offered greater sensitivity compared to UC for the detection of all grade bladder cancers, with high detection rate among HG or pT ≥ 1 diseases
- Has the potential to significantly optimize resource utilization and streamline the endoscopic resection process, ultimately reducing costs and saving valuable time
- A multicentric study remains mandatory

A stylized, low-poly illustration of a hospital scene. In the foreground, a patient lies in a hospital bed, partially covered by a white sheet. To the right, three medical professionals in white scrubs are walking away from the viewer. The background shows a brightly lit hospital corridor with other figures in the distance. The entire image has a soft, ethereal glow and a low-poly, geometric aesthetic.

THANK YOU!