

Long-term health related quality of life outcomes following radical cystectomy

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Abstract

Objective:

To evaluate the long-term (>5 years) health-related quality of life outcomes following radical cystectomy, comparing Indiana pouch (IP), neobladder (NB), and ileal conduit (IC).

Materials and Methods:

The departmental radical cystectomy database was queried to identify patients who underwent radical cystectomy and urinary diversion for bladder cancer between 1991 and 2009 and had not died. Three hundred patients were identified and sent the validated Bladder Cancer Index (BCI) instrument.

Results:

A total of 128 (43%) of the patients completed the survey. When adjusted for gender, age at surgery, surgeon, and time since surgery, IC and IP patients had significantly better urinary function than NB patients ($p=0.0013$). Sexual bother was less in NB than IP ($p=0.0387$). Among males ≥ 65 years of age, IC patients had significantly better urinary function ($p=0.0376$) than NB patients (91.6 vs. 49.4, respectively). Among males < 65 years of age, IC and IP patients (76.0 and 82.8, respectively) had significantly better urinary function than NB patients (50.7) ($p=0.0199$). Among females greater than 65 years, bowel bother was significantly better ($p=0.0095$) for IC patients than IP patients (44.8 vs. 69.5, respectively).

Conclusions:

Urinary diversion type after radical cystectomy affects health-related quality of life (HRQOL) differently in long-term survivors. Age and gender at surgery influenced HRQOL based on diversion procedure. Urinary function but not urinary bother were significantly better in IC and IP compared to NB diversions. Prospective longitudinal studies using validated HRQOL tools will further help guide preoperative diversion choice decisions between patient and surgeon.

Introduction

Approximately 74,000 new cases of bladder cancer are diagnosed annually in the United States⁽¹⁾. Radical cystectomy (RC) with urinary diversion is performed for muscle invasive disease, high-risk nonmuscle invasive tumors such as high grade T1 with

carcinoma in situ (CIS), early recurrence of high-grade T1 tumors, and BCG failures including BCG refractory CIS disease^(2, 3). Annually, over 7,000 patients are estimated to undergo RC with diversion in the United States⁽⁴⁾. These patients are currently counseled through surgeon experience and the limited data available that suggest benefits of certain diversions over others. Although RC is associated with improved overall survival, it can affect health-related quality of life (HRQOL) with regard to urinary, bowel, and sexual function⁽⁵⁻⁸⁾.

Prior to surgery, patients are typically presented with three options for urinary diversion including continent (i.e. Indiana pouch (IP) or neobladder (NB)) and incontinent diversion (ileal conduit (IC)). Current literature has conflicting and inconclusive results regarding a superior diversion type in terms of quality of life. Each diversion type poses disparate benefits and drawbacks. The IP provides a continent option without the need for urethral utilization; however, it also is recognized to have the highest incidence of Clavien grade I-II complications⁽⁹⁾. NB provides daytime continence and physical normality, but it is associated with nocturnal enuresis and the potential need for urethral catheterization.⁽⁹⁾ As an incontinent option, the IC is associated with the lowest incidence of perioperative complications; however, it provides the least degree of lifestyle normalcy⁽⁹⁾. Most of the quality of life data comparing these diversion types are limited by short follow-up, which is usually within 12 months⁽¹⁰⁾. This has resulted in a paucity of literature comparing the long-term HRQOL outcomes based on diversion type. It remains unclear which diversion would provide the best HRQOL over the long term to meet the needs of individual patients.

The primary objective of this study is to evaluate the long-term HRQOL following RC, comparing IP, NB, and IC. These data could provide useful information when

counseling patients regarding which urinary diversion may be their best option in the long term.

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Methods

After obtaining Institutional Review Board approval, the Indiana University departmental bladder cancer database was queried to identify patients who underwent RC and urinary diversion for bladder cancer between 1991 and 2009. Urinary diversions were performed as previously reported⁽¹¹⁻¹³⁾ with vesicica ileale Padovana (VIP), Studer, or Hautmann NBs. IP is a detubularized folded right colon pouch with 10cm of terminal ileum used as an efferent catheterizable channel. This limb was tapered using a GIA stapler over a 12-french red rubber catheter. Continence was improved by plication stitches at the ileocecal valve. Folding the colon pouch increased the compliance and capacity. Patients were eligible to be included if they had the following: at least five years of follow-up after RC, alive based on medical records or Social Security death index data, and had a current address in the medical record. Based upon these criteria, 300 patients were identified. Surveys were mailed to patients with a stamped return envelope for survey return. Patients were also offered a secure online portal to complete the survey if they preferred. A total of 128 (43%) of the patients completed the survey. The survey consisted of the Bladder Cancer Index (BCI) instrument.^(14, 15) The BCI is a validated HRQOL instrument with disease-specific items aimed at determining urinary, bowel, and sexual domains of function and bother. The BCI is scored on a scale of 0 to 100, with higher numbers representing better HRQOL outcomes. Clinical, demographic, and pathologic characteristics were extracted for each patient using our institutional database.

ANOVA was used for continuous variable comparison between groups, and chi-squared or Fisher's exact tests were used for categorical variables. ANCOVA was used to examine differences in the six BCI subscales among types of diversion, adjusting for

gender, surgeon, age at surgery, and time from surgery to survey. Final pathological characteristics were not included for adjustments, since these data are not available during pre-operative patient counseling for diversion type. Since age and gender were highly associated with type of diversion, sub-analyses were performed including only males < 65 years, males \geq 65 years, and females \geq 65 years. The decision to stratify outcomes at age 65 was based on previously published literature⁽¹⁶⁾. A sub-analysis was unable to be performed on females under 65 years because only one had a NB, and none had an IC. Sexual function in females \geq 65 years was unable to be evaluated due to absence of survey response to sexual function-specific questions. For all analyses with a significant diversion type effect, a pair-wise comparison was performed to determine which diversion significantly differed. When pair-wise comparisons were made, Hochberg's step-up Bonferroni adjustment for multiple comparisons was used. All statistical tests were two-sided, and SAS version 9.4 (SAS, Cary, NC, USA) was used for the analysis.

Results

Of the 128 respondents, 102 (80%) were male. The mean (SD) age at surgery was 62 years; the range was 28-82 years. The mean (SD) time from surgery to survey was 11 years, with a minimum follow-up of 5.9 years and maximum of 23.9 years. Forty-nine patients underwent a NB. Twenty-four (50%) underwent a VIP, 20 (42%) underwent a Studer, and 4 (8%) underwent a Hautmann neobladder. Both gender and age were significantly associated with type of diversion ($p < 0.0001$). Females were more likely to have IP than NB or IC ($p < 0.0001$). IC patients were significantly older than NB and IP patients ($p < 0.0001$). Unadjusted urinary function scores were highest in IP patients, $p < 0.0001$. Pathological stage and lymph node involvement were not significantly different between diversion types. Patient, pathological characteristics, and unadjusted BCI outcomes were shown in **Table 1**.

The multivariable results, adjusting for gender, age at surgery, surgeon and time from surgery to survey are presented in **Table 2**. There was a significant difference between types of diversion and urinary and sexual function. IC and IP patients had significantly better urinary function than NB patients ($p = 0.0013$). NB had significantly less sexual bother than IP ($p = 0.0387$).

Figure 1A, 1B, and 1C display the adjusted means based on gender and age ($<$ or ≥ 65 years old). These statistical differences are summarized in **Supplemental Table 1**.

Among males ≥ 65 years of age, IC patients had significantly better urinary function than NB patients ($p = 0.0376$; 91.6 vs. 49.4, respectively). Among males < 65 years of age, IP

patients (82.8) had significantly better urinary function than NB patients (50.7) ($p=0.0199$). Male urinary function differences by age are summarized in **Figure 2**.

There was not an overall significant difference in bowel function or bother between diversion types. In the sub-analysis, differences were noted among females greater than 65 years. For example, IC patients had significantly less bowel bother (91.7) than IP (69.0) patients. However, these were small sample sizes ($n=9$ and $n=5$, respectively).

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Discussion

To our knowledge, the cohort studied provides the longest follow-up for reported HRQOL for bladder cancer survivors. We report that urinary function was better overall in IP and IC patients compared with NB patients. There were differences in outcomes based on age and gender. Older males with IC had better urinary function than older men with NB. In younger men, IP patients had significantly better urinary function than NB patients. These results were statistically significant and also likely demonstrate clinical significance, with a score difference of 25-40 points out of 100. BCI urinary function questions focus primarily on urinary leakage. While leakage can occur from IP stomas or poor fitting ostomy devices for IC, these are more rare events than leakage from NB^(6, 9-10). This likely accounts for the difference in urinary function score between diversions. Despite worse urinary function or leakage in NB, urinary bother was not significantly different between diversions. In the BCI, a portion of the bother component is reflected in question 9a, which relates to affecting social activity. This certainly could be the most important question to consider in regards to HRQOL after RC. This urinary bother question evaluated how often the urinary diversion limited activity with friends. These data are depicted in **Supplemental Figure 1**. Regardless of diversion type, most patients answered with 'not at all' or 'a little bit' bothered ($p=0.10$). This emphasizes the need to consider both function and bother in HRQOL analyses to provide a more complete description. For example, the NB had worse urinary function mainly due to leakage, but the bother domain suggested this was not a significant concern. Sexual bother was better in NB than IP. This could be attributed to higher rates of nerve-sparing during cystectomy with NB. Bowel bother differences were likely related to the relocation the ileocecal valve away from the gastrointestinal tract in IP patients⁽¹⁷⁾.

Our findings differ from previous reported HRQOL studies. This may be partially explained by their shorter follow-up time^(10, 18-20). A recent review of non-randomized studies using other validated HRQOL tools (SF-36, EORT QLQ-C30 and FACT BL) comparing NB to IC found that 16 studies reported no difference between the two diversions, four studies that reported NB was superior to IC, and a single study indicated that IC had better HRQOL outcomes than NB⁽²¹⁾. Of note, however, two of the reviewed studies also reported better HRQOL outcomes in young, fit NB patients^(22, 23). This review concluded that NB was marginally better than IC, particularly in younger, fitter patients⁽²¹⁾. The results of our study contrast with their findings. Specifically, we found that urinary function was better for IC compared to NB in the overall adjusted cohort as well as both male group subgroups (<65 and ≥65 years old). Additionally, we found that IP had the highest urinary function in the overall adjusted cohort and younger male subgroup.

There is a paucity of literature detailing HRQOL outcomes following cutaneous continent urinary reservoir, such as the IP, following RC. One prospective study using the SF-36 instrument reported that patients with cutaneous continent urinary reservoir diversions had return of HRQOL back to baseline at one year after surgery, compared to IC scores that declined after surgery⁽²⁴⁾. However, the SF-36 instrument does not evaluate bladder cancer-specific outcomes such as urinary function and bother, a finding that represents a significant limitation to the study. Our study demonstrates minimal long-term differences in urinary function and bother between IP and IC patients.

Several limitations should be considered. Patients were treated at a high-volume tertiary care center with a large experience with IP diversion. The results may not be generalizable to centers that are less familiar with cutaneous continent urinary reservoir

diversions. There was likely a selection bias in this retrospective, cross-sectional design with only a 43% patient response rate. However, this response is similar to that in previous studies with shorter follow-up.^(9,10) Short-term complications have been previously reported⁽⁹⁾; thus, they were not reported or statistically controlled in this analysis. In addition, short-term complications may not be relevant to this cohort that has a mean follow-up of ten years. However, in this mail-based survey we are unable to adjust to for long-term complications (i.e. incisional hernia, stones, infections, etc.) which may have biased our results. Moreover, this was a long-term survivor group of bladder cancer patients. It is unclear how these results would compare to those who died of their disease. Results may reflect a “healthy worker” effect⁽²⁵⁾ and therefore may not be valid in patients without long-term survival. Furthermore, our cross-sectional assessment of HRQOL does not allow us to evaluate how these scores change over time. However, we are currently performing a prospective study to understand any such temporal changes. The BCI is a bladder cancer-specific instrument; therefore, we cannot comment on other aspects of HRQOL, such as physical and emotional function. It may be difficult to determine which diversion has superior HRQOL when function and bother are not congruent, such as our finding of the urinary function and bother. Additionally, the BCI has only been validated in IC and NB diversions. However, previous publications have reported its use in continent cutaneous urinary diversions^(26,27). Nevertheless, the strength of the BCI is its validation in patients with bladder cancer⁽¹⁵⁾.

These limitations notwithstanding, our findings have several relevant clinical implications regarding patient counseling prior to RC and urinary diversion. First, males <65 years of age should be equally counseled about IP or IC as an alternative to NB in terms of urinary function. Second, older women with preoperative bowel issues may benefit from

IC rather than IP. Regardless, any diversion decision should be made with a patient-centered approach with careful consideration of the individual patient's characteristics and surgeon's ability. Future studies based on preoperative baseline characteristics and HRQOL scores could help elucidate the ideal choice for a patient during preoperative counseling. We plan to study HRQOL in patients with RC in a longitudinal prospective fashion.

We conclude that urinary diversion type after RC affects HRQOL differently in long-term survivors. Age and gender at surgery were associated with HRQOL based on diversion choice. Urinary function but not urinary bother were significantly better in IC and IP compared to NB diversions. Prospective longitudinal studies using validated HRQOL tools will further help guide preoperative diversion choice decisions between patient and surgeon.

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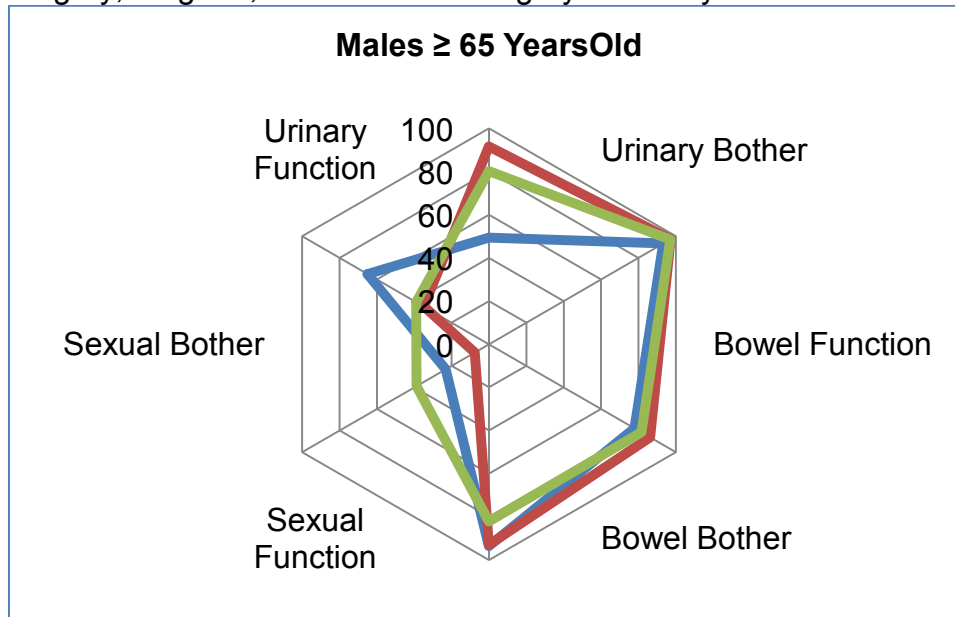
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Figure 1A: Neobladder (n=13)† [blue], Ileal Conduit (n=17) [red], Indiana Pouch (n=15) [green].

†Neobladder has significantly worse urinary function than ileal conduit.

Bladder Cancer Index for males ≥ 65 years of age at surgery, adjusting for age at surgery, surgeon, and time from surgery to survey

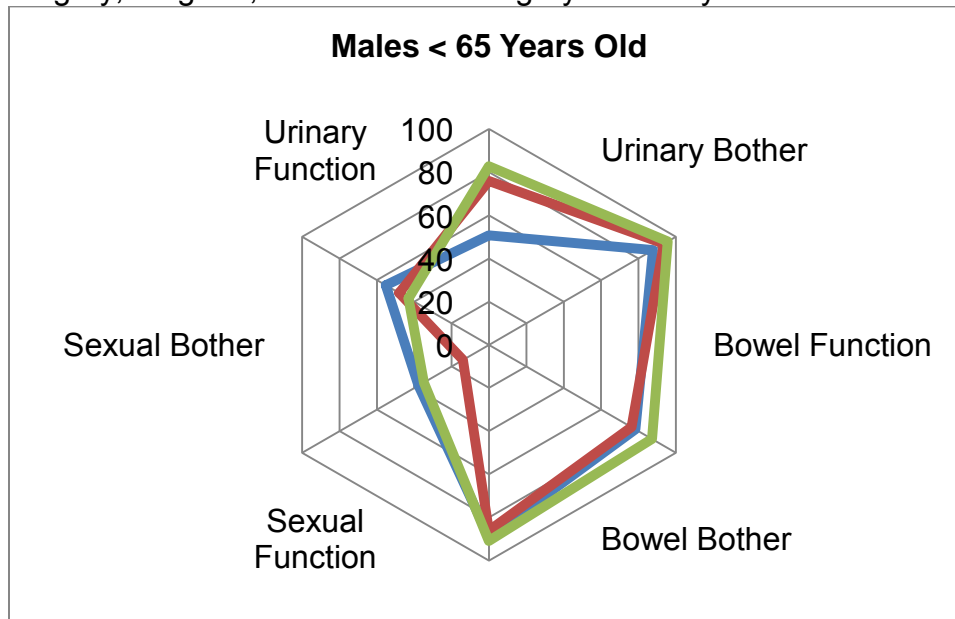


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Figure 1B: Neobladder (n=34)‡ [blue], Ileal Conduit (n=17) [red], Indiana Pouch (n=15) [green]. †Neobladder has significantly worse urinary function than ileal conduit.

‡Neobladder has significantly worse urinary function than both ileal conduit and Indiana pouch.

Bladder Cancer Index for males < 65 years of age at surgery, adjusting for age at surgery, surgeon, and time from surgery to survey



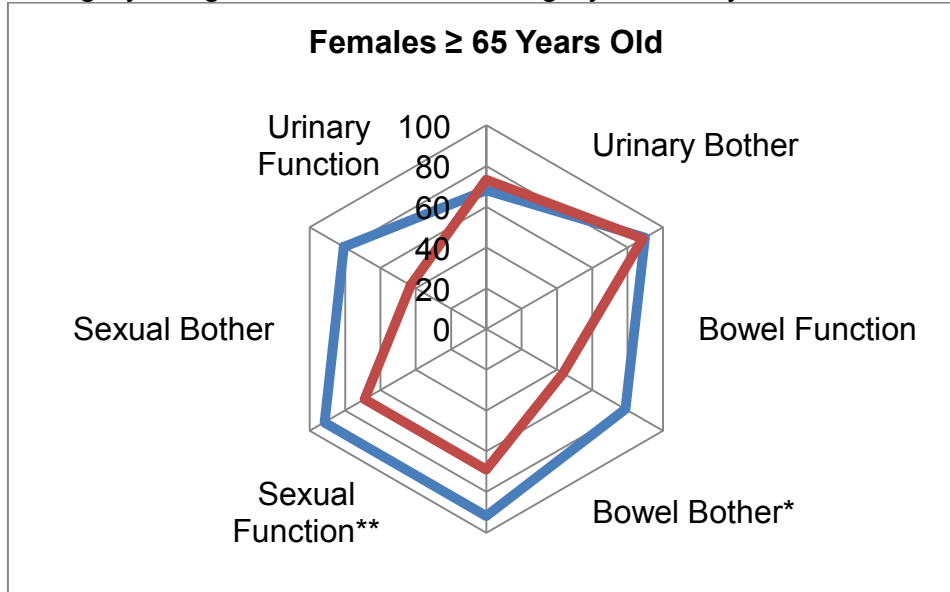
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Figure 1C: Ileal Conduit (n=9) [blue], Indiana Pouch (n=5) [red].

*Bowel bother was significantly worse in IP than IC

** Sexual function data absent due to lack of survey response to sexual function-specific questions in female ≥ 65 years.

Bladder Cancer Index for females ≥ 65 years of age at surgery, adjusting for age at surgery, surgeon, and time from surgery to survey

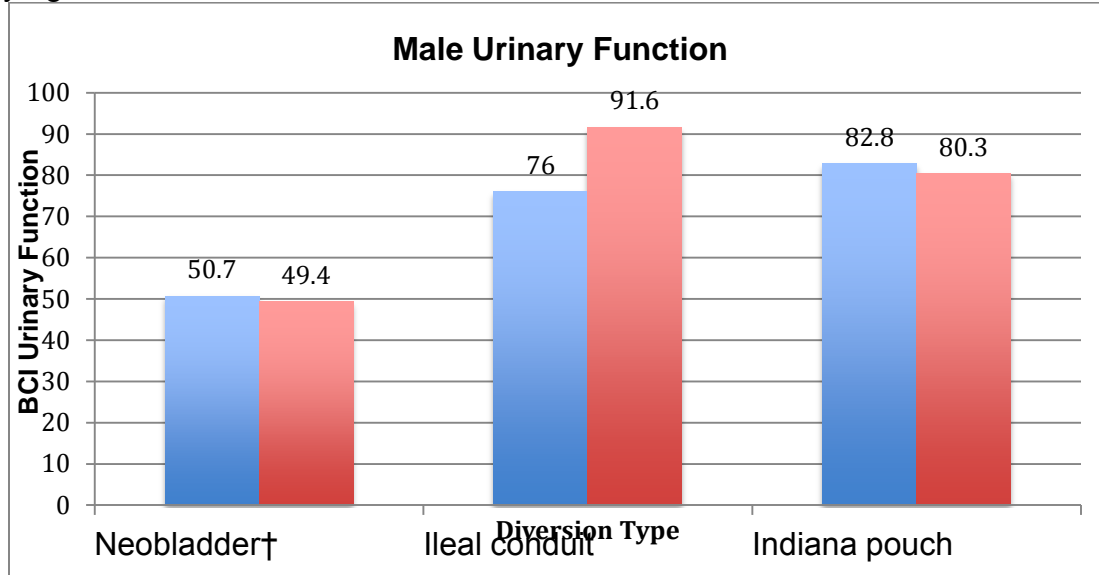


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Figure 2: <65 years [blue], ≥ 65 years [red].

†For men ≥65 years, neobladder has significantly worse urinary function than ileal conduit. In men <65 years old, neobladder had worse urinary function than Indiana pouch and ileal conduit.

Adjusted male Bladder Cancer Index urinary function by diversion type compared by age.



Supplemental Figure 1:

Ileal Conduit [blue], Indiana Pouch [red], Neobladder [green].

Table 1. Patient, Pathological characteristics, and BCI outcomes

	Neobladder (n=48)	Ileal Conduit (n=44)	Indiana Pouch (n=36)	P-value
Gender				<0.0001
Male	47 (98%)	35 (80%)	20 (56%)	
Female	1 (2.1%)	9 (21%)	16 (44%)	
Stage				0.7606
≤ pT1	30 (63%)	18 (40%)	21 (14%)	
pT2	9 (19%)	12 (28%)	6 (17%)	
pT3	7 (16%)	11 (26%)	7 (19%)	
pT4	2 (4.2%)	2 (4.7%)	2 (5.6%)	
Lymph node status				0.9408
Positive	7 (15%)	6 (14%)	6 (17%)	
Negative	41 (85%)	37 (86%)	30 (83%)	
Age at surgery, Mean (SD) (16)	58.4 (9.1)	67.2 (9.4)	61.8 (8.5)	<0.0001
Years from surgery to survey, Mean (SD)	10.1 (3.3)	10.8 (5.6)	12.7 (5.6)	0.0513
BCI, Mean (SD)				
Urinary function	50.1 (30.6)	79.5 (26.8)	81.6 (25.6)	<0.0001
Urinary bother	88.2 (14.7)	92.8 (8.9)	94.6 (7.2)	0.04
Bowel function	82.6 (15.3)	79.9 (14.7)	80.0 (23.4)	0.74
Bowel bother	90.5 (11.4)	89.7 (10.5)	84.8 (13.9)	0.11
Sexual function	30.7 (25.8)	18.0 (21.7)	30.1 (28.4)	0.14
Sexual bother	53.0 (26.8)	53.5 (32.5)	47.1 (30.8)	0.67

Table 2. Analysis of covariance adjusting for gender, age at surgery, surgeon, and time from surgery to survey.

	Neobladder		Ileal Conduit		Indiana Pouch		P-value
	Mean	SE	Mean	SE	Mean	SE	
Urinary Function	55.3	7.1	80.4	6.2	84.4	5.7	0.0013*
Urinary Bother	89.7	2.9	93.3	2.5	95.3	2.3	0.2400
Bowel Function	74.1	4.4	78.0	3.6	77.3	3.5	0.7208
Bowel Bother	90.5	3.0	90.4	2.4	86.3	2.4	0.3685
Sexual Function	39.7	6.2	23.8	6.2	36.4	5.2	0.1017
Sexual Bother	76.9	7.3	65.3	6.6	54.0	6.0	0.0387†