

Initial Diagnosis of Bladder Cancer Using a Point-of-Care Assay

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and
the NMP22 Clinical Investigation Group

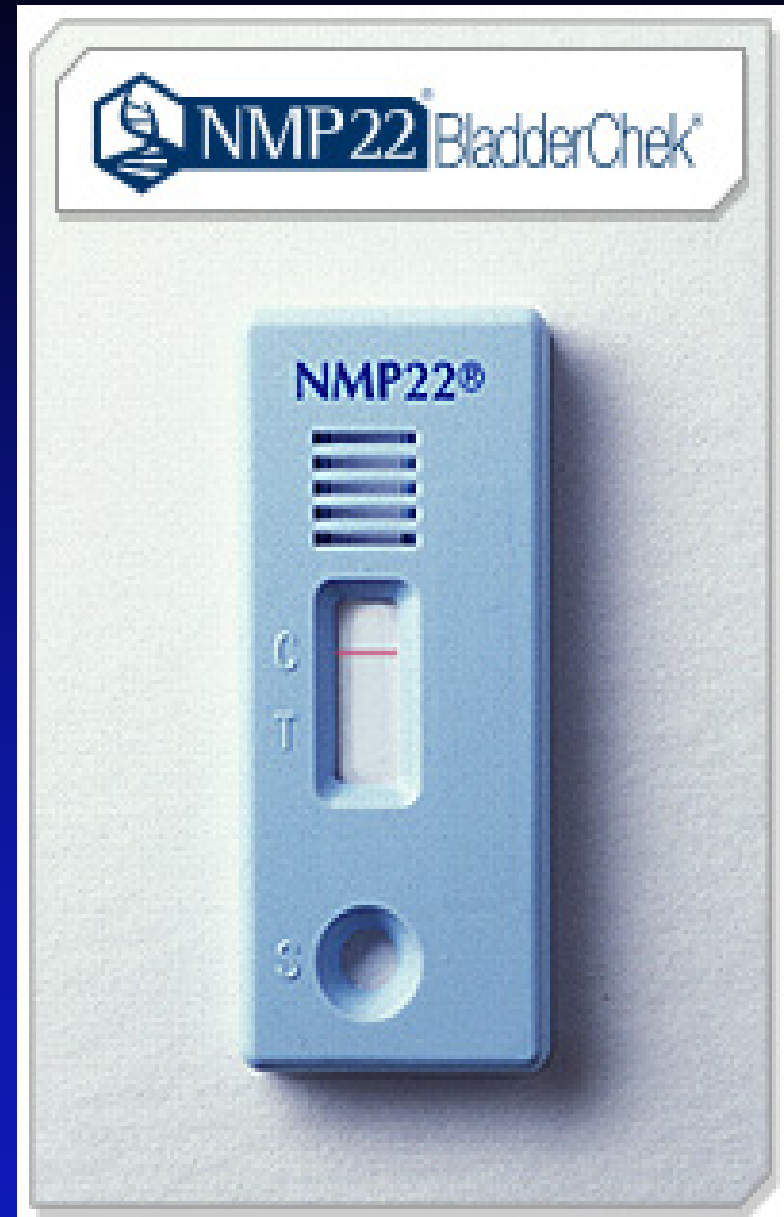
THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER

NMP22 Antigen

- **Nuclear matrix proteins (NMP) make up the structural framework of the nucleus and are important in gene expression**
- **Malignant urothelial cells contain up to 80 times higher concentration of NMP22 antigen than normal urothelial cells and release it upon cell death**
- **Unlike urine cytology, detection of NMP22 antigen in urine is not dependent on recovery of intact cells**
- **Based on previous studies, an NMP22 test result ≥ 10 U/ml in the urine is associated with a high probability of bladder cancer**

Created to identify urine with NMP22 antigen ≥ 10 U / mL

- Can be performed by non-physician staff members (CLIA waived)**
- Requires 4 drops of freshly voided urine**
- results available in 30 minutes**
- Built-in quality control**
- Positive result if NMP22 antigen level ≥ 10 U / mL**

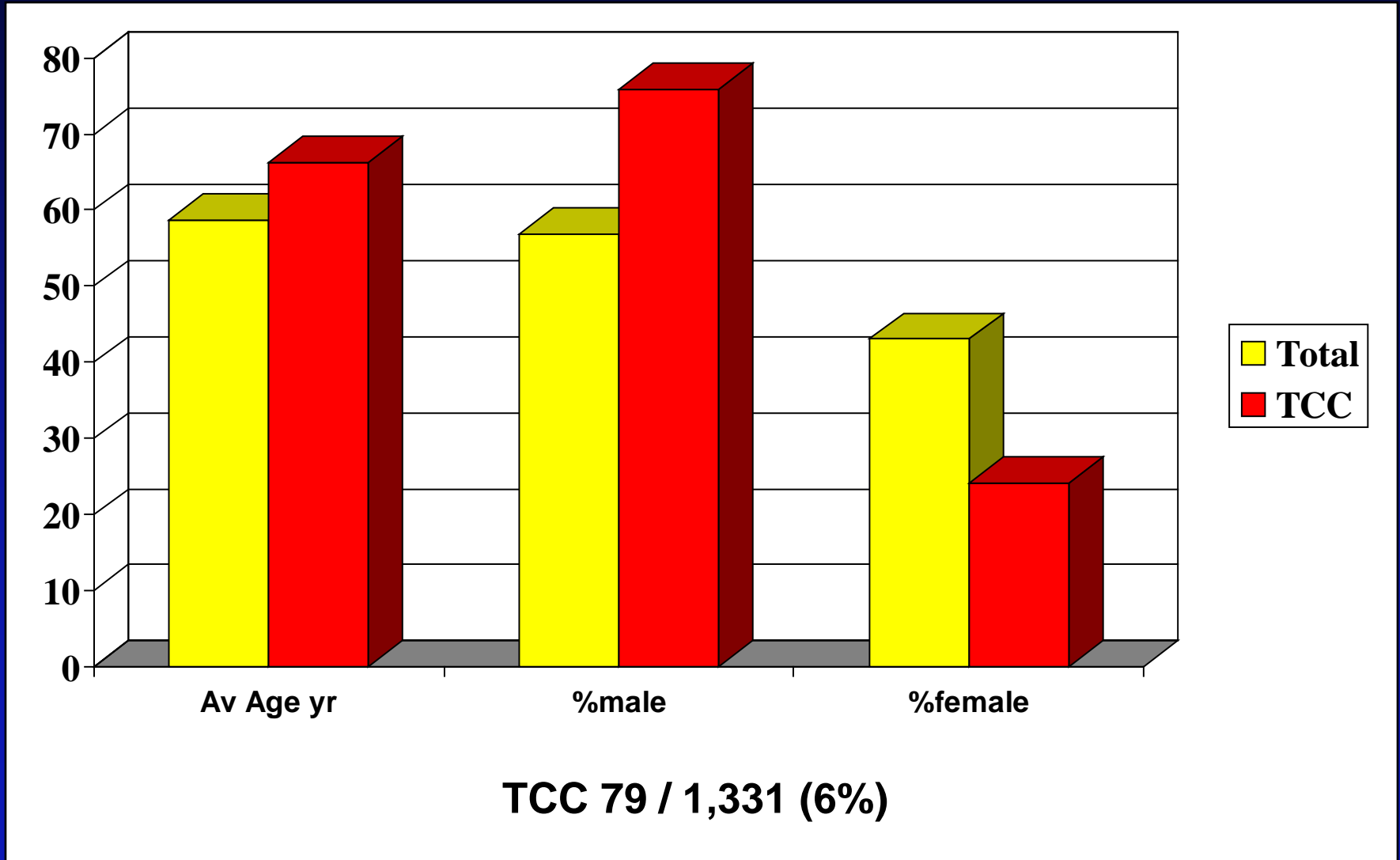


Study Design

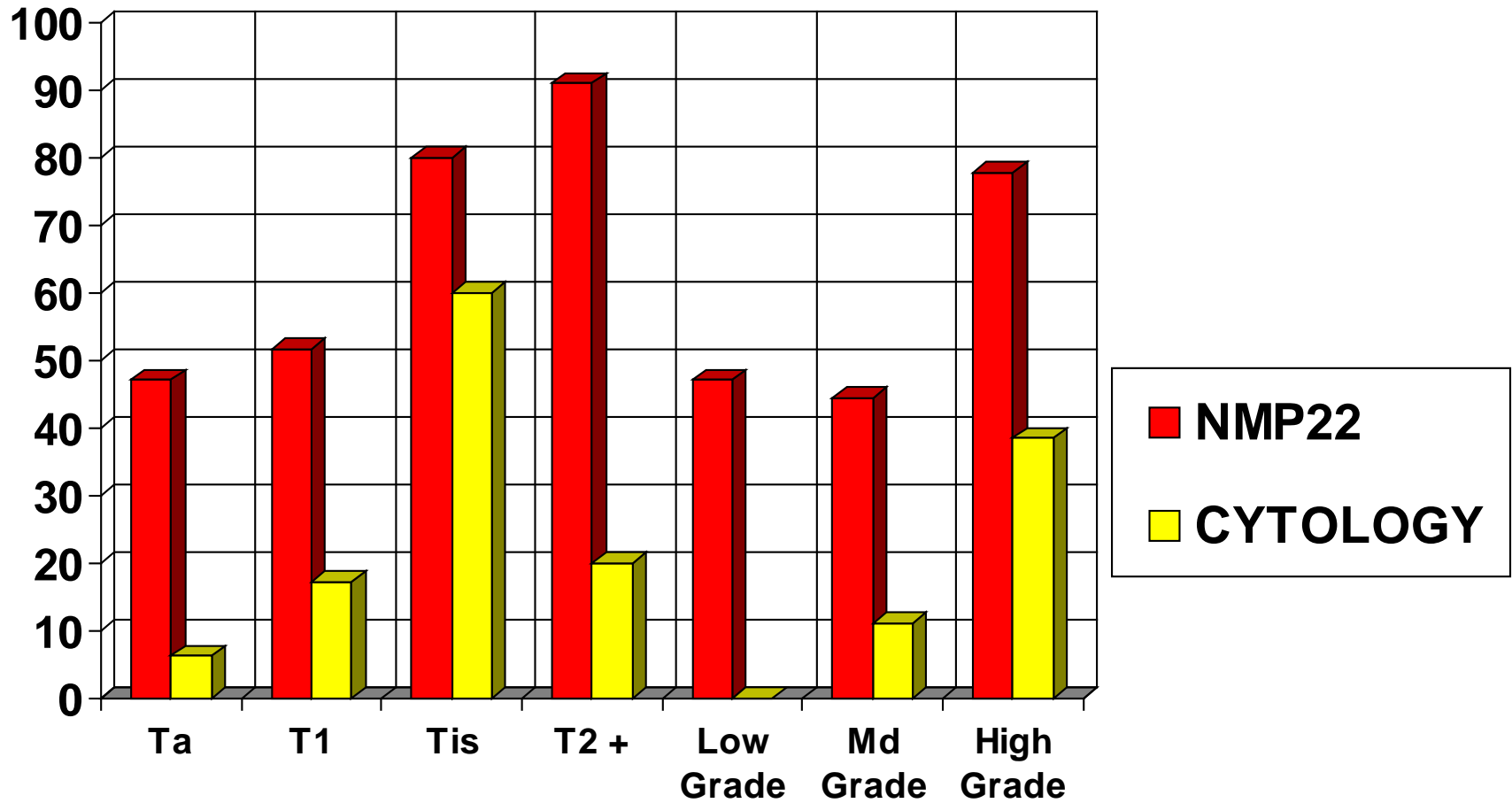
- **Prospective study: 23 facilities in 10 states; Academic, private practice and Veterans Hospitals**
- **September 2001 to May 2002: 1,331 patients scheduled for cystoscopy due to increased risk of bladder cancer such as hematuria, history of smoking, irritative voiding symptoms**
- **Voided urine sample for analysis of NMP22 antigen and cytology collected prior to diagnostic cystoscopy**
- **Cytology was performed per each site's standard protocol**
- **NMP22 test : 4 drops of voided urine added to the test cassette and result read 30-50 minutes later**
- **Urologists were blinded to NMP22 test and cytology results while performing and reporting the result of cystoscopy**
- **Further work-up on clinical findings and results of cystoscopy and cytology; TCC diagnosis based on pathology**

Demographics

Total Tested Population (1331) vs Patients with TCC (79)



Sensitivity for Detecting TCC



NMP22 Test = 57% Cytology = 16%

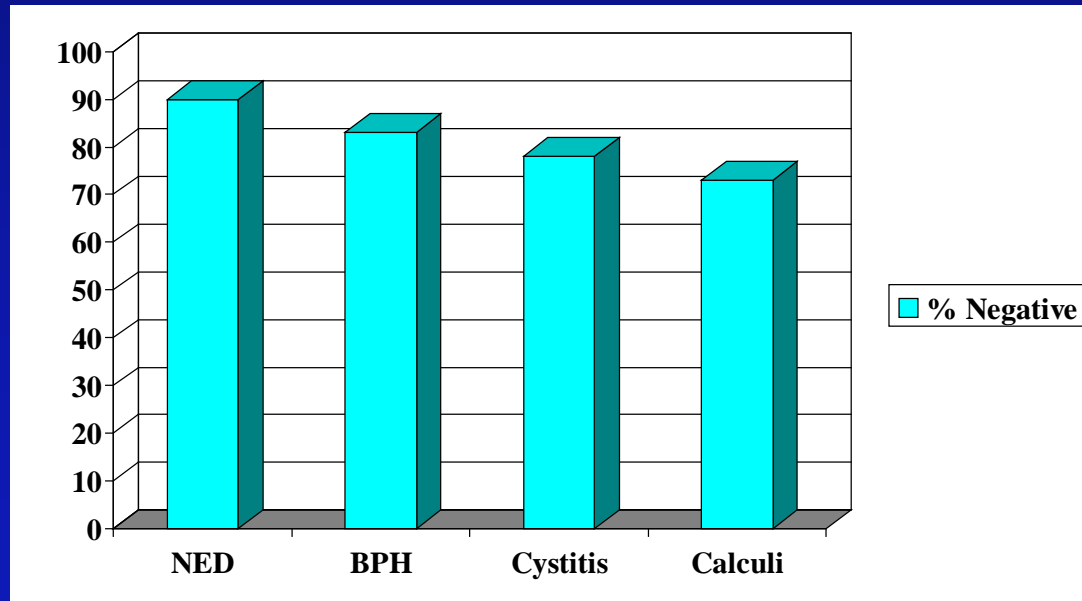
Improved Detection with NMP22 BladderChek Test and Cystoscopy

	Muscle Invasive	All Cancers	
Cystoscopy & NMP22 Test	91% (10/11)	94% (74/79)	} P=0.014
Cystoscopy alone	55% (6/11)	86% (68/79)	

**Cancers not seen by cystoscopy but detected by NMP22 Test:
Bladder CIS, T2, T3; Ureter T2; Renal Pelvis T1, T3**

Specificity

	No GU Disease	No Cancer
NMP22	90%	86%
Test	(512/567)	(1072/1249)
Cytology	99%	99%
	(544/547)	(1198/1208)



Conclusions

- **Cystoscopy combined with the NMP22 BladderChek Test detected significantly more urothelial cancers than cystoscopy alone ($P = 0.014$)**
- **NMP22 test detected 3 upper tract TCC missed by cytology**
- **NMP22 test is significantly more sensitive than cytology in detecting cancer ($P < 0.001$)**
- **Test can be performed by clinic staff in any doctor's office, results in 30 minutes, at half the cost of voided cytology**

Collaborating Investigators

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Study supported by Matritech, Inc.