

DiagnoCure ImmunoCyt™ uCyt+™

Last Updated Friday, 14 November 2008

{niftybox width=180px,float=right,textalign=left}Nov.7,2006

Between October 2000 and August 2005, 189 consecutive patients with newly diagnosed painless microhaematuria without prior transitional cell carcinoma were examined using cytology and ImmunoCyt/uCyt+™;

Bladder cancer was detected in 8 patients (4%)...Immunocytology was positive in 7 of 8 bladder tumours (87%) and negative in 154 of 170 patients with haematuria for other reasons (91%).

Conclusions

The high sensitivity and good specificity of immunocytology in the diagnosis of bladder cancer was confirmed in this population with a low disease prevalence. Only one tumour of low malignant potential was missed by immunocytology. If assessment of these patients would have been based only on immunocytology, 154 costly and invasive diagnostic procedures could have been avoided, with only 16 of 170 individuals (9%) undergoing these examinations unnecessarily. The findings justify a prospective investigation of this issue.

European Urology, december 2006; Medline: Immunocytology in the Assessment of Patients with Asymptomatic Microhaematuria Bernd J. Schmitz-Dräge, Birgit Beicheab, Lenuta-Ancuta Tirsara, Claudia Schmitz-Dräger, Ekkehardt Bismarcka, Thomas Eberta

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Bladder Cancer Monitoring Test

DiagnoCure's ImmunoCyt™, 510(k) cleared by the FDA, is indicated for use as an aid in the management of bladder cancer in conjunction with urinary cytology and cystoscopy as of February 2000.

ImmunoCyt™ Studies & Take Home Messages

Messing EM, Teot L, Korman H, Underhill E, Barker E, Stork B, Qian J, Bostwick DG, Performance of Urine Test in Patients Monitored for Recurrence of Bladder Cancer: A Multicenter Study in the United States, J Urol. 2005 Oct;174(4, Part 1 of 2):1238-1241.

Take home messages:

1. ImmunoCyt is a sensitive test for detecting bladder cancer. Because of its high sensitivity for detecting small tumors (smaller than 1 cm), even those of low histological grade, and its high negative predictive value, this test may have a role in decreasing the frequency of cystoscopic examination for patients with low risk bladder cancer.
2. The ability of ImmunoCyt to detect low grade, superficial, small tumors makes it the most suitable available marker to test for monitoring strategies for patients with low risk bladder cancer.

Mian C, Lodde M, Comploj E, Palermo S, Mian M, Maier K, Pycha A, The value of the ImmunoCyt/uCyt+ test in the detection and follow-up of carcinoma in situ of the urinary bladder, *Anticancer Res.* 2005 Sep-Oct;25(5):3641-4.

Take home message:

1. The sensitivities of other available markers are disappointing in the diagnosis of CIS.
2. The overall sensitivity of ImmunoCyt in the BCG-group was reported to be about 85%, which is much higher than that of cytology and in accordance with most reports in large series.
3. ImmunoCyt test could reflect the presence of cells expressing antigens a time when they cannot be correctly interpreted morphologically due to the therapy effect.
4. The presence of cells expressing the antigens after a weekly course of instillation with BCG could identify non-responders or a group of tumors which really benefit from longer cycles of instillation.
5. ImmunoCyt could play an important role in controlling the response of patients to instillation therapies or in modifying their application schedules.

Tetu B, Tiguert R, Harel F, Fradet Y, ImmunoCyt/uCyt+ trade mark improves the sensitivity of urine cytology in patients followed for urothelial carcinoma, *Modern Pathology* (2005) 18, 83–89.

Take home message:

1. If ImmunoCyt is positive, a cystoscopy should be performed and, if no tumor is seen, a tumor from the upper urinary tract should be suspected and ruled out.
2. A 95% NPV means that if ImmunoCyt is negative, patients undergoing a standard cystoscopy protocol for histories of bladder cancer are unlikely to have recurrent bladder tumor and that the next control cystoscopy may be postponed.
3. A 95% NPV means that, in young patients investigated for urinary symptoms, presence of a bladder tumor is unlikely

with a negative ImmunoCyt and cystoscopy might be omitted.

4. A positive ImmunoCyt with a negative cystoscopy predicted higher recurrence rate in the next few months.
5. The high sensitivity of ImmunoCyt may help pathologists and cytologists to save screening time, more specifically in cases with atypias suspicious for malignancy and in low-stage and low-grade tumors.
6. ImmunoCyt may improve the particularly low sensitivity of cytology at detecting upper urinary tract urothelial cell carcinoma.

Mian C, Lodde M, Comploj E, Palermo S, Mian M, Marziani F, Lusuardi L, Longhi E, Pycha A, The uCyt+ test: an update on 1991 analyses, EAU 2005.

Take home message:

1. The study confirms the clinical usefulness of ImmunoCyt in the detection and follow-up of UC patients.
2. The use of ImmunoCyt could reduce the morbidity and cost of follow-up patient with low-grade and low-recurrence rate tumors, avoiding superfluous cystoscopy.

Toma MI, Friedrich MG, Hautmann SH, Jakel KT, Erbersdobler A, Hellstern A, Huland H, Comparison of the ImmunoCyt test and urinary cytology with other urine tests in the detection and surveillance of bladder cancer, World J Urol. 2004 Jun;22(2):145-9. Epub 2004 Feb 27.

Take home message:

1. ImmunoCyt alone or in combination with cytology has a superior sensitivity to the BTA stat test, the NMP22 test, the 486p3/12 test, or the UroVysion test.
2. The specificity of ImmunoCyt was 73,8% and was therefore comparable to the specificity of other markers including BTA stat, NMP22, and immunocytology with 486p3/12.
3. ImmunoCyt in combination with conventional cytology may improve the surveillance of patients with a history of bladder carcinoma.

Mian C, Lodde M, Comploj E, Negri G, Egarter-Vigl E, Lusuardi L, Palermo S, Marberger M, Pycha A, Liquid-based cytology as a tool for the performance of uCyt+ and Urovysion Multicolour-FISH in the detection of urothelial carcinoma, Cytopathology. 2003 Dec;14(6):338-42.

Take home message:

1. Using liquid-based urinary specimens further diagnostic and prognostic analyses such as ImmunoCyt may be performed on the residual material.
2. ImmunoCyt could be an adequate procedure for the screening of patients at risk for urothelial carcinomas and the surveillance of patients under follow-up, avoiding superfluous cystoscopies.

Piaton E, Daniel L, Verrielle V, Dalifard I, Zimmermann U, Renaudin K, Gobet F, Caratero A, Desvaux D, Pouille Y, Seigneurin D, Improved detection of urothelial carcinomas with fluorescence immunocytochemistry (uCyt+ assay) and urinary cytology: results of a French Prospective Multicenter Study, *Lab Invest.* 2003 Jun;83(6):845-52.

Take home message:

1. This multicenter prospective study demonstrate that ImmunoCyt increases the diagnostic value of urine samples and that better results are obtained by combining the results of ImmunoCyt and cytology; in all the centers that participated in the study (10 departments of urology, 9 departments of pathology)
2. A positive ImmunoCyt has a strong predictive value for tumor recurrence at 1 year (47% vs. 11,9% in the control group).
3. In comparison with other assays that show insufficient sensitivity, lack specificity for cancer, or demonstrate serious technical constraints, fluorescence immunocyto-chemistry using the ImmunoCyt assay appears as the most promising test.
4. The ImmunoCyt technique is easy to perform and observer subjectivity is reduced.
5. ImmunoCyt data can simply be expressed as positive or negative for tumor cells.

Pfister C, Chautard D, Devonec M, Perrin P, Chopin D, Rischmann P, Bouchot O, Beurton D, Coulange C, Rambeaud JJ, Immunocyt test improves the diagnostic accuracy of urinary cytology: results of a French multicenter study, *J Urol.* 2003 Mar;169(3):921-4.

Take home message:

1. This prospective multicenter study confirms that observer subjectivity is reduced and that fluorescence interpretation can easily be surmounted by training and systematic comparison with controls.
2. The combination of urinary cytology and ImmunoCyt could significantly reduce inter-laboratory variability of bladder cancer detection.
3. The diagnostic performance of noninvasive assays combining urinary cytology and ImmunoCyt suggest that it may replace cystoscopy in select patients, especially in follow-up protocols of low-grade TCC.
4. Sensitivity and specificity of ImmunoCyt are sufficient to be cost saving per patient within 3 years of follow-up.
5. Noninvasive methods that could replace time-consuming and tedious cystoscopy follow-up, which sometimes induce nosocomial infections, would be useful in routine urology practice.

Lodde M, Mian C, Negri G, Berner L, Maffei N, Lusuardi L, Palermo S, Marberger M, Brossner C, Pycha A, Role of uCyt+ in the detection and surveillance of urothelial carcinoma, *Urology.* 2003 Jan;61(1):243-7.

Take home message:

1. The use of ImmunoCyt could reduce the morbidity and cost of follow-up patient with low-grade and low-recurrence rate tumors, avoiding superfluous cystoscopy.
2. The use of ImmunoCyt would improve the detection of patients with suspicion of upper tract UC.
3. The use of ImmunoCyt would be justified in patients with an unknown primary and those who want to undergo screening.

Olsson H, Zackrisson B., ImmunoCyt a useful method in the follow-up protocol for patients with urinary bladder carcinoma, Scand J Urol Nephrol. 2001 Sep;35(4):280-2.

Take home message:

1. Compared with other urine-bound tests, ImmunoCyt has a higher overall sensitivity.
2. BTA stat and NMP22 can detect low-grade tumors more efficiently than conventional urinary cytology, but it is uncertain whether they can replace cystoscopy. ImmunoCytTM has a higher sensitivity and it is possibly reliable enough to replace some cystoscopies.
3. It is possible to perform the test in a relatively small laboratory and still obtain good results.
4. Compared with other test (especially BTA stat), ImmunoCyt is fairly time consuming, but it is possible to obtain a result on the same day the urine sample reaches the laboratory.

Mian C, Pycha A, Wiener H, Haitel A, Lodde M, Marberger M., Immunocyt: a new tool for detecting transitional cell cancer of the urinary tract, J. Urol. 1999 May;161(5):1486-9. / Lodde M, Mian C, Pycha A, Wiener H, Haitel A, Marberger M, Immunocyt: a new tool for detecting transitional cell cancer of the urinary tract, AUA 1999.

Take home message:

1. ImmunoCyt is a non-invasive highly sensitive test in detecting TCC of all grades and stages and with a 100% sensitivity for pTis.
2. In combination with conventional urinary cytology ImmunoCyt may replace cystoscopy in low-grade (G1) low stage (Ta) TCC.
3. ImmunoCyt seems to play an important role for the detection of upper urinary tract TCC.
4. TCC follow-up patients with a false positive ImmunoCyt test have a recurrence within 3-6 months in 36% of the cases.

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