
Exploration of health-related quality of life areas that may distinguish between continent diversion and ileal conduit patients

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Objectives: We explored the specific impact of urinary diversion type on HRQOL in men after cystectomy for bladder cancer. Our intent was to provide a basis for the development of a diversion-specific instrument.

Methods: We invited 13 ileal conduit and 12 orthotopic urinary diversion (neo-bladder) male patients to several open-ended interviews. We explored HRQOL domains that may have been affected by cystectomy and urinary diversion, and that could then be used to form a basis for a diversion-specific HRQOL measure.

Results: The average age of neo-bladder patients was 59 versus 65 years for ileal conduit patients. We identified 10 HRQOL domains, ranging from involuntary urine leakage to dietary modifications, which were recognized as important by ileal conduit and neobladder patients. Within each domain, a sufficient amount of overlap existed to allow developing a measure that might be applied to both groups of patients.

Conclusions: Ten HRQOL domains were identified as important by ileal conduit and neobladder patients. These demonstrated a significant amount of overlap between conduit and neobladder patients. Potentially, these domains could be used to develop scales for distinguishing between conduit and neobladder-specific HRQOL detriments.

Key Words: bladder cancer, urinary diversion, health-related quality-of-life

Introduction

Health-related quality-of-life (HRQOL) is an important outcome measure after radical cystectomy. In absence of medical or surgical contraindications, continent orthotopic diversions represent a standard of care at many institutions. The intent of these

technically more challenging surgeries is to provide patients with fewer HRQOL detriments relative to ileal conduit diversions. Despite suggested neo-bladder benefits, controversy exists regarding their real HRQOL advantages.¹⁻³ Indeed, several studies explored HRQOL after cystectomy and urinary diversion. To date, these failed to demonstrate definite or appreciable differences between patients treated with different types of bladder reconstruction.^{1,4-14}

Several explanations may be proposed to explain lack of important HRQOL differences between different diversion forms. True lack of HRQOL differences may account for these observations. However, the inability to demonstrate HRQOL advantages of one versus another diversion form may also relate to absence of adequate diversion-specific HRQOL measures. Existing instruments may lack the capacity to discriminate between diversion-specific detriments.^{1,5,7-11,13-17}

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Existing diversion-specific HRQOL measures, may demonstrate content validity limitations.^{4,6,7,12} In consequence, they may not possess adequate discriminant properties to distinguish between diversion-specific HRQOL differences. Therefore, it is possible that the methodology used in previous HRQOL contributions did not allow discriminating between diversion-specific HRQOL detriments.

These observations prompted us to explore HRQOL after cystectomy. Our goal was to identify HRQOL areas that apply to different diversion types, with the intent of using these HRQOL areas for purpose of future questionnaire development.

Methods

Radical cystectomy intervention codes allowed us to identify men treated with radical cystectomy for bladder cancer at our institution. Further inclusion criteria consisted of a minimum of 6 months follow-up, no evidence of disease recurrence or secondary malignancy. Exclusions consisted of severe comorbidity, such as cardiovascular, cerebrovascular, peripheral vascular, chronic pulmonary, renal, bowel, and hepatic diseases, neurological deficits, or insulin-dependent diabetes. Current hospital admissions, neoadjuvant or adjuvant radiotherapy and/or chemotherapy during the last 6 months represented further exclusions.

After institutional review board approval, and after confirming adequate communication skills, patients were invited to individual and group interviews. Interviews began in an open-ended format, to explore perceived HRQOL detriments related to after cystectomy and diversion. Subsequently, a semi-structured format was used to explore the objective and subjective severity of these detriments. Related HRQOL areas, such as sleep, body image, self-esteem, intestinal symptoms, and fatigue were also addressed. Based on availability of established, validated erectile dysfunction and generic HRQOL assessment tools, we intentionally avoided these domains.

Results

Overall, 12 neo-bladder and 13 ileal conduit patients participated in the interviews Table 1. We identified several HRQOL areas that affect neo-bladder and ileal conduit patients Table 2.

Problems with sleep

Both patient groups experienced detriments related to sleep, such as restrictions in sleep position and sleep interruptions. Specifically, seven (54%) ileal conduit patients adopted new sleeping positions, which affected the quality of their sleep. They felt restricted to sleeping on their backs or on the side opposite the stoma. This was secondary to physical discomfort caused by the contact of the stoma with the bed, and by fear of potential detachment of the ostomy bag, and urine spillage. Three (25%) neo-bladder patients reported sleep problems. These men avoided sleeping on their stomach fearing incontinence caused by increased abdominal pressure. All neo-bladder patients (100%) complained of sleep interruptions related to nocturia. Moreover, all men reported distress in anticipation of fragmented sleep. Five (39%) ileal conduit patients reported sleep interruptions caused by fullness and weight of ostomy bag. These men did not feel comfortable using the large capacity, nocturnal drainage bag, because of discomfort caused by the connection tubing.

Problems with voids and involuntary urine leakage

Involuntary urine leakage during the day was a concern for both patient groups. Four (31%) ileal conduit patients experienced problems associated with urine spillage, which caused embarrassment and fear. Similarly, three (25%) neo-bladder patients reported detriments related to incontinence. Both groups reported that the process of eliminating urine represented a problem, and was caused by altered perception of the need to eliminate urine. Ileal conduit patients were bothered by the need to pay attention to the fullness of the ostomy bag. They feared that

TABLE 1. Mean patient age at surgery and median time since surgery across diversion subgroups

Diversion type	Average age, in years (range)	Time since cystectomy in months (range)	Married or living with a partner	Working full time or part time
Neo-bladder (n=12)	59.1 (53–66)	28 (12–49)	10 (83%)	3 (25%)
Ileal conduit (n=13)	65.3 (47–76)	31 (8–71)	10 (77%)	7 (54%)

TABLE 2. HRQOL areas, item phrasing, diversion-specific HRQOL detriment

Areas of HRQOL	Questions addressing both groups	Ileal conduit specific detriment	Neo-bladder specific detriment
Sleep	How much has the surgery to remove your bladder restricted the position in which you sleep?	Fear of ostomy bag detachment	Incontinence
Involuntary urine leakage	Have you worried about involuntary urine leakage during the day?	Urine spillage	Incontinence
Eliminating urine	Has it bothered you to be sure about when to eliminate urine?	Weight of ostomy bag	Abdominal cramps
Use of washrooms	Were you worried about being able to easily access washrooms?	Washroom accessibility	Washroom accessibility
Body image, masculinity	Has your physical appearance, following your bladder surgery, made you feel excluded?	Stoma	Abdominal scar
Body function	Have physical limitations in moving your body limited your recreational activities?	Ostomy bag	Incontinence
Hygiene and cleanliness	Have you felt physically uncomfortable taking a bath?	Fear of ostomy bag detachment	Incontinence
Wardrobe	Has it bothered you to change your wardrobe, due to your surgery to remove your bladder?	Alterations/purchases of clothes	Belts, tight pants
Travel and transport	Has involuntary urine leakage at night made you feel uncomfortable about sleeping somewhere other than at home?	Overnight stays	Overnight stays
Liquid intake	Did you restrict your liquid intake during the day?	Changing the ostomy bag	Urinary control

the weight of the full appliance could lead to urine spillage. Neo-bladder patients were bothered by the need to be attentive to body signals related to neo-bladder filling, such as abdominal cramps or lower back discomfort. Moreover, neo-bladder patients experienced difficulties with determining the proper time to void, which resulted in episodes of incontinence. Compared to their native bladder function, the majority (75%) of neo-bladder patients reported needing more time to empty their neo-bladder, which was perceived as bothersome. Longer voiding times required more privacy and different bathroom habits. Two (17%) neo-bladder patients reported sitting down to facilitate voids, which caused embarrassment and the feeling of exclusion.

Use of washrooms

Both groups reported problems related to washroom accessibility. Seven (53%) neo-bladder patients feared

urinary incontinence due to lack of washroom accessibility. When at home or away from home, neobladder patients adapted their schedules and activities to ensure that washrooms are accessible and available. These modifications caused psychological distress and limited their social activities. All (100%) ileal conduit patients reported fewer problems with bathroom accessibility. Their central problem related to privacy when using public washrooms, as they required individual washrooms to empty the collection device. Embarrassment related to urine malodor, presence of an external appliance, and body image changes dictated an increased need for privacy.

Body image and masculinity

Both groups reported emotional problems related to body image changes, and to loss of masculinity. Eight (62%) ileal conduit patients were bothered by the physical presence of the stoma, and avoided showing

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their abdomen. Three (25%) neo-bladder patients had self-image problems. None reported detriments related to body-image. Two (15%) ileal conduit patients reported problems with masculinity, due to loss of penile function for urination. Three (25%) neo-bladder patients reported that incontinence affected their perception of masculinity.

Problems with body function

Both groups experienced objective and/or subjective detriments related to the use of their body. All felt uncomfortable with excessive body movements, and all felt that the usefulness of their body was diminished. Ten (77%) ileal conduit patients reported important restrictions in the type and intensity of body movements. They avoided certain sports, certain household chores, and activities that could result in detachment of the collection device. Similarly, all (100%) neo-bladder patients avoided physical activities that could result in an increase in abdominal pressure and incontinence. The extent and severity of emotional fear, and role limitations appeared more important in ileal conduit patients.

Changes in personal hygiene

Ileal conduit and neo-bladder patients modified their hygiene, body cleaning and grooming habits. Ten (77%) ileal conduit patients washed less frequently due to fear of water detaching the collection device. Nine (69%) ileal conduit patients avoided taking showers and used a bath filled halfway. Conversely, four (33%) neo-bladder patients washed their bodies more frequently due to incontinence.

Changes in clothing

Six (46%) ileal conduit patients reported altering existing wardrobe or having to purchase new clothing, to accommodate the presence of the ostomy bag. In comparison, two (17%) neo-bladder patients experienced difficulties wearing belts or tight pants, due to fear increased abdominal pressure causing incontinence.

Problems with travel and transport

Four (31%) conduit patients reported limiting their travel activities, and restricting time spent away from home. These men avoided overnight stays, as they feared having difficulty in obtaining ostomy supplies, feared embarrassment related to potential urine spillage, and felt uncomfortable due to increased privacy needs. Three (25%) neo-bladder patients expressed concerns about travel and overnight stays, which were related to potential episodes of incontinence.

Liquid intake adjustments

Both groups reported restrictions in liquid intake. Three (23%) ileal conduit patients restricted fluid intake before changing the ostomy bag to avoid leakage and difficulty when attaching the collection device. Five (42%) neo-bladder patients reported monitoring liquid intake during the day and evenings, due to fear of incontinence.

Discussion

The goal of this study was to explore HRQOL detriments after cystectomy and urinary diversion for bladder cancer. Unfortunately, this represents a difficult task due to paucity of formal studies and formal measures addressing HRQOL after cystectomy and urinary diversion.^{1,4-14}

Several investigators attempted to explore HRQOL differences in men treated with ileal conduit or continent diversion.^{1,6-14} Several attempts relied on questionnaires developed by clinicians, which focused on functional detriments that are known to affect patients after cystectomy, such as sexual function scales, body image scales, and scales from established generic HRQOL questionnaires.^{5,6,8,12,18,19} Other investigators complemented existing cancer-specific HRQOL questionnaires with items that were rephrased to address urinary diversion.^{4,8,20} Finally, some used generic HRQOL tools to compare patients with ileal conduit and continent diversions.^{1,7,9-11,13-15}

Studies that relied on generic HRQOL found no difference between ileal conduit and continent diversion.^{9-11,13-15} However, generic HRQOL questionnaires address HRQOL areas that are not diversion-specific.²⁰⁻²² Therefore, they lack discriminant properties necessary to distinguish between the impact of one versus another diversion type.²⁰ Nonetheless, these studies provided valuable information regarding generic HRQOL of patients treated with cystectomy: continent diversion patients reported minimal detriments relative to population controls.^{9,11,18} Moreover, comparisons of ileal conduit and continent diversion patients found no appreciable generic HRQOL differences.⁹⁻¹⁴ These findings are not surprising, as generic HRQOL addresses relatively basic physical, social, and emotional areas. These HRQOL areas are unlikely different in conduit versus neobladder patients. Taken together these data suggest that cystectomy and urinary diversion do not appreciably decrease patients' generic HRQOL, relative to population controls. Moreover, these data suggest that generic HRQOL is similar between ileal conduit and orthotopic urinary diversion patients. Finally, the interpretation of these

data suggests that generic HRQOL cannot discriminate between ileal conduit and continent diversion patients.

Investigators from Vanderbilt University and University of Southern California in Los Angeles attempted to address post-cystectomy diversion-specific HRQOL detriments.⁴ Both groups developed diversion specific scales from existing items. Between five and seven items were selected to form diversion-specific scales. This methodology is in disagreement with the preferred approach, where items are selected from an exhaustive list of candidate items, using established data reduction techniques such as factor analysis.^{20,23,26}

Hart discusses the lack of applicability of their 'diversion-specific' scales to different diversion types. The limitation is due to excessive scale brevity, where presence of too few items preclude the use of the scale in populations with more complex diversion-specific HRQOL detriments.¹² Applicability to different patient populations represents an important quality of HRQOL tools. Such tools need to be versatile and capable of quantifying detriments in subgroups of patients with urinary diversions, such as ileal conduit and continent diversion. By analogy, this quality may be compared to prostate cancer urinary function scales. These scales are generally capable of discriminating between irritative symptoms and stress incontinence, in addition to being capable of quantifying the degree of HRQOL impairment. In contrast, due to their content validity limitations, existing diversion-specific instruments lack versatility.

Our work adds to existing contributions, which are aimed at developing a diversion-specific HRQOL instrument. Our goal was to explore HRQOL after cystectomy and ileal conduit or continent, orthotopic urinary diversion. We limited the patient population to men, and to patients with a minimum of 6 months follow-up. Moreover, we excluded patients with important comorbidity, and those with bladder cancer recurrence. Restriction of patients to men was based on important differences in HRQOL detriments that may distinguish between the two sexes. In our opinion, the difficult task of exploring diversion-specific HRQOL would have been even more difficult by including female patients. Therefore, only male patients were invited. However, in future analyses consideration should be given to both genders, to allow comparisons of gender differences.

Using a similar rationale as above, where consideration is given to problem complexity and also driven by incidence, we chose to address HRQOL detriments of two specific groups: men with ileal conduits, and of those with orthotopic neo-bladders. Exclusion of continent cutaneous diversions was based

on small numbers of patients at our centre. Moreover, we hypothesized that HRQOL detriments that affect continent cutaneous diversion patients are situated in-between those affecting neo-bladder and ileal conduit patients. In consequence, a tool with good discriminant properties might be applicable to patients with continent cutaneous diversions. However, this property needs to be confirmed in formal psychometric studies.

We used the above selection criteria, to include 13 ileal conduit and 12 neo-bladder patients. All agreed to participate in several in-person interviews. Their dedication and outstanding motivation may represent selection biases. These may falsely underestimate the severity of HRQOL detriments after cystectomy and urinary diversion. However, we felt that selection and participation biases would not compromise the validity of common and important HRQOL areas that were identified after cystectomy and diversion. If operational, these biases may have rendered minor HRQOL detriments more difficult to identify. Therefore, the participation of a larger sample of patients may have contributed to identification of a greater number of HRQOL domains. However, it may be postulated that these detriments would have likely been of lesser severity, and would have exhibited discriminant properties of lesser magnitude.

To avoid subjecting patients to preconceived notions about urinary diversion, whenever possible we used open-ended questions. These explored patients' HRQOL. Comparisons with HRQOL before surgery were made to facilitate the discussion. Finally, in the focused part of the interview, the interviewer targeted specific areas of HRQOL that were not volunteered by patients. The interview process identified nine areas, which were considered important by most participants. These are shown in Table 2, and range from urinary leakage to fluid intake. For example, urinary leakage affected both groups of patients. However, it affected neo-bladder patients differently than ileal conduit patients. For example, diurnal and nocturnal incontinence affected men with neo-bladders. Conversely, leakage of urine on clothing while emptying the ostomy bag, accidental detachment of the ostomy bag, detachment of nocturnal collection device and urine spillage plagued men with ileal conduits. Both groups feared problems related to involuntary urinary leakage. Despite apparent overall similarity, the urinary leakage domain demonstrated important heterogeneity. This heterogeneity requires careful item phrasing, if omissions of important domain areas are to be kept at a minimum. This situation is similar to other disease-specific tools, where main HRQOL domains are shared between different patient subgroups. For example,

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in prostate cancer - specific urinary scales, urinary dysfunction items allow exploration of obstructive and irritative urinary symptoms, in addition to addressing stress incontinence in other patients.²⁷ Their summated input quantifies overall urinary dysfunction. The same methodology is required in the setting of diversion-specific detriments after cystectomy.

In addition to careful item phrasing, attention to detail is required with initial item development. As suggested by Litwin and colleagues, several hundreds of items need to be generated in an attempt to eventually reduce that number to several dozen of important and relevant items.¹⁰ Input from patients and clinicians, as well as adherence to rules of item and response scale generation are necessary, to ensure that psychometric properties are observed, and that the broadest possible scope of HRQOL is explored. Individual interviews and focus groups may subsequently be used to improve item and response scale selection. Final item reduction may be based on factor analytic, reliability, and validity criteria of novel scales.

Conclusion

We identified nine diversion-specific HRQOL domains, in men treated with cystectomy and either an ileal conduit or an orthotopic neobladder. These detriments overlap between neobladders ileal conduits, as they affect both groups of patients. Despite apparent similarity, within these domains areas that are diversion-specific can distinguish between a neobladder and an ileal conduit patient. These characteristics represent important criteria for consideration for inclusion in future diversion-specific scales. □

References

1. Dutta SC, Chang SS, Coffey CS, Smith JA Jr, Jack G, Cookson MS. Health related quality of life assessment after radical cystectomy: comparison of ileal conduit with continent orthotopic neobladder. *J Urol* 2002;168:164-167.
2. Bhojwani AG, Mellon JK. Contemporary cystectomy combined with ileal conduit or bladder substitution. *Surg Oncol* 2002;11:65-75.
3. Hautmann RE. Urinary diversion: ileal conduit to neobladder. *J Urol* 2003;169:834-842.
4. Cookson MS, Dutta SC, Chang SS, Clark T, Smith JA Jr, Wells N. Health related quality of life in patients treated with radical cystectomy and urinary diversion for urothelial carcinoma of the bladder: development and validation of a new disease specific questionnaire. *J Urol* 2003;170:1926-1930.
5. Yoneda T, Igawa M, Shiina H, Shigeno K, Urakami S. Postoperative morbidity, functional results and quality of life of patients following orthotopic neobladder reconstruction. *Int J Urol* 2003;10:119-125.
6. Kitamura H, Miyao H, Yanase M et al. Quality of life in patients having an ileal conduit, continent reservoir or orthotopic neobladder after cystectomy for bladder carcinoma. *Int J Urol* 1999;6:393-399.
7. Hobisch A, Tosun K, Kinzl J et al. Quality of life after cystectomy and orthotopic neobladder versus ileal conduit urinary diversion. *World J Urol* 2000;18:338-344.
8. Bjerre BD, Johansen C, Steven K et al. Health-related quality of life after cystectomy: bladder substitution compared with ileal conduit diversion. A questionnaire survey. *Br J Urol* 1995;75:200-205.
9. Hara I, Miyake H, Hara S et al. Health-related quality of life after radical cystectomy for bladder cancer: a comparison of ileal conduit and orthotopic neobladder replacement. *BJU Int* 2002;89:10-13.
10. McGuire MS, Grimaldi G, Grotas J, Ruso P. The type of urinary diversion after radical cystectomy significantly impacts on the patient's quality of life. *Ann Surg Oncol* 2000;7:4-8.
11. Fujisawa M, Isotani S, Gotoh A, Okada H, Arakawa S, Kamidono S. Health-related quality of life with orthotopic neobladder versus ileal conduit according to the SF-36 survey. *Urology* 2000;55:862-865.
12. Hart S, Skinner EC, Meyerowitz BE, Boyd S, Lieskovsky G, Skinner DG. Quality of life after radical cystectomy for bladder cancer in patients with an ileal conduit, or cutaneous or urethral kock pouch. *J Urol* 1999;168:164-177.
13. Raleigh ED, Berry M, Montie JE. A comparison of adjustments to urinary diversions: a pilot study. *J Wound Ostomy Continence Nurs* 1995;22:58-63.
14. Hardt J, Filipas D, Hohenfellner R, Egle UT. Quality of life in patients with bladder carcinoma after cystectomy: first results of a prospective study. *Qual Life Res* 2000;9:1-12.
15. Filipas D, Egle UT, Budenbender C et al. Quality of life and health in patients with urinary diversion: a comparison of incontinent versus continent urinary diversion. *Eur Urol* 1997;32:23-29.
16. Miyake H, Nakamura I, Eto H et al. An evaluation of quality of life in patients who underwent orthotopic bladder replacement after cystectomy: comparison of ileal neobladder versus colon neobladder. *Urol Int* 2002;69:195-199.
17. Kulaksizoglu H, Toktas G, Kulaksizoglu IB, Aglamis E, Unluer E. When should quality of life be measured after radical cystectomy? *Eur Urol* 2002;42:350-355.
18. Henningssohn L, Steven K, Kallestrup EB, Steineck G. Distressful symptoms and well-being after radical cystectomy and orthotopic bladder substitution compared with a matched control population. *J Urol* 2002;168:168-174.
19. Bhojwani AG, Mellon JK. Contemporary cystectomy combined with ileal conduit or bladder substitution. *Surg Oncol* 2002;11:65-75.
20. Litwin MS. Measuring health related quality of life in men with prostate cancer. *J Urol* 1994;152:1882-1887.
21. Weijerman PC, Schurmans JR, Hop WC, Schroder FH, Bosch JL. Morbidity and quality of life in patients with orthotopic and heterotopic continent urinary diversion. *Urology* 1998 51:51-56.
22. Mansson A, Davidsson T, Hunt S, Mansson W. The quality of life in men after radical cystectomy with a continent cutaneous diversion or orthotopic bladder substitution: is there a difference? *BJU Int* 2002;90:386-390.
23. Spector PE. Summated rating scale construction: an introduction. ed. 1, Newbury Park, SAGE, 1992.
24. David W Stewart, Prem N. Shamdasani. Focus groups: theory and practice, ed. 1, Newbury Park, SAGE, 1990.
25. Floyd J Fowler Jr. Survey research methods, ed. 2, Newbury Park, SAGE, 1993.
26. Nunnally, JC. Psychometric theory. 2nd ed. New York: McGraw-Hill, 1978.
27. Litwin MS, Hays RD, Fink A, Ganz PA, Leake B, Brook RH. The UCLA Prostate Cancer Index: development, reliability, and validity of a health-related quality of life measure. *Med Care* 1998;36:1002-1012.