Xpert in hematuria patients suppl material R2 1/9/2024

**Supplemental material:**

**Supplemental figures:**

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Supplemental figure 1: Flow chart patient recruitment



Supplemental figure 2: ROC Analysis with AUC for urine cytology and Xpert BC-D in hematuria patients vs. reference standard (pathology)

**Supplemental tables:**



Supplemental table 1: Reasons for excluding patients from study.

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Prospective (n=263)** | **Retrospective (n=61)** | **p-value****(Fisher Exact)** |
| **Age**(19, 30)(30, 50)(50, 65)(65, 75)(75, 90) | 10 (3.8%)44 (16.7%)120 (45,6%)55 (20.9%)34 (12.9%) | 0 (0%)6 (9.8%)24 (39.3%)20 (32.8%)11 (18%) | 0.0911 |
| **Sex**FemaleMale | 117 (44.5%)146 (55.5%) | 19 (31.1%)42 (68.9% | 0.0622 |
| **Hematuria**MicrohematuriaGross hematuria | 170 (64.6%)93 (35.4%) | 43 (70.5%)18 (29.5%) | 0.455 |
| **Xpert BC-D result**NegativePositive | 198 (75.3%)65 (24.7%) | 42 (68.9%)19 (31.1%) | 0.458 |
| **Urine cytology**noneNegativePositive | 20 (7.6%)204 (77.6%)39 (14.9) | 4 (6.6%)41 (67.2%)16 (26.2%) | 0.147 |
|  | **Included in Analysis****(n=262)** | **Included in Analysis****(n=59)** |  |
| **Urothelial cancer\***NegativePositiveNone (excluded) | 239 (90.9%)23 (8.7%)1 (0.4%) | 54 (88.5%)5 (8.2%)2 (3.3%) | 1 |
|  | **UC Positive** **(n=23)** | **UC Positive****(n=5)** |  |
| **Tumor grade**Low gradeHigh grade | 7 (2.7%)16 (6.1%) | 1 (1.6%)4 (6.6%) | 1 |

Supplemental table 2: Patient characteristics in prospective (n=263) and retrospective (n=61) patient cohort. 3 excluded per protocol as TURBT was recommended but not completed

|  |  |  |
| --- | --- | --- |
| **Parameter** | **NUE (n = 324)\*** | **IMC (n = 828)\*\*** |
| Age median (years) | 61 | 65 |
| Male (%) | 58 | 56 |
| Microhematuria (%) | 66 | 46 |
| Urothelial tumors (%) | 8.6 | 7.1 |
| Sensitivity Xpert BC-D (%) | 96 | 78 |
| Sensitivity cytology (%) | 61 | 44 |
| Specificity Xpert BC-D (%) | 80 | 84 |
| Specificity cytology (%) | 86 | 97 |

\* This study, \*\* Valenberg FJPV et al. Eur Urol Oncol 2021 [11]

Supplemental table 3: Comparison of key data from this study and the international multicenter trial.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Total** | **Xpert BC-D neg/ WLC pos** | **Xpert BC-D neg/ WLC neg** | **Xpert BC-D pos. + WLC pos-** | **Xpert BC-D pos./ WLC neg.** | **Extended follow-up** |
|  | **321** | 5 | 234 | 37 | 45 |  |
| **US only** | 235 | 4 | 180 | 29 | 22 (%) |  |
| **US + advanced imaging (CT, MRI)** | 86 (27%) | 1 (20%) | 54 (30%) | 8 (22%) | 23 (51%) | + 3 (=58%) |
|  |  |  | RR: 1.64, 95% CI [1.14, 2.36]p = 0.013 |  |

Supplemental table 4: Correlation between Xpert BC-D result and referral for advanced imaging

**Further supplemental material (not for publication)**

**Sample size calculations:**

1. **The sample size to detect sensitivity between GX and cytology for all grade tumors**
	1. The aim of study :

A recent multicenter studies has demonstrated that the Xpert bladder cancer detect has a higher sensitivity than urinary cytology in the detection of UC including low-grade tumors .

* 1. **Hypothesis :**

H0: The sensitivity of GX > the sensitivity of Cytology among **HG & LG** patients

Ha: The sensitivity of GX <= the sensitivity of Cytology among **HG & LG** patients

* 1. The parameters used in sample size calculation :

The estimated true sensitivity of GX: 91.7%

The estimated true sensitivity of Cytology:58.3%

Alpha:5%

The prevalence :8.2%

Software :PASS15

* 1. **Sample size result**



* 1. **Conclusion :**

A sample size of 341 subjects achieves 85% power to detect a difference of 0.334 between two diagnostic tests whose sensitivities are 0.917 and 0.583. This procedure uses a one-sided McNemar test with a significance level of 0.05000. The prevalence of disease in the population is 0.082. The proportion of discordant pairs is 0.431.

with 350 subjects, we should have more than 85% power to detected difference between GX and cytology for all grade tumors.

1. **The sample size to detect sensitivity between GX and cytology for Low grade tumor**
	1. **Aim of study :**

A recent multicenter studies has demonstrated that the Xpert bladder cancer detect has a higher sensitivity than urinary cytology in the detection of UC including low-grade tumors .

* 1. **Hypothesis :**

H0: The sensitivity of GX > the sensitivity of Cytology among  **LG** patients

Ha: The sensitivity of GX <= the sensitivity of Cytology among **LG** patients

* 1. The parameters used in sample size calculation :

The estimated true sensitivity of GX: 66.7%

The estimated true sensitivity of Cytology:10%

Alpha:5%

The prevalence :2.1%

Software :PASS15

* 1. **Sample size result**



* 1. **Conclusion :**

A sample size of 476 subjects achieves 71% power to detect a difference of 0.560 between two

diagnostic tests whose sensitivities are 0.660 and 0.100. This procedure uses a one-sided

McNemar test with a significance level of 0.05000. The prevalence of disease in the population

is 0.021. The proportion of discordant pairs is 0.596.

with 350 subjects, we only have 34.8% power to detected difference between GX and cytology for low grade tumors.