# Prognostic Features for Objectively Defined Urinary Continence after Radical Cystectomy and Ileal Orthotopic Neobladder in a Contemporary Cohort



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From the Department of Urology, Ludwig-Maximilians-University (AKr, TG, AB, JG, MG, FJ, BSS, MA, GS, RMB, CGS, AKa) Munich, Germany, and Department of Urological Sciences, University of British Columbia (AKr), Vancouver, British Columbia, Canada

## Abbreviations and Acronyms

CHD = coronary heart disease

ONB = orthotopic ileal neobladder

RC = radical cystectomy

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The corresponding author certifies that, when applicable, a statement(s) has been included in the manuscript documenting institutional review board, ethics committee or ethical review board study approval; principles of Helsinki Declaration were followed in lieu of formal ethics committee approval; institutional animal care and use committee approval; all human subjects provided written informed consent with guarantees of confidentiality; IRB approved protocol number; animal approved project number.

\* Correspondence: Department of Urology, Ludwig-Maximilians-University, Marchioninistrasse 15, 81377 Munich, Germany (telephone: +4989-4400-0; FAX: +49894400-75444; e-mail: alexander.kretschmer@med.uni-muenchen.de). **Purpose:** We objectively quantified daytime and nocturnal continence rates, and defined predictive features for favorable continence outcomes after radical cystectomy and orthotopic ileal neobladder creation.

Materials and Methods: At 1 institution 1,012 cystectomies were performed between 2004 and 2015. Questionnaires evaluating the continence status were sent to 244 patients. To objectify postoperative urine loss daytime and nocturnal pad tests were performed. Continence was defined as the need for up to 1 safety pad and urine loss 10 gm or less per test. Predefined associative features were tested for an influence on continence outcomes. Statistical analysis was done with the Fisher exact and Mann-Whitney U tests, and linear logistic regression models. Significance was considered at p <0.05.

**Results:** A total of 188 patients (77.0%) returned the questionnaires. Median followup was 61 months. Median daytime pad use was 1 pad per day (range 0 to 9). Median daily urine loss based on standardized pad testing was 8 gm (range 0 to 2,400). During the night a median of 1 pad (range 0 to 7) was used and median nocturnal urine loss was 28.5 gm (range 0 to 1,220). The continence rate was 54.3% during the day and 36.3% at night. On multivariate analysis good preoperative ECOG (Eastern Cooperative Oncology Group) status (OR 2.987, p = 0.010), retained sensation of bladder filling (OR 6.462, p = 0.003) and preoperative coronary heart disease (OR 0.036, p = 0.002) were independent predictors of daytime success. Based on preoperative risk factors a simple predictive score for daytime continence was created (AUC 0.725, p <0.001).

**Conclusions:** Continence rates after orthotopic ileal neobladder creation are lower than previously described when objective continence definitions are applied. Patients with good performance status, without coronary heart disease and with retained sensation of orthotopic ileal neobladder filling have better daytime continence outcomes.

**Key Words:** urinary bladder neoplasms, urinary diversion, cystectomy, urinary incontinence, coronary disease

Based on current guidelines, neoadjuvant chemotherapy followed by RC extended pelvic lymphadenectomy and urinary diversion using an ileal conduit or ONB is the gold standard therapeutic approach for muscle

<sup>†</sup> Equal study contribution.

invasive bladder cancer. However, RC significantly impacts patient well-being even if innovative concepts are applied. <sup>2</sup>

Among other complications, stress urinary incontinence is a frequent postoperative complication after ONB and it has a devastating impact on patient quality of life.<sup>3–6</sup> According to current literature postoperative daytime continence rates are postulated to vary between 87% and 95.9% whereas nocturnal continence rates range between 72% and 95%.<sup>3</sup> Comparing the current literature is still difficult since definitions of continence vary among large contemporary studies and the results of these studies are based on subjective patient reports of pad use.<sup>7–10</sup>

In our cross-sectional study we present objective functional results after ONB using the well established pad testing method recommended by current urinary incontinence guidelines. <sup>11</sup> In addition to our objectified functional results, we provide an analysis of predictive features for urinary continence after ONB. Based on these results, we created a score to facilitate clinical decision making.

#### **MATERIALS AND METHODS**

#### **Patient Population and Standard Procedures**

At a tertiary care center 1,012 RCs were performed between April 2004 and January 2015. In the same period 360 patients underwent RC due to bladder cancer and consecutive urinary diversion with an ONB. RC was performed as described by Hautmann et al. A nerve sparing procedure was done when optimal resection was not compromised. Postoperative implantation of an activated or nonactivated artificial urinary sphincter was a study exclusion criterion.

### Study Design and Data Assessment

Of 360 patients 116 identified as deceased based on institutional records were excluded from further analysis. After receiving approval from an institutional review board questionnaires were sent to 244 patients by physicians who were not part of the team that performed cystectomy. Daily and nocturnal pad use, and background information about previous conservative incontinence treatments were assessed and medical records were analyzed.

Patients were provided with a detailed description of how to perform a home pad test. This description is well established at our institution and it has been used previously. Patients were asked to perform a separate nocturnal pad test to differentiate between daytime and nocturnal incontinence. Patients were instructed to not use any assistive device during the standardized pad test.

To assess bladder capacity patients were instructed to allow the bladder to fill to capacity and then measure voided volume.

Continence was defined as the need for no pad or 1 safety pad and urine loss 10 gm or less per test. Based on

this objective definition, daytime and nocturnal success rates were determined. Total continence was defined as 0 pad and 0 gm urine loss per pad test. Patients who performed clean intermittent self-catheterization and patients who started to experience subjectively impaired voiding were defined as hypercontinent and not considered successful.

Surgeons were divided into subgroups based on the number of previously performed cystectomies, including experienced—more than 100, moderately experienced—50 to 100 and less experienced—fewer than 50.

#### **Statistical Analysis**

For categorical data the Fisher exact and chi-square tests were used. For continuous data the Mann-Whitney U test was applied. In addition, the Spearman rank correlation was used. We performed multivariate analysis using a multiple logistic regression model with the end point of continence success. Following multivariable analysis independent preoperative risk factors were used to create a simple prognostic model as previously described. Using this model the regression coefficient of each parameter was divided by the coefficient of the parameter with the highest regression coefficient, multiplied by 2 and rounded to the nearest integer. All statistical analyses were created using SPSS®, version 23.0 with p <0.05 considered statistically significant.

#### **RESULTS**

## Preoperative and Perioperative Patient Characteristics

In the institutional cystectomy cohort ONB was generally offered to significantly fewer women (14.3% vs 36.2%, p <0.001), significantly younger patients (age 64.7 vs 70.2 years, p <0.001) and patients with better preoperative ECOG performance status (ECOG 0 in 57.0% vs 43.6%, p <0.001) compared to patients who were offered incontinent urinary diversion.

Of 244 patients 188 (77.0%) returned the guestionnaires and underwent further analysis of the functional outcome. None of them underwent implantation of an artificial urinary sphincter in the meantime. Median followup, defined as the period between ONB and the time that the questionnaires were sent, was 61 months (range 9 to 136). Median patient age was 66 years (range 44 to 83). Supplementary table 1 (http://jurology.com/) lists patient characteristics. Analysis of intraoperative characteristics revealed a median operative time of 223 minutes (range 134 to 468). Of 188 analyzed procedures 136 (72.3%) were performed by experienced surgeons. A nerve sparing procedure was performed in 98 cases (52.1%). All recorded congestive heart failures were classified as NYHA (New York Heart Association) II.

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