

## Bladder Cancer in Spain 2011: Population Based Study

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**Purpose:** We estimate the annual incidence of bladder cancer in Spain and describe the clinical profile of patients with bladder cancer enrolled in a population based study.

**Materials and Methods:** Using the structure of the Spanish National Health System as a basis, in 2011 the AEU (Spanish Association of Urology) conducted this study with a representative sample from 26 public hospitals and a reference population of 10,146,534 inhabitants, comprising 21.5% of the Spanish population.

**Results:** A total of 4,285 episodes of bladder cancer were diagnosed, of which 2,476 (57.8%) were new cases and 1,809 (42.2%) were cases of recurrence, representing an estimated 11,539 new diagnoses annually in Spain. The incidence of bladder cancer in Spain, age adjusted to the standard European population, was 20.08 cases per 100,000 inhabitants (95% CI 13.9, 26.3). Of patients diagnosed with a first episode of bladder cancer 84.3% were male, generally older than 59 years (81.7%) with a mean  $\pm$  SD age of  $70.5 \pm 11.4$  years. Of these patients 87.5% presented with some type of clinical symptom, with macroscopic hematuria (90.8%) being the most commonly detected. The majority of primary tumors were nonmuscle invasive (76.7%) but included a high proportion of high grade tumors (43.7%). According to the ISUP (International Society of Urologic Pathology)/WHO (2004) classification 51.1% was papillary high grade carcinoma. Carcinoma in situ was found in 2.2% of primary and 5.8% of recurrent cases.

**Conclusions:** The incidence of bladder cancer in Spain, age adjusted to the standard European population, confirms that Spain has one of the highest incidences in Europe. Most primary nonmuscle invasive bladder cancer corresponded to high risk patients but with a low detected incidence of carcinoma in situ.

### Abbreviations and Acronyms

BC = bladder cancer  
BCG = bacillus Calmette-Guérin  
BMI = body mass index  
CIS = carcinoma in situ  
MMC = mitomycin C  
NMIBC = nonmuscle invasive bladder cancer  
TURBT = transurethral bladder tumor resection

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**Key Words:** incidence, urinary bladder neoplasms, neoplasm staging, Spain

BLADDER cancer is the most common cancer to affect the urinary tract and is one of the most prevalent oncologic diseases in the United States and

Europe, where it represents 4.4% of all new cancer diagnoses (not including nonmelanoma skin cancer).<sup>1,2</sup> The age standardized rate in the European

population is 26.9 cases per 100,000 inhabitants in men and 5.1 per 100,000 in women.<sup>3</sup>

In Spain bladder cancer is the fifth most common tumor type (the fourth most common among men), and represents 6.4% of new cancer diagnoses in men and women.<sup>3</sup> More than two-thirds of newly diagnosed BC involves low grade nonmuscle invasive papillary tumors, which recur in up to 75% of patients. However, less than 10% of these tumors progress to muscle invasive bladder cancer.<sup>4,5</sup> The remaining third are aggressive high grade tumors that significantly affect patients, especially when infiltration of the detrusor muscle is involved.<sup>6</sup>

Data from current cancer registries, which include a small portion of the Spanish population, place Spain among the countries with the highest incidence of BC in Europe.<sup>7</sup> Determining the true incidence and clinical and pathological characteristics of patients diagnosed with bladder cancer is important not only for planning the costly disease related care, but also for assigning priorities for research to improve disease prevention, diagnosis and treatment.

The Spanish National Health System organizes health care around specific health regions with reference populations assigned to specific hospitals. On the basis of that organizational structure and with the knowledge that private health care accounts for less than 20% of medical care in Spain,<sup>8</sup> in 2011 the AEU registered all cases of BC at selected hospitals in a population based registry for the purposes of estimating incidence and determining the clinical profile of diagnosed patients. In this report we present the results of this project.

## PATIENTS AND METHODS

This study was approved by the independent ethics committee of Hospital Virgen de las Nieves (Granada). All patients included in the study were of legal age and signed the obligatory informed consent form. The population based study included the participation of 26 urology departments from hospitals in different regions selected in proportion to the population in each of Spain's autonomous regions to ensure a representative sample.

The population assigned to the participating urology departments totaled 10,146,534 inhabitants, corresponding to 21.5% of the Spanish population according to 2011 data from the INE (Spanish National Statistics Institute).<sup>9</sup> Each site registered all patients diagnosed between January 1 and December 31, 2011 with primary or recurrent BC for whom histopathological confirmation was available.

Data were collected on a special electronic form and included sociodemographic data (gender, age, ethnic background, place of residence), clinical data (weight, height, smoking status, comorbidities, bladder cancer history, symptoms), diagnostic tests, endoscopic results (number of tumors, size, location and appearance of

largest lesion, and appearance of adjacent mucosa), histopathological data (date diagnosed, UICC/TNM and ISUP/WHO 2004 classifications, grade, associated carcinoma in situ) and treatment.

The data entered and pathology reports were reviewed by an external team trained to ensure the quality of the information. Statistical analysis was performed using SPSS® version 17.0. Data from patients residing outside the basic area of reference defined for the individual site were not included in the analysis.

The annual crude incidence rate was calculated as the number of cases of BC in 2011 at all participating sites compared to the total aggregate population assigned to them. The crude rates by age and gender were obtained by weighting the resulting assigned population by the age and gender distribution of Spain's population given in the INE 2011 census.<sup>9</sup> Age and gender standardization were performed using the direct method, taking the standard European population as reference.<sup>10</sup> The overall incidence rate was estimated with its corresponding 95% CI. Lastly the results were compared with the most recent EUCAN estimates.<sup>7</sup>

## RESULTS

A total of 4,285 episodes of BC were diagnosed in 2011 at the 26 study sites, of which 2,476 (57.8%) were new cases and 1,809 (42.2%) were cases of recurrence. The crude incidence rate of newly diagnosed patients with BC was 24.4 per 100,000 inhabitants (95% CI 23.4, 25.4), with 41.83 and 7.53 cases per 100,000 inhabitants for men and women, respectively. This indicates an incidence rate in Spain, age adjusted to the standard European population, of 20.08 cases per 100,000 inhabitants (95% CI 13.9, 26.3), representing 11,539 new cases of BC diagnosed annually, and incidence rates for men and women of 32.71 (95% CI 21.5, 43.9) and 6.23 (95% CI 1.3, 11.1) cases per 100,000 inhabitants, respectively (9,739 new cases of BC diagnosed annually in men and 1,801 in women).

The crude incidence rate of recurrent cases was 17.8 episodes per 100,000 inhabitants (95% CI 17.0, 18.7), with 30.91 episodes for men and 5.09 for women per 100,000 inhabitants. This corresponded to a recurrence rate in Spain, age adjusted to the standard European population, of 14.36 per 100,000 inhabitants (95% CI 9.1, 19.6), with 23.41 (95% CI 13.9, 32.9) for men and 4.18 (95% CI 0.2, 8.2) for women, representing 8,414 episodes of recurrent BC diagnosed annually (7,196 and 1,218 in men and women, respectively). Table 1 shows these figures and SEER (Surveillance, Epidemiology and End Results) Program data.<sup>11</sup>

The majority of new diagnoses of BC were in men (84.3%) with a mean age of  $70.5 \pm 11.4$  years (range 21 to 98). Patients older than 59 years comprised 81.7% of the total sample. Grade 1 obesity according to WHO classification was found in 20.1% of

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