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ORIGINAL ARTICLE

Predicting results of daily-practice cystoscopies☆

F. García-Velandria[a], J.F. Sánchez-García[a], L.A. Rodríguez-Toves[a], L. Alvarez-Buitrago[a], C. Conde-Redondo[a], V. Rodríguez-Tesedo[a], J.H. Amón-Sesmero[a], M. Cepeda-Delgado[a], A. Cobos-Carbó[b,*], D. Alonso-Fernández[a], J.M. Martínez-Sagarra[a]

[a] *Servicio de Urología, Hospital Universitario Río Hortega, Valladolid, Spain*
[b] *Unidad de Bioestadística, Departamento de Salud Pública, Universidad de Barcelona y Saalig Clinical, SL, Barcelona, Spain*

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Abstract

Objective: Our objective was to elaborate a predictive model of bladder cancer, in an unselected clinical population submitted to cystoscopy.

Materials and methods: We recruited consecutive patients who underwent cystoscopy due to suspicion of bladder cancer or surveillance of a previously diagnosed bladder cancer. Urine cytology and a BTA-stat® (BTA) test were carried out for all patients. To avoid an assessment bias, the BTA-tests, cytologies and cystoscopies were conducted in a blinded fashion. We used logistic regression to predict cystoscopy results from cytology, BTA-test and clinical variables.

Results: From August 2011 to July 2012, we recruited 244 patients and 237 were valid for analysis. Newly diagnosed and surveillance cases were 13% and 87% respectively. Cytology and BTA-test sensitivities were 57.9% (CI 95: 42.2–72.1) and 63.2% (CI 95: 47.3–76.6) with specificities of 84.4% (CI 95: 78.7–88.8) and 82.9% (CI 95: 77.1–87.5). The predictive model included the BTA-test, cytology, time since previous tumor, and treatment with mitomicin or BGC during the last three months. The model predictive accuracy (AUC) was 0.85 (0.78–0.92), and dropped to 0.79 when excluding the BTA-test ($p = 0.026$). For the surveillance of bladder cancer, a 10% threshold on the model predicted probabilities resulted in an overall negative predictive value of 95.7%, and 95.0% in low grade tumors.

Conclusion: In a cost containment environment, our prediction model could be used to space out cystoscopies in patients with previous, low grade tumors, resulting in a more efficient use of resources in the healthcare system.

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* Corresponding author.
E-mail address: acobos@ub.edu (A. Cobos-Carbó).

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PALABRAS CLAVE
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Cáncer de vejiga urinaria;
Marcadores tumorales

Predicción de resultados de cistoscopias en la práctica

Resumen

Objetivo: Elaborar un modelo predictivo de cáncer de vejiga en una población clínica no seleccionada derivada a cistoscopia.

Materiales y métodos: Pacientes consecutivos sometidos a cistoscopia debida a sospecha o seguimiento de un cáncer de vejiga previamente diagnosticado. Todos los pacientes fueron sometidos a citología urinaria y un BTA-stat®-test (BTA). Para evitar sesgos de evaluación, BTA, citologías y cistoscopias fueron realizados de forma ciega. Usamos regresión logística para predecir los resultados de la cistoscopia a partir de citología, BTA y variables clínicas.

Resultados: Entre agosto de 2011 y julio de 2012 seleccionamos 244 pacientes y 237 fueron válidos para el análisis. Un 13% fueron de nuevo diagnóstico y un 87% de seguimiento. Las sensibilidades de la citología y el BTA fueron 57,9% (IC 95%: 42,2–72,1) y 63,2% (IC 95%: 47,3–76,6) con especificidades de 84,4% (IC 95%: 78,7– 88,8) y 82,9% (IC 95%: 77,1–87,5). El modelo predictivo incluyó BTA, citología, tiempo transcurrido desde el diagnóstico del tumor previo y tratamiento con mitomicina o BGC en los últimos 3 meses. La precisión del modelo (AUC) fue 0,85 (0,78–0,92), y bajó a 0,79 al excluir el BTA (p = 0,026). En los casos de seguimiento, un umbral de 10% en las probabilidades predichas por el modelo resultó en un valor predictivo negativo de 95,7%, y 95,0% en los tumores de bajo grado.

Conclusión: En un contexto de contención de costes nuestro modelo puede usarse para espaciar las cistoscopias en pacientes con tumores de bajo grado previos, resultando en un uso más eficiente de recursos del sistema de salud.

Introduction

Bladder cancer is the most common malignancy of the urinary tract, with global age-standardized rates of 10.1 and 2.5 per 100,000 people/year (PY) for men and women respectively.[1] In Spain, the incidence of bladder cancer is 41.5 per 100,000 PY, with a mortality rate of 6.9 per 100,000 PY,[2] one of the highest figures in the European Union.

When bladder cancer is suspected, the initial assessment consists of urine cytology, cystoscopy, and a radiological study of the upper tract. Although at present urine cytology is the non-invasive test of choice, it has low sensitivity, especially in the case of low-grade tumors.[3] Many urine tests for the diagnosis of bladder cancer have been developed. Although different studies have shown the superiority of urine markers regarding sensitivity for bladder cancer detection as compared with cytology, several authors consider that none of these tests are ideal,[4] and that they are insufficient for effective monitoring and management of the patient.[5] In fact, current guidelines state that ''urinary cytology or markers cannot safely replace cystoscopy in the monitoring of non-muscle-invasive bladder cancer''.[1] However, other authors have suggested that urine tests may play a role in the monitoring of bladder cancer, replacing routine cytology in patients with low-grade/stage tumors[6] or extending the period between cystoscopies in the monitoring of patients with transitional cell carcinoma,[7,8] and facilitating the early detection of tumor recurrence in patients with high-grade tumors.[8]

The BTA stat test® (BTA) is a rapid, single-step immunochromatographic test for the detection of the antigen associated with bladder tumors in the urine,[4] which has significantly showed more sensitivity, and similar specificity when compared to cytology.[6] It is a test that is done in medical centers, with the characteristics of what an ideal test is considered: objectivity, accuracy, speed, and it is easily administered.[7] A study comparing 7 urine tests for bladder cancer in terms of validity (sensitivity and specificity), reliability (reproducibility), and efficiency (predictive value, complexity and costs) concluded that the most convenient (individual) assessment method was the BTA stat test®.[9]

Few attempts to develop a predictive model of bladder cancer have been made,[10,11] but none of them provided an appropriate model for routine clinical practice, since they were limited to selected patients or used a ''convenience'' sample. The aim of our study was to explore the possibility of developing such a predictive model of bladder cancer in an unselected and natural clinical population.

Patients and methods

We selected for our study all the consecutive patients who had undergone cystoscopy at our urology service throughout a year, either due to suspicion of bladder cancer or surveillance of previously diagnosed bladder cancer. The monitoring of previous tumors was carried out in accordance with the program recommended by the European guidelines.[1] Such guidelines were also followed to establish the indication for adjuvant treatment with MMC or BCG. Cytoscopies were always performed by the same team of experts in urology. Urine cytology and the BTA test were performed in all patients on the 7 days prior to cystoscopy. Urine samples for cytology (the second urine void in the morning) were taken on 3 consecutive days and cytology was always performed by the same team of general pathologists; the outcome was considered positive if malignant or atypical