

Outcomes/Epidemiology/Socioeconomics

HEALTH RELATED QUALITY OF LIFE AFTER ORTHOTOPIC NEOBLADDER CONSTRUCTION AND ITS COMPARISON WITH NORMATIVE VALUES IN THE JAPANESE POPULATION

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ABSTRACT

Purpose: We report the difference in quality of life (QOL) between patients with an orthotopic neobladder and normative values in the age matched Japanese population.

Materials and Methods: Between November 1996 and June 2003, 75 patients underwent orthotopic neobladder construction at our institution, of whom 47 males and 9 females were enrolled in this study. A total of 19 patients were excluded because of death or insufficient followup (less than 6 months). Two types of questionnaire, namely the RAND 36-Item Health Survey, version 2 and the Functional Assessment of Cancer Therapy-Bladder Cancer, were mailed to all 56 patients. The 48 patients (86%) who returned the completed forms were included in our analysis. Postoperative QOL was compared with age matched normative values in the control Japanese population.

Results: Overall there was no significant difference in any scale between patients with a neobladder and the age matched control Japanese population. The patient bodily pain score in the seventh decade of life and the role-physical score in those older than 70 years were better than age matched normative values in the Japanese population ($p < 0.005$ and $p < 0.05$, respectively). Male patients in the seventh decade of life were more likely to have better QOL in the physical functioning, role-physical and role-emotional subscales in addition to the bodily pain subscale compared to age matched control values ($p < 0.05$, < 0.05 , < 0.001 and < 0.001 , respectively). Likewise in male patients older than 70 years role-physical scores remained better than age matched normative values in the Japanese population ($p < 0.01$). Further analysis of bladder cancer related QOL showed that patients followed more than 24 months were more likely to have a lower incontinence score than those followed less than 24 months ($p < 0.05$). In addition, the continence related QOL change alone did not affect any health related QOL scales, as analyzed by RAND 36-Item Health Survey.

Conclusions: Our study shows that there is no essential difference in health related QOL between patients with a neobladder and the age matched Japanese control population. The current results provide some primary evidence to help in decision making and eliminate potential anxiety about worse QOL after cystectomy.

KEY WORDS: urinary diversion, quality of life, questionnaires, Asian continental ancestry group, cystectomy

Orthotopic neobladder construction has enabled patients to maintain voluntary voiding after cystectomy through the urethra without any urinary stoma requiring a specific appliance. However, in addition to problems related to micturition and urinary continence, health related quality of life (QOL) after surgery appears to be another important issue in the decision making process of urinary diversion following cystectomy. Potential changes in health related QOL after cystectomy with urinary diversion could affect the decision making process in terms of which would be suitable and/or desirable in individuals. Recently several groups analyzed QOL in patients with total cystectomy and subsequent orthotopic neobladder construction using certain question-

naires,^{1–3} in which orthotopic neobladder QOL was compared to that of different types of urinary diversion. Using a sickness impact profile⁴ we noted that surgical impact on QOL in patients with a neobladder appeared to be less significant than what we had expected, ie mental, physical and social functioning related QOL was better in those with a neobladder than in those with an ileal conduit. Based on this result the assessment of health related QOL appears to be essential and realistic compared with that in the age matched healthy population.

In the literature only 1 study is available on the difference in QOL between the neobladder and age matched normal populations.⁵ Unfortunately this study was not done using a universal questionnaire that is validated and used extensively throughout the world. Although several questionnaires on QOL assessment are available in the literature, the validity and reliability of the RAND 36-Item Health Survey

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(SF-36) have been confirmed to assess general health related QOL.⁶ SF-36 has been extensively used throughout the world⁷ to evaluate comprehensive QOL in patients with a neobladder and/or other types of urinary diversion.⁸ In addition, standard QOL values in the Japanese population using SF-36, version 2 were published as a population based score and SF-36 health related QOL survey results in the neobladder and age matched normative populations appear to be fully comparable.⁹ On the other hand, the Functional Assessment of Cancer Therapy (FACT)-General (G) is a generic tool for analyzing QOL that was developed by Webster et al.¹⁰ In this FACT system several disease specific subscales are available for patients with breast, lung and bladder cancer, of which FACT-Bladder (Bl) is a questionnaire especially designed for patients with bladder cancer.¹¹ In this study to achieve more profound insight into changes in health related QOL after neobladder construction postoperative QOL was compared to that in the age matched Japanese population using SF-36, version 2.⁷ In addition, the relationship between disease specific QOL analyzed by FACT-Bl, especially focusing on continence status and health related QOL in patients with a neobladder, was also evaluated.

MATERIALS AND METHODS

Between November 1996 and June 2003, 75 patients underwent orthotopic neobladder construction at our institution, of whom 47 males and 9 females were selected for study. The remaining 19 patients, who were dead or followed less than 6 months after surgery, were excluded.

SF-36, version 2 and FACT-Bl were mailed to all 56 patients as a self-reporting survey and 48 (86%) who returned the completed forms were included in this analysis. The preoperative diagnosis was bladder cancer in 46 cases, and bladder sarcoma and urachal cancer in 1 each. No patients experienced any form of recurrence in this study. The modified Studer technique was used in all except 1 patient, in whom the Hautmann technique was used.^{12,13} Mean patient age at surgery and QOL assessment was 65.6 (range 29 to 76) and 69.3 years (range 35 to 80), respectively. Mean followup was 51.6 months (range 7 to 86). Patients were divided into subgroups according to age and sex, and postoperative QOL was compared with Japanese population normative values.

SF-36, version 2 comprises 8 scales of health related QOL, namely physical functioning, role-physical functioning, bodily pain, general health, vitality, social functioning, role-emotional functioning and mental health. A score of 0 to 100 was assigned for each question and the mean score of each scale was then calculated. A higher score on each question implies better QOL. Patients were divided into 3 subgroups according to the age, ie 50 to 59, 60 to 69 and older than 70 years, since age is a potential factor that could contribute to health related QOL. In this study we analyzed the difference in the mean score of each scale between the orthotopic neobladder and age matched control Japanese populations.

In addition, FACT-Bl is a questionnaire especially designed for patients with bladder cancer that comprises 10 items, including urinary tract, intestinal and sexual symptoms.¹¹ We evaluated disease specific QOL in patients with a neobladder using FACT-Bl, especially focusing on incontinence related QOL. SF-36 scales in the orthotopic neobladder and age matched Japanese populations were analyzed using the 1-sample t test. The relationship between FACT-Bl (urinary incontinence item) and SF-36 scales was statistically analyzed using the unpaired t test. The association of followup with FACT-Bl urinary incontinence related QOL was statistically evaluated using the chi-square test with $p < 0.05$ considered statistically significant.

TABLE 1. Health related QOL evaluated by SF-36 and FACT-G

SF-36 Subscale	Coefficient	p Value	95% CI
Physical functioning	0.489	0.0018	0.196–0.702
Role-physical	0.422	0.0070	0.122–0.651
Bodily pain	0.455	0.0038	0.157–0.675
General health	0.456	0.0036	0.160–0.677
Vitality	0.386	0.0145	0.081–0.626
Social functioning	0.352	0.0274	0.041–0.601
Role-emotional	0.331	0.0391	0.017–0.585
Mental health	0.572	<0.0001	0.312–0.752

RESULTS

We analyzed the association of SF-36 and FACT-G to verify the potential significance of SF-36 as an adequate instrument for postoperative health related QOL. Table 1 shows that correlating FACT-G with each SF-36 scale attained statistical significance.

Mean values of the 8 scales in patients with an orthotopic neobladder and the age matched Japanese population were compared. Table 2 lists SF-36 survey data. Overall there was no significant difference in any SF-36 scales between patients with an orthotopic neobladder and the age matched Japanese population. Likewise 50 to 59-year-old patients showed no significant difference in any SF-36 scale vs the age matched Japanese population. In 60 to 69-year-old patients the mean bodily pain value was significantly higher than in the age matched Japanese population ($p < 0.01$). On the other hand, patients older than 70 years were more likely to have a lower role-physical score than the age matched Japanese population ($p < 0.05$).

Table 3 shows that QOL analysis in 50 to 59-year-old male patients revealed no significant difference in SF-36 QOL items between the neobladder and control Japanese populations. On the contrary, 60 to 69-year-old male patients with a neobladder were more likely to have better QOL in physical functioning, role-physical and role-emotional besides bodily pain than the age matched control ($p < 0.05$, < 0.05 , < 0.001 and < 0.001 , respectively). In male patients older than 70 years role-physical related QOL remained better than in the age matched Japanese population ($p < 0.01$).

Table 4 shows the effect of the postoperative period on continence related QOL, as analyzed by FACT-Bl. Patients with a neobladder who were followed more than 24 months were more likely to have a lower FACT-Bl incontinence score than those followed less than 24 months ($p < 0.05$). On the other hand, the continence related QOL alteration alone did not appear to affect health related QOL, as analyzed by SF-36 (see figure).

DISCUSSION

Previously groups have discussed the issue of health related QOL in patients with an orthotopic neobladder and other types of urinary diversion, that is an ileal conduit or continent urinary reservoir. Hart et al compared long-term QOL outcomes in patients with an ileal conduit, cutaneous Kock pouch and urethral Kock pouch,¹ while Kitamura et al compared QOL in patients with an ileal or colon conduit, continent urinary reservoir and ileal neobladder.² In these 2 reports in which a validated survey was not done no significant difference was observed in QOL among the types of urinary diversion. Previously we have analyzed the effects of an orthotopic neobladder and ileal conduit on health related QOL using the sickness impact profile and found that mental, physical and social functioning QOL was better for the neobladder than for the ileal conduit.⁴ Likewise Weijerman et al reported that orthotopic replacement offers a minimum but significant advantage of QOL over heterotopic substitution.³ Using SF-36 Fujisawa et al compared QOL in patients with an neobladder and ileal conduit, and noted that role-

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