

NJIMEGEN STUDY

Uromonitor Correlation with Cystoscopy

Cystoscopy		Uromonitor		
		Positive	Negative	N.F.
Total cohort	85			
Abnormal or Suspicious	22	20	0	2
Normal/No Bladder cancer H.	61	4	57	0
Not Performed	2	2	0	0
Total		26	57	2

Uromonitor Performance

Total Cohort	83*
Sensitivity % for Abn./Susp. Cyst.	100%
Specificity % in Norm./No BC Hist.	93,4%
Positive Predictive Value (PPV) %	84,6%
Negative Predictive Value (NPV) %	100%

* Two cases with Non Functional molecular analysis were excluded

Study enrollement of over 100 cases; expected to end in June

NJIMEGEN STUDY

Uromonitor Correlation with TURBTs

TURBTs		Uromonitor	
		Positive	Negative
Total cohort	10	10	0
Ta G2a/b	3	3	0
Tis	2	2	0
CIS	2	2	0
Atypia	1	1	0
Not known	2	2	0

Performance in Detecting TUR-Pathology-confirmed Tumor

Total Cohort	10
Sensitivity %	100%
Specificity %	100%

Study enrollement of over 100 cases; expected to end in June

SPANISH ARM OF MULTICENTRE STUDY §

Uromonitor Correlation with Cystoscopy

Cystoscopy		Uromonitor		
Follow-up (n=32) and Diagnosis (n=15) Cohort	Total	Positive	Negative	N.F.
Positive Cystoscopy	27	24	1	2
Negative Cystoscopy	20	2	18	0
Total		26	19	2

Uromonitor Performance

Total Cohort	45*
Sensitivity % for Posit./Susp. Cystoscopy	96,0%
Specificity % in Negative Cystoscopy	90,0%
Positive Predictive Value (PPV) %	92,3%
Negative Predictive Value (NPV) %	95%

* Two cases with Non Functional molecular analysis were excluded

§ Part of na enrollement of over 250 samples,already analysed; expecting clinical data on30additional Spanish samples

SPANISH ARM OF MULTICENTRE STUDY §

Uromonitor Correlation with TURBTs

	TURBTs	Uromonitor	
		Positive	Negative
Total cohort	20	20	0
Ta	8	8	0
T1	7	7	0
T2	1	1	0
T0*	4	4	0
Low Grade	11	11	0
High Grade	5	5	0

* Cases that Pathology reported No Tumor; despite clear Positive Cystoscopy

Performance in Detecting TUR-Pathology-confirmed Tumor

Total Cohort	20
Sensitivity %	100%
Specificity %	100%

§ Part of na enrollement of over 250 samples,already analysed; expecting clinical data on30additional Spanish samples

COMBINED DATA

Uromonitor Correlation with Cystoscopy

Cystoscopy		Uromonitor		
		Positive	Negative	N.F.
Total cohort	132			
Positive/Abnormal or Suspicious	49	44	1	4
Negative/Normal/No BC.	81	6	75	0
Not Performed	2	2	0	0
Total		52	76	4

Uromonitor Performance

Total Cohort	128*
Sensitivity % for Abn./Susp. Cyst.	98%
Specificity % in Norm./No BC Hist.	92,6%
Positive Predictive Value (PPV) %	88,5%
Negative Predictive Value (NPV) %	99%

* Four cases with Non Functional molecular analysis were excluded

COMBINED DATA

Uromonitor Correlation with TURBTs

TURBTs		Uromonitor	
		Positive	Negative
Total cohort	30	30	0
Ta	11	11	0
T1	7	7	0
Tis	2	2	0
T2	1	1	0
CIS	2	2	0
Atypia	1	1	0
Not known	2	2	0
T0	4	4	0
Low Grade	11	11	0
High Grade	8	8	0

Performance in Detecting TUR-Pathology-confirmed Tumor

Total Cohort	30
Sensitivity %	100%
Specificity %	100%
