Orthotopic Neobladder Versus Indiana Pouch in Women: A Comparison of Health Related Quality of Life Outcomes

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Purpose: Little is known about the health related quality of life of women who have undergone continent urinary diversion. We compared health related quality of life outcomes for women who underwent radical cystectomy with an orthotopic neobladder or Indiana pouch.

Materials and Methods: From 1995 to June 2008 a single surgeon (GDS) performed radical cystectomy with an orthotopic neobladder in 47 women and radical cystectomy with an Indiana pouch in 45. A comprehensive database provided clinical, pathological and outcomes data. The validated Functional Assessment of Cancer Therapy-Vanderbilt Cystectomy Index was mailed to 92 patients.

Results: Complete data were available for 87% of patients treated with radical cystectomy with an orthotopic neobladder and 93% of those treated with radical cystectomy with an Indiana pouch, with a median followup of 34 and 24 months, respectively ($p = 0.8$). Median (IQR) age was 65 (58, 71) and 61.5 (51, 67) years for patients with an orthotopic neobladder and Indiana pouch, respectively ($p = 0.03$). No significant differences were found for pathological stage, nodal status, blood loss, Clavien grade III or greater complications, adjuvant therapy or hospital stay between the 2 treatment groups, or between respondents and nonrespondents. Five-year survival rates for patients with an orthotopic neobladder and Indiana pouch were 65% and 58%, respectively ($p = 0.9$). There were 21 (75%) living patients with an orthotopic neobladder and 19 (61%) with an Indiana pouch who completed the Functional Assessment of Cancer Therapy-Vanderbilt Cystectomy Index, and physical ($p = 0.53$), social ($p = 0.97$), emotional ($p = 0.61$), functional ($p = 0.55$) and radical cystectomy specific ($p = 0.54$) health related quality of life domains were not significantly different between the groups.

Conclusions: Women undergoing radical cystectomy with an orthotopic neobladder vs an Indiana pouch have similar health related quality of life outcomes. Larger series with longer followup and multiple surgeons are necessary to confirm these findings.

Key Words: urinary diversion, urinary bladder neoplasms, quality of life, women, cystectomy

Abbreviations and Acronyms

FACT-VCI = Functional Assessment of Cancer Therapy-Vanderbilt Cystectomy Index

HRQOL = health related quality of life

IP = Indiana pouch

ONB = orthotopic neobladder

RC = radical cystectomy

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THE goal of continent catheterizable urinary diversion and orthotopic neobladder is improved HRQOL with equal complications compared to ileal conduit following RC. The concept of continent urinary diversion was pioneered by Gustav Simon more than 150 years ago, who performed ureterosigmoidostomies in a patient with bladder exstrophy.[1] Subsequently the

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continent reservoir was introduced with Kock, Ghoneim and Skinner serving as early pioneers. Most recently the Camey, Le Duc, Studer and Hautmann ONBs emerged as the most prevalent methods for continent urinary diversion after RC.[2–7] Initially offered to males in the 1980s, ONB reconstruction is now increasingly offered to women after further delineation of the female pelvic and urethral anatomy.[8–11]

The significant psychological and physical impact of noncontinent urinary diversion has fueled this evolution in technique.[12] Recently 2 validated questionnaires for HRQOL outcomes following RC have been published.[13,14] Prior attempts used generic cancer questionnaires for the bladder cancer population.[12,15–17] However, HRQOL following RC depends not only on physical, social, emotional and functional factors, but also on those related to the intra-abdominal operation and subsequent voiding mechanism. Because ONB reconstruction is performed for an increasing percentage of female patients we used the FACT-VCI to compare the HRQOL of women treated with IP or ONB procedures.

MATERIALS AND METHODS

Patient Population

From 1995 to 2008 a single surgeon (GDS) performed RC-ONB in 47 women and RC-IP in 45 women. All patients underwent RC for oncological indications, predominantly high grade T1, or T2 or greater urothelial carcinoma. One patient underwent conversion of an ileal conduit to an IP, and all data were gathered pertaining to the IP procedure and outcome.

Preoperatively all patients received mechanical bowel preparation and prophylactic perioperative antibiotics. Women undergoing RC since 2003 underwent a nerve sparing procedure when indicated. Patients undergoing RC-ONB received a Hautmann ileal neobladder with chimney modification.[18,19] Tumor at the bladder neck or urethra was considered a contraindication to ONB creation. If the patients wanted continent diversion they were offered IP reconstruction. Patients who underwent RC-IP reconstruction received a right colon continent reservoir, a modification based on the description by Rowland et al.[20] The efferent limb was composed of 8 to 10 cm terminal ileum. Plication stitches of the valve were not used. The reservoir was placed with the continent catheterizable channel most commonly in the right lower quadrant. Contraindications to ONB or IP creation were serum creatinine greater than 2.0 mg/dl, inflammatory bowel disease, liver failure, or advanced pathological findings at surgery including grossly positive lymphadenopathy or pelvic sidewall invasion.

Collection of Clinical and Pathological Data

A comprehensive database was used to obtain clinical, pathological and outcomes data for all women who had undergone RC with continent diversion. The institutional review board approved the study, and patients were contacted by telephone and mail. All complications subsequent to surgery were graded according to the Clavien classification system.[21] Grade III complications require surgical, endoscopic or radiological intervention. Grade IV complications are life threatening, requiring intensive care management, and grade V complications result in death.

The FACT-VCI was mailed to 92 eligible patients who on postoperative month 3 or more after RC. Rarely patients were unable to be contacted by telephone, mail or e-mail. For these patients contact was initiated with the extended family or primary care physician. The online Social Security Death Index was consulted when necessary. The FACT-VCI is a validated HRQOL tool consisting of the 27-item FACT-G, itself divided into 4 subscales of physical, social, emotional and functional well-being plus 17 additional RC specific questions.[22] Each item is scored from 0—not at all to 4—very much. The FACT-VCI was validated by Cookson et al and was found to have internal consistency (Cronbach's $\alpha > 0.70$), with intraclass correlation between first and second administration of 0.79.[13] Compared to the Rand 36-Item Health Survey the VCI showed good correlation ($r = 0.81$).

Statistical Methods

Statistical analysis was performed using STATA® 10 software. Continuous and categorical variables were compared using 2-sided t tests and chi-square tests, respectively. Univariate and multivariate analyses of HRQOL end points were performed using linear regression. Kaplan-Meier analysis was performed to assess overall and 5-year survival of patients with complete followup who received orthotopic neobladder or Indiana pouch reconstruction, and $p < 0.05$ was considered statistically significant.

RESULTS

Complete clinical and pathological data were available for 41 of 47 (87%) women treated with an ONB and 42 of 45 (93%) women with an IP, with a median (IQR) followup of 34 (10, 80) and 24 (11, 45) months, respectively ($p = 0.77$, table 1). Median age of patients undergoing ONB and IP reconstruction was 65 (58, 71) and 61.5 (51, 67) years, respectively

Table 1. *Demographic data*

	ONB		IP		p Value
No. pathological stage:					
T0	11		6		0.12
Tis	5		2		
T1	1		4		
T2	13		9		
T3	10		14		
T4	1		7		
Median (IQR) days hospital stay	10	(8, 10)	9	(8, 13)	0.28
Mean (IQR) cc blood loss	895	(700, 1,000)	988	(600, 1,000)	0.36
Mean (IQR) nodal harvest	16.6	(12, 20)	15.8	(12, 21)	0.58