Impact of Complete Bladder Neck Preservation on Urinary Continence, Quality of Life and Surgical Margins After Radical Prostatectomy: A Randomized, Controlled, Single Blind Trial

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Purpose: We investigated the influence of bladder neck preservation on urinary continence, quality of life and surgical margins after radical prostatectomy.

Materials and Methods: A total of 208 men who presented for radical prostatectomy were randomized to complete bladder neck preservation with subsequent urethro-urethral anastomosis or to no preservation as controls. Patients with failed bladder neck preservation were not included in study. We documented objective continence by the 24-hour pad test, social continence by the number of pads per day and quality of life outcomes by the validated Incontinence Quality of Life questionnaire in a single blind setting. Cancer resection was assessed by surgical margin status.

Results: At 0, 3, 6 and 12 months mean urine loss in the control vs the bladder neck preservation group was 713.3 vs 237.0, 49.6 vs 15.6, 44.4 vs 5.5 and 25.4 vs 3.1 gm, respectively (each $p < 0.001$). At 3, 6 and 12 months in the control vs the preservation group the social continence rate was 55.3% vs 84.2% ($p < 0.001$), 74.8% vs 89.5% ($p = 0.05$) and 81.4% vs 94.7% ($p = 0.027$), and the quality of life score was 80.4 vs 90.3 ($p < 0.001$), 85.4 vs 91.7 ($p = 0.016$) and 86.0 vs 93.8 ($p = 0.001$), respectively. We noted significantly less urine loss, higher objective and social continence rates, and higher quality of life scores after complete bladder neck preservation at all followup points. On multiple logistic regression analysis complete bladder neck preservation was an independent positive predictor of continence. No significant difference was found in surgical margin status between the control and bladder neck preservation groups (12.5% vs 14.7%, $p = 0.65$).

Conclusions: In what is to our knowledge the first prospective, randomized, controlled, single blind trial complete bladder neck preservation during radical prostatectomy was associated with a significantly higher urinary continence rate and increased patient satisfaction without compromising resection margins.

Key Words: prostate, urinary bladder, prostatectomy, urinary incontinence, quality of life

Abbreviations and Acronyms

BNP = bladder neck preservation
CaP = prostate cancer
cBNP = complete BNP
I-QOL = Incontinence QOL
ITT = intent to treat
PSA = prostate specific antigen
QOL = quality of life
RALP = robot assisted laparoscopic RP
RP = radical prostatectomy
SM = surgical margin

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DUE to increasing public awareness and PSA testing, the detection of localized CaP has increased even in healthy younger men.[1–4] RP remains a major treatment option.[1–3] Since the primary goal of cancer control can be achieved in most cases, attention is shifting toward additional improvement in functional outcomes, such as urinary continence and QOL.[5–7] In fact, the latter is

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increasingly considered to be as important as optimal cancer control.[5–7]

The significance of the bladder neck for urinary continence even in the absence of normal rhabdosphincter activity was revealed in a study of trauma cases.[8] This led to the postulation that BNP during RP may improve urinary continence. With this perception, bladder neck reconstruction and subsequently bladder neck sparing techniques during RP were developed and analyzed.[9–13] Most published studies of this subject were nonrandomized with a single arm, had small cohorts and/or were performed retrospectively.[9–13] In some studies evaluation was based on the intraoperative surgeon decision for or against BNP rather than on reliable preoperative randomization.[11–13] In regard to QOL outcomes, we found only 1 single arm trial that analyzed patient satisfaction postoperatively in a small cohort after BNP RP.[10] Few groups have investigated the influence of BNP on SM status.[10,12,14,15] Therefore, we evaluated the impact of cBNP on urinary continence, QOL outcomes and SM status in a prospective, randomized, controlled, single blind setting.

METHODS

We recruited patients after receiving approval from the local institutional review board. Sample size was calculated for a 5% type I error and 80% study power. Men diagnosed with CaP by routine core biopsies who presented for RP to our institution were potential subjects for study. Those with a history of incontinence or transurethral prostate resection were excluded from analysis. The 208 men who provided informed, formal written consent were preoperatively randomized to cBNP or no BNP. They remained blinded to randomization and treatment during followup.

RP was performed by 4 experienced surgeons. Surgical technique differed only at the bladder neck. During RALP, the vas and seminal vesicles were dissected in retrovesical fashion. The plane between the prostate base and posterior bladder neck was developed. The bladder neck and proximal urethra were completely dissected after anterior release of the bladder from the abdominal wall.

Retropubic RP was performed due to contraindications for laparoscopy, eg prior abdominal surgery. During retropubic RP, the prostate apex was dissected first, and then the vas and seminal vesicles. Finally, the bladder neck was dissected from the prostate base circumferentially and the proximal urethra was exposed. We developed this Heidelberg cBNP technique in 2007, as described at the 2012 American Urological Association (abstract 1388). Recently, the feasibility of this technique was also reported by others.[16]

Men randomized to BNP were assigned to the cBNP group when bladder neck circular fibers were preserved and urethro-urethral anastomosis was performed (fig. 1, *A*). When the bladder neck was not preserved, men were assigned to the no BNP group (fig. 1, *B*). To avoid destruction of the preserved bladder neck and bias due to secondary bladder neck resection in case of a positive SM, no intraoperative, fresh frozen sectioning of the bladder neck was performed.

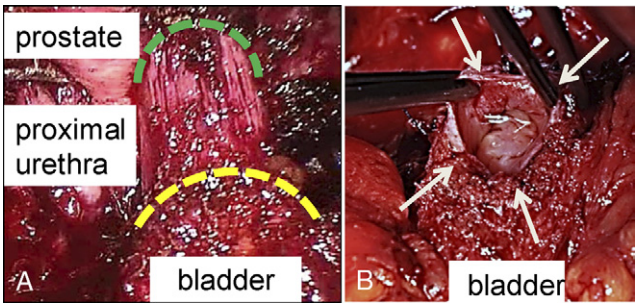

Figure 1. Anatomy. *A*, before bladder neck dissection and urethro-urethral or vesicourethral anastomosis. Green line indicates cBNP dissection plane. Yellow line indicates no BNP dissection plane. *B*, no BNP after bladder neck dissection. Arrows indicate resected bladder neck.

The 24-hour pad test was applied to evaluate continence objectively beginning immediately after Foley catheter removal. The test was repeated at 3, 6 and 12 months. The primary end points were continence at 0, 3, 6 and 12 months. To further evaluate urine loss by the metrically scaled 24-hour pad test, patients were grouped, including group 1—objectively continent, and incontinence groups 2, 3 and 4—urine loss up to 50, 51 to 200 and greater than 200 gm/24 hours, respectively. Social continence was analyzed at 1, 4 and 6 weeks, and 3, 6 and 12 months by daily pad use, including continent—1 security pad per day or less, and incontinence deemed mild—2 or more, moderate—3 or 4 and severe—5 or more pads per day.

We evaluated self-reported urinary continence specific QOL by the I-QOL questionnaire at 3, 6 and 12 months.[17] This validated self-assessment tool includes major QOL aspects influenced by incontinence. The 5-point ordinal response scale ranges from 1—extremely to 5—not at all. There is a section to specify further symptoms, eg incontinence frequency. Higher scores indicate better QOL outcomes.

The influence of cBNP on cancer resection was investigated by SM status. Specimens were analyzed independently by 2 pathologists blinded to the ongoing trial to achieve a blinded, unbiased evaluation. We also collected data on patient age, prostate volume, nerve sparing and UICC WHO tumor stage (t stage).

Statistical analysis was performed using SPSS® and SAS® for treatment (cBNP vs no BNP) and for ITT, ie men randomized vs not randomized to BNP. We analyzed data using the Pearson chi-square, Fisher exact, log rank and Wilcoxon rank sum tests, and multiple logistic regression analysis with $p \leq 0.05$ considered statistically significant.

RESULTS

All 208 men completed 12 months of followup. For treatment 95 men (91.3%) randomized to BNP and