

Urinary diversion: evidence-based outcomes assessment and integration into patient decision-making

Cheryl T. Lee and David M. Latini*

*Departments of Urology, University of Michigan, Ann Arbor, MI, and *Baylor College of Medicine, and Houston Center for Quality of Care & Utilization Studies, Houston, TX, USA*

INTRODUCTION

There continues to be keen interest in assessing quality of life (QoL) after cystectomy and urinary diversion, given the recent evidence-based analyses [1,2] and systematic reviews [3–6] evaluating QoL studies in this population. A resounding characteristic of contemporary reports is the preponderance of cross-sectional, retrospective, single-institution studies. Very few prospective longitudinal studies and no randomized controlled trials have been reported, greatly limiting the ability to draw conclusions from reported observations. Despite this limitation, most of these studies show similarly favourable overall QoL after cystectomy, irrespective of the chosen urinary diversion.

As clinicians struggle with existing reports that fail to suggest a superior type of diversion, patients continue to face the ominous task of selecting a diversion that will almost certainly affect their urinary function for the remainder of their lives. The challenge for urologists is to take the suboptimal medical reporting, objectively relay the information to patients, and facilitate integration of this information into the patient's decision-making process. Thus an understanding of this decision process is essential.

The examination of patient decision-making has gained increasing attention in the recent past. As a result, the medical community has become aware of the importance of health knowledge, communication and improved patient–physician encounters, all factors that improve patient education and permit patients to seek greater engagement in

healthcare choices. Coupling accurate health information with high-quality decision counselling helps patients to understand the potential risks, benefits and uncertainties of clinical options, and assists them in selecting the option that best accommodates their personal preferences. Difficulty in interpreting information about risks can lead patients to make treatment decisions that are incompatible with their preferences, resulting in a decline in patient care and satisfaction.

Patients facing radical surgical treatment for high-risk bladder cancer have substantial fears about body image, sexuality and urinary function. These concerns not only involve potentially negative perceptions of their future health and functional well-being, but also encompass uncertainties about the practical impact of treatment and recovery on family members. These issues can greatly influence the choice of treatment and diversion, resulting in patient withdrawal from health decisions, limited treatment-seeking behaviour and potential delays in treatment delivery. For these reasons, it is imperative that urologists accurately counsel patients about the long-term experiences with various urinary diversions, to realistically set patient, spousal and family expectations in an attempt to ensure long-term satisfaction and willing adaptation.

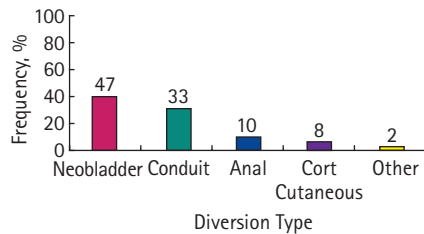
QoL AFTER URINARY DIVERSION

Urinary tract reconstruction attempts to provide an acceptable alternative to the native bladder by creating adequate storage and continence or a reasonable conduit. Clinicians have presumed that the development of orthotopic continent

diversions would replicate the normal voiding pattern and provide improved QoL over the incontinent cutaneous diversion. As a result, orthotopic diversion has globally become the most common type of urinary diversion performed after cystectomy in patients with bladder cancer (Fig. 1). Although surgical practice patterns have changed, reflecting trends towards orthotopic diversion, a real improvement in patient QoL has been difficult to show.

Recently, a consensus conference convened by the WHO and the Société Internationale d'Urologie met to review world reports on urinary diversion [2]. No level 1 evidence was available within the reports and very few level 2 citations were found, leaving the committee to rely heavily on expert opinion and single-institution retrospective studies. This review, as supported by others, could not show any superiority of orthotopic diversion or continent cutaneous diversion over the ileal conduit [1–6]. Without randomized clinical trials or well-designed prospective longitudinal studies, the optimum form of urinary diversion remains unknown. Unfortunately, several major challenges make the traditional randomized trial impractical in this setting. Both patient and provider biases and expectations would greatly hamper randomization of sometimes frail patients with a multitude of comorbidities. Given the number of individual patient and family factors that enter into the choice of urinary diversion, it might be more realistic to study differences between diversion populations with a well-designed prospective study using a design founded on practice-based evidence [7]. This type of design provides comprehensive practice-based evidence for clinical practice improvement by

FIG. 1. Worldwide experience with urinary diversion after cystectomy for bladder cancer, from an international consensus panel on urinary diversion. (Data from Hautmann *et al.* [2])



incorporating natural variation within data from routine clinical practice.

Despite the limitations in existing QoL studies, it is imperative that patients be informed not only about the perioperative risks and anatomical limitations of each type of urinary diversion, but also about short- and long-term outcomes, so an adequate choice of diversion can be made. Although retrospective studies suggested that patients with ileal conduit diversions have good acceptance of their stoma and overall good QoL, there remains a sense of uneasiness because of fear of urine leakage, skin problems, altered body image and sexual dysfunction, as described by both men and women [1]. Also, bowel disturbance and UTI appear to be increased over those in control populations. Early studies using primarily unvalidated instruments compared ileal conduit and continent cutaneous diversion [1]. These studies confirmed that stomal problems were more common in patients with a conduit; however, adjustment and satisfaction with current life did not differ between groups. There was substantial compromise of sexual life of the patients in both groups. Ultimately, both incontinent and continent cutaneous diversions have high perceived overall satisfaction at 1 year [8].

More recently, the importance of using valid and reliable instruments to assess QoL has become clear, even in the retrospective, single-institution study. Various validated instruments have thus been developed and used to evaluate QoL of patients with urinary diversion (Table 1) [9–14]. In this setting, comparisons of the ileal conduit diversion and the orthotopic neobladder still have not shown major differences in QoL, although some have reported a greater concern about urinary leakage in patients with a conduit,

despite having leakage less commonly than patients with a neobladder [1]. Others suggest that patients with a conduit have a poorer body image, but overall satisfaction has been high in these patients, and notably similar to the overall satisfaction of those undergoing orthotopic diversion [1–6,15,16]. Only one study has suggested a clear QoL benefit in patients undergoing orthotopic diversion.

In a study of 102 (69 neobladder and 33 ileal conduit) patients, Hobish *et al.* [17] retrospectively examined postoperative QoL using the European Organization for the Research and Treatment of Cancer (EORTC) QoL Core Questionnaire (QLQ-C30) and an unvalidated local questionnaire. In this series, patients undergoing orthotopic diversion had significantly better adaptation, self-confidence and rehabilitation than those with an ileal conduit. In addition, patients with a neobladder had greater restoration of leisure, professional and social activities than those undergoing ileal conduit diversion. Moreover, 97% of those with a neobladder would recommend their diversion type to a friend, compared with only 36% of those with an ileal conduit. However, the median follow-up might have contributed to differences in this cross-sectional study, with the follow-up being substantially longer in the conduit group (56 months) than in the neobladder group (28 months).

Apart from this series, most of the experience at the institutional level reflects similar QoL in patients undergoing ileal conduit, continent cutaneous and orthotopic diversions [1–6]. The lack of qualitative differences in QoL lends credibility to the theory that patients adapt to their diversion over time and have generally high satisfaction if they have accurate pretreatment expectations of the 'performance' of their diversion.

ADMINISTRATION OF QoL SURVEYS

When considering the best time to evaluate QoL after cystectomy and urinary diversion, one must consider the time required to restore psychological and health-related QoL measures back to baseline. Kulaksizoglu *et al.* [18] prospectively evaluated 68 patients undergoing radical cystectomy for bladder cancer. In an effort to determine the time required for these patients to adapt to their new health status, they administered the Beck Depression Inventory and the EORTC QLQ-C30

before and at 3, 6 and 12 months after surgery, and then every 6 months thereafter. The mean (range) follow-up was 28 (12–46) months. Psychological and health-related QoL measures returned to baseline values after 12 months, suggesting that either QoL improves to a baseline level at 12 months, or that it takes that long for patients to adapt to their status after cystectomy. In either case, QoL instruments are less likely to be informative when administered before this time.

In comparing QoL studies, one must also consider the confounding methods used to measure patient responses. Use of a face-to-face interview, telephone interview and home survey with a disease-specific questionnaire might give differing results. Office questionnaires remain attractive to optimize response rates and minimize missing data. However, although potentially more cumbersome, it is most advantageous to engage a neutral party for interviews to optimize legitimacy [19].

QoL INSTRUMENTS

Historically, the assessment of QoL after urinary diversion was hampered by a lack of valid and reliable tools to measure bladder cancer-related QoL, resulting only in speculation about the outcomes of diversion. In the recent past, several tools have been developed (Table 1) to measure general and cancer-specific QoL. The sensitivity of these instruments to distinguish differences in QoL between patients with conduit, orthotopic and continent cutaneous diversions remains unclear. However, several institutions have attempted to adapt earlier versions of general or cancer-specific instruments to try to improve this sensitivity, creating bladder cancer-specific instruments. The ultimate success of these instruments certainly depends on consideration of several aspects of the patient's outcome, and expectations of patients and providers, as well as attention to recurring limitations in QoL assessments and necessary remedies (Table 2).

The Functional Assessment of Incontinence Therapy (FACT)-Vanderbilt Cystectomy Index represents the first treatment-specific QoL measure for patients undergoing cystectomy [9]. The 45-item questionnaire comprises the FACT-General [10], four questions from the FACT-Bladder Cancer [11], six questions from

TABLE 1 QoL instruments

Instrument	Institution	Domains	Validated	Reliable	Cancer-specific	Bladder cancer -specific	No. of items
BCI [12]	Univ Michigan	Urinary Bowel Sexual function	Yes	Yes	Yes	Yes	34
FACT-VCI [9]	Vanderbilt Univ	See FACT-G Urinary Bowel Sexual function	Yes	Yes	Yes	Yes (limited to cystectomy)	14
QLQ-BLM30 module	EORTC	Urinary Bowel Sexual function	Ongoing studies	Ongoing studies	Yes	Yes (muscle-invasive disease)	30
QLQ-BLS24 module	EORTC	Urinary Bowel Sexual function	Ongoing studies	Ongoing studies	Yes	Yes (non-muscle-invasive disease)	24
FACT-BL [11]	FACIT	See FACT-G Limited urinary Limited bowel Limited sexual function	Ongoing studies	Ongoing studies	Yes	Yes	39
FACT-G [10]	FACIT	Physical Social Emotion Function	Yes	Yes	Yes	No	27
QLQ-C30 [13]	EORTC	5 Functional Scales 3 Symptom Scales 1 overall health/QoL scale	Yes	Yes	Yes	No	30
SF-36 [14]	RAND	8 Domains including Physical Mental Social function Emotional	Yes	Yes	No	No	36

FACIT, The Functional Assessment of Chronic Illness Therapy; FACT-BL, FACT-Bladder Cancer (Extension of the FACT-G + 12 additional bladder cancer-specific items including incontinence, diarrhoea, body image, sexual function, and stoma care); FACT-G; FACT-General; FACT-VCI, FACT-Vanderbilt Cystectomy Index (Extension of the FACT-G + 17 additional bladder cancer and treatment specific items); QLQ-BLM30, Bladder Cancer Muscle Invasive (extension of the QLQ-C30 + 30 additional bladder cancer-specific items; <http://www.eortc.be/home/qol/modules.htm>); QLQ-BLS 24, Bladder Cancer Superficial (extension of the QLQ-C30 + 24 additional bladder cancer-specific items; <http://www.eortc.be/home/qol/modules.htm>); RAND, Research and Development Corp.; SF-36: Medical Outcomes Study 36-Item Short Form.

the FACT-Colorectal [11] and seven from the FACT-Urinary, all validated instruments. Preliminary results from an ongoing prospective study using this cystectomy-specific instrument suggest that patients with a neobladder have a higher QoL at baseline and 1 year after cystectomy than those undergoing ileal conduit diversions. However, at 1 year, patients with a conduit have a consistent improvement in scores over their initial presentation, while those with a neobladder do not; additional studies are forthcoming.

The Bladder Cancer Index (BCI) represents the next generation of QoL assessment, developed as a reliable and valid QoL instrument for patients with bladder cancer managed with endoscopic, intravesical or radical surgical treatments [12]. The instrument was developed using standard psychometric methods; it consists of 34 items with three primary domains measuring urinary, bowel, and sexual health, and two subdomains, function and bother. Recently the BCI was administered retrospectively to a group of 315 patients with bladder cancer; 127 with a

native bladder, 66 treated with cystectomy and ileal conduit diversion, and 122 with cystectomy and neobladder diversion. Patients with native bladders uniformly had higher adjusted urinary, bowel and sexual function domain scores than those undergoing orthotopic diversion (Table 3) [12]. Patients undergoing ileal conduit and orthotopic diversion had similar adjusted bowel and sexual function scores. Patients with ileal conduit diversion had significantly higher functional urinary domain scores than those with orthotopic diversion, yet the

TABLE 2 Hurdles in QoL studies

Variable	Limitation	Remedy
QoL instruments	Previously unvalidated Lack of sensitivity to discern intergroup differences	All instruments must have proper psychometric evaluation. Optimize the content and number of survey items.
Questionnaire administration	Similar surveys yield differing results based on mode of survey administration	Standardized administration by a neutral party
Single-institution study	Lack of general applicability	Multicentre study with academic and community-based subjects
Small samples in comparison groups	Statistical power	Multicentre study
Retrospective study	Selection bias	Prospective study
Cross-sectional study	No baseline (pretreatment) comparison	Baseline and longitudinal data collection
Low survey response	Response bias	Reconsider the survey item content, number and/or method of administration

TABLE 3 Adjusted mean BCI domain scores (with permission, from [12])

Variable	Native bladder		Cystectomy	
	No IVT	IVT	Ileal conduit	Neobladder
No. of patients	52	75	66	122
BCI score:				
Urinary domain				
Function	90.7†	89.2†	86.5*	49.8*††
Bother	95.4*	93.4†	88.4	86.3*†
Bowel domain				
Function	82.0	88.6*†	77.6*	76.6†
Bother	93.0*†	92.3†¶	80.8*†	85.7†¶
Sexual domain				
Function	45.7*†	42.2†¶	20.0*†	25.5†¶
Bother	67.4*†	71.7†¶	50.3*†	49.9†¶

*†¶¶ The same symbol in the same row indicates a statistically significant pair-wise difference of mean scores between treatment groups (multiple-comparison adjusted $P = 0.05$). Scores adjusted for age, gender, income, education, relationship status, and follow-up time. IVT, intravesical therapy.

bother in both groups was similar. Overall, the BCI showed functional and bother differences in patients with bladder cancer treated with various approaches. Longitudinal studies are forthcoming.

SURVIVORSHIP IN PATIENTS WITH BLADDER CANCER

In the 1940s and 50s, when radical cystectomy was being popularized by Marshall and Whitmore [20], the concept of cancer therapy encompassed large operations with multi-organ resection. Over the past 10–20 years the preservation of organ function coupled with local cancer control has become a major objective of urological oncologists. The logical extension of this

conceptual practice is the restoration of QoL after cancer surgery. Previously, postoperative adjustment to changes in body image, sexual function, urinary function and self-esteem were unevaluated, and to some degree, ignored. Continued improvements in urinary diversion must consider health-related QoL and other aspects of long-term survivorship that have become increasingly important.

More recently, survivorship clinics have been established to facilitate psychosocial rehabilitation. Multidisciplinary teams consisting of nursing professionals, sex therapists, social workers, and urological oncologists collaborate on methods to reduce patient stress, diminish fear, improve sexual and urinary function, and regain a sense of well-being. Such clinics are models for

potential psychosocial interventions that can assist in the psychosocial recovery of patients undergoing urinary diversion.

Some remain sceptical about the impact of psychosocial interventions in the urinary diversion population, although there might be a benefit for selected patients. Mansson *et al.* [21] randomized 50 patients with a diversion (17 ileal conduit, 17 continent cutaneous, and 16 neobladders) to undergo a psychosocial intervention, comprising weekly counselling 4–9 weeks after surgery. All patients were evaluated with the Sickness-Impact Profile (SIP) and the meta-contrast technique (MCT), an analysis used to reflect individual defensive strategies at the subconscious or unconscious level. The patient's general philosophical outlook was recorded before and after surgery. They found no significant difference in the results of the SIP between the intervention and the no-intervention groups. In a subset analysis, the intervention appeared to benefit patients with continent cutaneous diversion, who had significantly lower psychosocial scores than those with a conduit or neobladder. Analyses from the MCT did not distinguish the intervention from the no-intervention group. Despite little overall impact of these generalized interventions, it might be that interventions tailored to specific patients with bladder cancer will facilitate aspects of QoL recovery.

CARE AFTER SURGERY

Like other cancer survivors, patients with bladder cancer also have concerns about receiving adequate follow-up care. To address these growing concerns, the Institute of

Medicine (IOM) recently released two reports with important implications for such patients [22,23]. First, the 2005 IOM report suggests 'Intervention for consequences of cancer and its treatment, for example: medical problems such as lymphedema and sexual dysfunction; symptoms, including pain and fatigue; psychological distress experienced by cancer survivors, and their caregivers.' [22] Patients with urinary diversions have ongoing needs for stoma care, as well as potential changes in body image and self-concept related to surgery [24]. Both men and women undergoing cystectomy report a range of localized side-effects, e.g. incontinence and sexual dysfunction [25,26]. Patients treated with radiotherapy can have some of the same problems, plus some might experience bowel dysfunction, such as diarrhoea, urgency or incontinence [27]. Effective education materials need to be developed to help patients to manage these physical concerns after treatment. In addition, many patients might need assistance with psychosocial concerns [28].

Besides the physical and psychosocial sequelae of bladder cancer, patients must understand their ongoing needs for follow-up care. Survivorship care-plans represent one approach to documenting previous cancer treatments and needs for future care [23]. Although such care plans are not yet in wide use, they hold promise as a way of assembling a patient's previous cancer-related treatments, their history of comorbid conditions, and other relevant medical information so that it can be accessible to both the patient and future healthcare providers. The plan might document both the need for late toxicity monitoring, and the surveillance needed for cancer recurrence or for a second primary cancer. The IOM recommends that care plans clearly identify providers responsible for survivorship care, encourage disease-preventive actions patients should take and document patients' needs for psychosocial or vocational assistance [23].

To date, research on health-related QoL for patients with bladder cancer has been limited, few patient education interventions exist, and funding for such research or intervention development has been marginal. Because some symptom concerns mentioned above are similar to those of patients with cancers at other sites (e.g. men after radical prostatectomy have erectile difficulties

similar to those experienced by men after cystectomy), it might be possible to adapt patient-education materials about other cancers for those with bladder cancer. As individual institutions explore survivorship strategies, it will be important to embark on collaborative plans to develop and assess interventions in a prospective and longitudinal fashion.

INTERVENTIONS FOR DECISION-MAKING

The development of patient-centred decision aids for urinary diversion will be a central component in the next phase of improved bladder cancer care. A key understanding of general principles in decision-making and in creating decision tools is necessary to establish a conceptual framework for this endeavour.

Based on the growing reports on clinical survival, resources for clinicians have been developed to improve treatment recommendations to patients. Nomograms can provide quantitative estimates of the probability of disease recurrence, permitting urologists to counsel patients about possible outcomes [29]. Other nomograms based on large international databases also predict recurrence after cystectomy, but with greater accuracy than traditional pathological staging [30]. However, efforts to translate data from nomograms or other clinical decision aids into patient decision aids have been limited, and might be further limited by difficulties many patients have in understanding quantitative data [31]. The only bladder-cancer decision-support tool available is the American Cancer Society NexProfiler Treatment Options Tool for Bladder Cancer [32]. After patients enter their clinical information, the tool generates two reports; one lists treatment options and the other reports survival, progression and recurrence data relevant to each patient's clinical situation. Such information is sorely needed by patients coping with both a cancer diagnosis and a confusing array of treatment options. No such tool exists to guide a patient's choice of urinary diversion. Although health information is increasingly available on the Internet, the quality of information provided is highly variable, so it is important for patients to seek information from many sources [33,34].

Fortunately, bladder cancer clinicians and researchers have a large body of literature from both other cancers and other disease

areas on which to draw in developing new patient-centred decision aids. Detailed guidelines have been published by the International Patient Decision Aids Standards (IPDAS) Collaboration on the best practices for developing patient-centred decision aids. The IPDAS recommendations list 12 criteria to consider in developing a decision aid: use of a systematic development process, provision of information about treatment options, presentation of probabilities, values clarification, use of patient stories, use of a guide or coach during decision-making, disclosure of conflicts of interest, provision of access to the tool via the Internet, presentation of options in a balanced fashion, use of up-to-date information on which patients can base their decisions, use of plain language, and evaluation of the effectiveness of the newly developed decision aid [35].

An important first step in a systematic process for developing a patient decision-aid for bladder cancer treatment such as urinary diversion is basic qualitative research to adequately understand patient values and concerns. While healthcare providers talk to patients as part of clinical care, providers might not understand their patients' concerns as well as they think [36]. Qualitative research, such as studies that involve focus groups or in-depth interviews, conducted after treatment would provide an opportunity for patients to discuss their values and concerns in a less than stressful situation, and allow patients to report side-effects after treatment and other factors that might affect decisional regret [37]. Such information can be an important foundation for developing new decision aids that allow patients to clarify their values during the decision-making process, and provide clinicians with more accurate information about their patients' concerns.

In addition to clarifying patient values, decision aids are needed that provide substantive information about treatment options, associated side-effects and probabilities for survival and disease recurrence. Another recommendation of the IPDAS collaboration is for the provision of decision aids using plain language that can be understood by a wide variety of patients.

Health literacy, 'the ability to which individuals have the capacity to obtain, process, and understand health information services needed to make appropriate health

decisions' [38], has been shown to be strongly related to health status and health outcomes [39,40]. Adults aged >65 years are more likely to be over-represented among persons with health literacy below what is considered a basic level [41]. Among patients with prostate cancer, African-Americans are also over-represented among persons with low health literacy [40]. Older adults tend to have poorer outcomes after cystectomy than younger adults, after controlling for other factors [42]. African-Americans tend to present with higher-stage disease and have a worse prognosis than other races, perhaps because they tend to be treated at hospitals with fewer patients with bladder cancer, or by physicians with less experience in treating bladder cancer [43,44]. It might be that one way of beginning to address these disparities is to provide patient decision aids that take into account the lower literacy of these groups that have poor outcomes after cystectomy.

With the growing interest in providing appropriate educational materials for low-literacy patients, several recommendations for developing such materials have been published. Materials should be written in an active voice, using common words and short sentences, and use examples to illustrate complex concepts. Materials should also include an interactive component, allowing the learner to demonstrate his/her mastery of the material and where he/she might need further instruction [45]. Other recommendations relate to formatting techniques, such as using serif type and lowercase lettering where possible, incorporating visual aids that help to explain the information being provided, and using headers and white space, which help low-literacy patients parse written materials more effectively [45]. Materials should also be developed keeping in mind that many patients with cancer are limited in their ability to understand numerical information [31]. The IPDAS Collaboration recommends including patient stories in decision aids. Such stories might be an effective way of presenting complex information about bladder-cancer treatment options and prognosis in a concrete way that can be more easily understood by low-literacy patients.

As with any new patient-education intervention, patient decision aids for those with bladder cancer need to be evaluated to ensure that they are providing accurate

information that is being correctly understood by the target audience. In addition, decision aids need to be re-evaluated and revised as new treatment options or other information relevant to patient decision-making becomes available [35].

CONCLUSION

QoL after continent diversion has not been confirmed to be better than after incontinent diversion; this observation makes the choice of urinary diversion a difficult and challenging one for the patient and clinician. The development of patient decision tools might help to improve the process of selecting appropriate bladder cancer treatments, including the choice of urinary diversion, for individual patients. There are many reported in prostate cancer on which to draw upon to begin to understand the needs of cancer survivors and ways to study the specific needs of bladder cancer patients and survivors. Urologists, outcomes researchers and patient educators all have important roles in helping patients make decisions that: (i) take into account patient preferences and values; (ii) are based on clearly presented information about treatment options, clinical outcomes and survivorship concerns; and (iii) involve healthcare providers in a conversation that can lead to shared decision-making. Patients need our help in understanding how to live with the physical and psychosocial burden of their cancer diagnosis and treatment-related side-effects. To further our understanding, we will also have the challenge of working with policy makers and funders to ensure that more money is available to support the development of patient-centred programmes in this understudied area of cancer decision-making and survivorship.

ACKNOWLEDGEMENTS

This material is the result of work supported with resources and the use of facilities at the Houston Center for Quality of Care & Utilization Studies, Michael E. DeBakey Veterans Affairs Medical Center. Dr Latini is supported by Mentored Research Scholar Grant 06-083-01-CPPB from the American Cancer Society. The authors thank Sonora Hudson, MA for her editorial assistance with this manuscript.

CONFLICT OF INTEREST

David M. Latini is funded by a Career Development Award from the American Cancer Society.

REFERENCES

- 1 Gerharz EW, Mansson A, Hunt S, Skinner EC, Mansson W. Quality of life after cystectomy and urinary diversion: an evidence based analysis. *J Urol* 2005; **174**: 1729-36
- 2 Hautmann RE, Abol-Enein H, Hafez K *et al*. World Health Organization Consensus Conference on Bladder Urinary diversion. *Urology* 2007; **69** (Suppl.): 17-49
- 3 Gerharz EW, Mansson A, Mansson W. Quality of life in patients with bladder cancer. *Urol Oncol* 2005; **23**: 201-7
- 4 Parkinson JP, Konety BR. Health related quality of life assessments for patients with bladder cancer. *J Urol* 2004; **172**: 2130-6
- 5 Porter MP, Wei JT, Penson DF. Quality of life issues in bladder cancer patients following cystectomy and urinary diversion. *Urol Clin North Am* 2005; **32**: 207-16
- 6 Wright JL, Porter MP. Quality-of-life assessment in patients with bladder cancer. *Nat Clin Pract Urol* 2007; **4**: 147-54
- 7 Horn SD, Gassaway J. Practice-based evidence study design for comparative effectiveness research. *Med Care* 2007; **45** (Suppl. 2): S50-7
- 8 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
- 9 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**: 1926-30
- 10 Cella DF, Tulsky DS, Gray G *et al*. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. *J Clin Oncol* 1993; **11**: 570-9
- 11 Cella DF. *FACIT Manual; Manual of the Functional Assessment of Chronic Illness Therapy (FACIT) Scales*. Evanston, IL:

- Evanston Northwestern Healthcare and Northwestern University, 1997
- 12 **Gilbert SM, Wood JD, Dunn RL et al.** Measuring health-related quality of life outcomes in bladder cancer patients using the newly validated bladder cancer index (BCI). *Cancer* 2007; **109**: 1756–62
 - 13 **Aaronson NK, Ahmedzai S, Bergman B et al.** The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993; **85**: 365–76
 - 14 **Ware JE Jr, Sherbourne CD.** The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992; **30**: 473–83
 - 15 **Dutta SC, Chang SC, 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**: 164–7
 - 16 **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 bladder replacement. *BJU Int* 2002; **89**: 10–3
 - 17 **Hobisch A, Tosun K, Kinzl J et al.** Life after cystectomy and orthotopic neobladder versus ileal conduit urinary diversion. *Semin Urol Oncol* 2001; **19**: 18–23
 - 18 **Kulaksizoglu H, Toktas G, Kulaksizoglu IB, Aglamis E, Unluer E.** When should quality of life be measured after radical cystectomy? *Eur Urol* 2002; **42**: 350–5
 - 19 **Mansson A, Henningsohn L, Steineck G, Mansson W.** Neutral third party versus treating institution for evaluating quality of life after radical cystectomy. *Eur Urol* 2004; **46**: 195–9
 - 20 **Whitmore WF Jr, Marshall VF.** Radical total cystectomy for cancer of the bladder: 230 consecutive cases five years later. *J Urol* 1962; **87**: 853–68
 - 21 **Mansson A, Colleen S, Hermeren G, Johnson G.** Which patients will benefit from psychosocial intervention after cystectomy for bladder cancer? *Br J Urol* 1997; **80**: 50–7
 - 22 **Institute of Medicine.** Executive Summary. In Hewitt M, Greenfield S, Stovall E eds, *From Cancer Patient to Cancer Survivor: Lost in Transition*. Washington, DC: National Academies Press, 2005: 1–15
 - 23 **Institute of Medicine.** *Implementing Cancer Survivorship Care Planning*. Washington, DC: National Academies Press, 2007
 - 24 **Porter MP, Wei JT, Penson DF.** Quality of life issues in bladder cancer patients following cystectomy and urinary diversion. *Urol Clin North Am* 2005; **32**: 207–16
 - 25 **Zippe CD, Raina R, Shah AD et al.** Female sexual dysfunction after radical cystectomy: a new outcome measure. *Urology* 2004; **63**: 1153–7
 - 26 **Kessler TM, Burkhard FC, Perimenis P et al.** Attempted nerve sparing surgery and age have a significant effect on urinary continence and erectile function after radical cystoprostatectomy and ileal orthotopic bladder substitution. *J Urol* 2004; **172**: 1323–7
 - 27 **Fokdal L, Hoyer M, von der Maase H.** Treatment outcome and prognostic variables for local control and survival in patients receiving radical radiotherapy for urinary bladder cancer. *Acta Oncol* 2004; **43**: 749–57
 - 28 **Institute of Medicine.** *Cancer Care for the Whole Patient. Meeting Psychosocial Health Needs*. Washington, DC: National Academies Press, 2007
 - 29 **Karakiewicz PI, Shariat SF, Palapattu GS et al.** Nomogram for predicting disease recurrence after radical cystectomy for transitional cell carcinoma of the bladder. *J Urol* 2006; **176**: 1354–61
 - 30 **Bochner BH, Kattan MW, Vora KC.** Postoperative nomogram predicting risk of recurrence after radical cystectomy for bladder cancer. *J Clin Oncol* 2006; **24**: 3967–72
 - 31 **Ahlers-Schmidt CR, Golbeck AL, Paschal AM, Zackula R, Taylor NT.** Breast cancer counts: numeracy in breast cancer information on the Web. *J Cancer Educ* 2006; **21**: 95–8
 - 32 **NexProfiler Treatment Options Tool for Bladder Cancer** [database on the Internet]. 2008. Available at: <http://www.cancer.nexcura.com/Secure/InterfaceSecure.asp?CB=269>. Accessed 15 January 2008
 - 33 **Black PC, Penson DF.** Prostate cancer on the Internet – information or misinformation? *J Urol* 2006; **175**: 1836–42
 - 34 **Lee CT, Smith CA, Hall JM, Waters WB, Biermann JS.** Bladder cancer facts: accuracy of information on the Internet. *J Urol* 2003; **170**: 1756–60
 - 35 **Elwyn G, O'Connor A, Stacey D et al.** Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ* 2006; **333**: 417
 - 36 **Elstein AS, Chapman GB, Knight SJ.** Patients' values and clinical substituted judgments: the case of localized prostate cancer. *Health Psychol* 2005; **24** (4 Suppl.): S85–92
 - 37 **Knight SJ, Latini DM, Chren MM.** Patient preferences for prostate cancer care. Measurement in ethnically diverse populations. *Ann Behav Med* 2005; **29** (Suppl.): S110
 - 38 **Ratzan SC, Parker RM.** Introduction. In Selden CR, Zorn M, Ratzan SC, Parker RM eds, *National Library of Medicine Current Bibliographies in Medicine: Health Literacy*. Bethesda, MD: National Institutes of Health, US Department of Health and Human Services, 2000: v–vi
 - 39 **Baker DW, Gazmararian JA, Williams MV et al.** Functional health literacy and the risk of hospital admission among Medicare managed care enrollees. *Am J Public Health* 2002; **92**: 1278–83
 - 40 **Bennett CL, Ferreira MR, Davis TC et al.** Relation between literacy, race, and stage of presentation among low-income patients with prostate cancer. *J Clin Oncol* 1998; **16**: 3101–4
 - 41 **Kutner M, Greenberg E, Jin Y, Paulsen C.** *The Health Literacy of America's Adults: Results from the 2003 National Assessment of Adult Literacy*. Washington, DC: US Department of Education National Center for Education Statistics, 2006
 - 42 **Nielsen ME, Shariat SF, Karakiewicz PI et al.** Advanced age is associated with poorer bladder cancer-specific survival in patients treated with radical cystectomy. *Eur Urol* 2007; **51**: 699–706
 - 43 **Lee CT, Dunn RL, Williams C, Underwood W 3rd.** Racial disparity in bladder cancer: trends in tumor presentation at diagnosis. *J Urol* 2006; **176**: 927–33
 - 44 **Konety BR, Allareddy V, Carroll PR.** Factors affecting outcomes after radical cystectomy in African Americans. *Cancer* 2007; **109**: 542–8
 - 45 **Doak CC, Doak LG, Root JH.** *Teaching Patients with Low Literacy Skills*, 2nd edn. Philadelphia: JB Lippincott Co, 1996

Correspondence: Cheryl T. Lee, Associate Professor of Urology, University of Michigan, 1500 E. Medical Center Dr, CCGC 7303, Ann Arbor, MI 48109, USA.
e-mail: ctlee@umich.edu

Abbreviations: **QoL**, quality of life; **BCI**, Bladder Cancer Index; **EORTC**, European Organization for the Research and Treatment of Cancer; **QLQ-C30**, EORTC Quality-of-Life Core Questionnaire; **FACT**, Functional

Assessment of Incontinence Therapy; **SIP**, Sickness-Impact Profile; **MCT**, meta-contrast technique; **IOM**, Institute of Medicine; **IPDAS**, International Patient Decision Aids Standards.