Quality of life in patients with ileal conduit cystectomy due to bladder cancer


Servicio de Urología, Unidad de Urooncología, Hospital Universitario 12 de Octubre, Madrid, Spain

Received 20 February 2013; accepted 21 April 2013
Available online 25 November 2013

**KEYWORDS**
Quality of life; Cystectomy; Ileal conduit; EuroQol 5-D-3L

**Abstract**
Objective: To determine the variables that affect quality of life of patients treated by radical cystectomy with ileal conduit.

Material and method: We analyzed quality of life using the EQ-5D-3L questionnaire. This questionnaire evaluates mobility, personal care, daily activities, pain/discomfort, anxiety/depression and a self-rating scale of the health condition. We compared the result with demographic variables (gender, age, work situation, studies, income, partner) and clinical variables (AJA classification, tumor stage, time since cystectomy was performed, adjuvant chemotherapy, recurrent and complications of the stoma). The statistical analysis included a descriptive study, univariate and multivariate analysis.

Results: A total of 59 patients were included in the study, with a mean age of 69 years (47–84). Mean time from cystectomy was 43 months (12–83), with 61% complications associated to the stoma.

Stoma complications were related with limitations in personal care, pain/discomfort, anxiety, depression and quality of life in general. Female gender was associated with limitations in daily activities and adjuvant chemotherapy with anxiety/depression and quality of life in general. The rest of the variables were not statistically significant in the multivariate analysis.

Conclusions: The limitations in quality of life in patients with cystectomy and ileal conduit are associated with the stoma-associated complications. Other related variables are female gender and administration of adjuvant chemotherapy.

© 2013 AEU. Published by Elsevier España, S.L. All rights reserved.
Introduction

Radical cystectomy is the treatment of choice in patients with invasive bladder cancer and high-grade superficial tumors, with significant risk of progression. Among the urinary diversions used after cystectomy, ileal conduit is not only the most performed non-continent diversion, but despite the introduction of bladder replacement techniques, it is still the most used diversion.

It is justified not only by reasons related to the patient’s disease, but also by demographic, socioeconomic reasons and preferences of the patient or the surgeon. Currently, the superiority of the continent diversions on the ileal conduit has not been demonstrated in any randomized or quasi-randomized clinical trial, the same as when we talk about quality of life, we cannot say that a diversion is better than another.

Patients with cystectomy and ileal conduit type diversion may have a worsening in their quality of life. However, there are multiple aspects that influence, including economic, social, and cultural determinants, as well as those related to the patient’s disease and the diversion used. Furthermore, most of the data related to the quality of life in patients undergoing cystectomy refer to studies conducted in Anglo-Saxon countries, so the findings may not be applicable to our population.

Thus, in this study, we tried to determine the importance, in our environment, of the different factors that can influence the quality of life of patients undergoing cystectomy for bladder cancer, with ileal conduit type diversion. Apart from issues related to the type of diversion (stoma complications), we included tumor characteristics, adjuvant treatments and comorbidities, and different socio-economic aspects.

Material and methods

Selection of the patients

We included patients treated with radical cystectomy who underwent an ileal conduit as urinary diversion in our department between January 2005 and June 2011, with a minimum interval between the cystectomy and the study of 12 months. The indication for cystectomy was in all cases presenting an invasive bladder cancer or high-grade superficial tumor, with significant risk of progression. The type of urinary diversion was decided according to the tumor characteristics (presence of involvement of the prostatic urethra in males or the bladder neck in females), as well as taking into account the medical contraindications for performing a neobladder. After evaluating all these factors, we discussed with the patient the advantages and disadvantages of the possible diversions, so that they could decide which one they preferred.

We excluded those patients who underwent ileal conduit only without cystectomy (diversion for mitigation), which was performed due to non-tumor cause and those with a follow-up shorter than 12 months.

Quality of life assessment

We used the validated Spanish version of the EuroQol 5-D-3L questionnaire. It consists of a descriptive system of health status with 5 dimensions: mobility, self-care, daily...
activities, pain/discomfort, and anxiety/depression. Each of them has 3 items, which define 3 levels of quality of life, from 1 (best quality of life) to 3 (worst quality of life). It also includes a visual analog scale of self-assessment of the health status, with scores ranging from 0 (worst possible health status) to 100 (best possible health status). For its statistical analysis, we turned the response to each of the 5 dimensions into a dichotomous variable, without problems (level 1) or with problems (levels 2 and 3). The result of the visual analog scale was treated as a quantitative variable.

The questionnaire was given to the patient in the Urology Office after explaining the objectives of the study and obtaining their consent to participate. After its completion, it was picked up by the doctor of the office, as well as the data on the clinical and socioeconomic variables. All these data were included in the study database anonymously, for later analysis.

**Variables analyzed**

We included sociodemographic variables of the patient and another group related to clinical aspects. Among the sociodemographic variables, we included gender, age, employment status (active worker, retired), level of education (illiteracy, primary, secondary, or higher studies), income (higher or lower than 1000 euros per month), and marital status (married or without regular partner).

In the clinical variables, we performed an assessment of the overall health status, using the scale of anesthetic risk (ASA), as well as tumor-associated factors (tumor stage after cystectomy, adjuvant chemotherapy, and active tumor disease at the time of the study) and with the diversion (elapsed time after surgery and complications related to the stoma).

For the statistical analysis, those qualitative variables with more than 2 possibilities were grouped to turn them into dichotomous variables. Thus, we grouped the scale of anesthetic risk (ASA I-II vs. ASA III-IV), level of education (illiteracy-primary vs. secondary-higher), tumor stage (pT0-2 NO vs. pT3-4 and/or N+) and recurrence (absence of this vs. local or distant recurrence).

**Statistical analysis**

For the statistical analysis we used the SPSS 15.0 program, including a descriptive analysis of the series, univariate study of each of the variables using Chi-square test, comparison of means and Pearson correlation coefficient, and multivariate analysis (linear logistic regression), considering $p < 0.05$ and 95% confidence intervals as statistical significance level.

**Results**

Between January 2005 and June 2011, 161 radical cystectomies were performed for bladder cancer in our center. The ileal conduit was the most used diversion in 138 patients, of whom 59 were included in the study. Of the 79 patients not included, 71 had died at the time of conducting the study (43 from progression of their bladder tumor and 28 from other causes), 2 patients refused to participate, and one could not do so due to physical disability from stroke.

The average age of the patients is 69 years (47–84 years), predominantly males (50 men vs. 9 women), with a mean time elapsed since the cystectomy of 43 months (12–83 months), including the rest of the characteristics of the series in Table 1. The complications related to the stoma occurred in 36 patients (61%), mostly mild, although the presence of 6 cases with stoma retraction stand out, which required the use of adapted collection devices, 4 stoma

### Table 1 Characteristics of the series.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age; years</strong></td>
<td>69 (47–84 years)</td>
</tr>
<tr>
<td><strong>Time elapsed after cystectomy; months</strong></td>
<td>43 months (12–83 months)</td>
</tr>
<tr>
<td><strong>Sex; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>Man</td>
<td>50 (84.7%)</td>
</tr>
<tr>
<td>Woman</td>
<td>9 (15.3%)</td>
</tr>
<tr>
<td><strong>ASA; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>ASA I</td>
<td>36 (61%)</td>
</tr>
<tr>
<td>ASA II</td>
<td>23 (39%)</td>
</tr>
<tr>
<td><strong>Employment status; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>4 (6.8%)</td>
</tr>
<tr>
<td>Retired</td>
<td>55 (93.2%)</td>
</tr>
<tr>
<td><strong>Level of education; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>Elementary-basic</td>
<td>45 (76.2%)</td>
</tr>
<tr>
<td>Intermediate-higher</td>
<td>14 (23.8%)</td>
</tr>
<tr>
<td><strong>Monthly income; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>Less than 1000 €</td>
<td>36 (61%)</td>
</tr>
<tr>
<td>More than 1000 €</td>
<td>23 (61%)</td>
</tr>
<tr>
<td><strong>Marital status; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>With regular partner</td>
<td>47 (79.7%)</td>
</tr>
<tr>
<td>With no regular partner</td>
<td>12 (20.3%)</td>
</tr>
<tr>
<td><strong>Tumor stage (pT); (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>pT0</td>
<td>16 (27.1%)</td>
</tr>
<tr>
<td>pT1</td>
<td>8 (13.6%)</td>
</tr>
<tr>
<td>pT2</td>
<td>17 (28.8%)</td>
</tr>
<tr>
<td>pT3</td>
<td>14 (23.7%)</td>
</tr>
<tr>
<td>pT4</td>
<td>4 (6.8%)</td>
</tr>
<tr>
<td><strong>Lymph node involvement (pN); (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>pN0</td>
<td>44 (74.6%)</td>
</tr>
<tr>
<td>pN1</td>
<td>8 (13.6%)</td>
</tr>
<tr>
<td>pNx</td>
<td>7 (11.9%)</td>
</tr>
<tr>
<td><strong>Adjuvant chemotherapy; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19 (32.2%)</td>
</tr>
<tr>
<td>No</td>
<td>40 (67.8%)</td>
</tr>
<tr>
<td><strong>Presence of recurrence; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>53 (89.8%)</td>
</tr>
<tr>
<td>Local</td>
<td>3 (5.1%)</td>
</tr>
<tr>
<td>Distant</td>
<td>3 (5.1%)</td>
</tr>
<tr>
<td><strong>Complications of the stoma; (n, %)</strong></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>23 (39%)</td>
</tr>
<tr>
<td>Yes</td>
<td>61 (61%)</td>
</tr>
</tbody>
</table>


significant, chemotherapy

95%

associated

activities

personal

have
to

visual

tomy

range

scale,

Multivariate

Univariate

stenoses treated with dilations, and 6 patients with parastomal hernia (2 cases surgically corrected). The rest of complications are specified in Table 2.

All 59 patients responded to all the sections of the EuroQol-5-D-3L questionnaire (Table 3). In terms of the perceived quality of life, expressed using a visual analog scale, the mean score obtained was 70.08 ± 19.1 SD, with a range between 20 and 100.

### Univariate analysis

Neither the patient age nor the time elapsed after cystectomy was related to any of the parameters of quality of life. Regarding the remaining variables, the results are detailed in Table 4. The quality of life measured by means of the visual analog scale showed association only, statistically significant, with adjuvant chemotherapy and the complications related to the stoma. The patients who had received adjuvant chemotherapy had an average score of 61 compared to 74.3 in those who had not received it (p = 0.01, 95% CI: 3.5–23.4). Similarly, the patients with stoma complications have a lower average score (62) than those without such complications (82.6), with a p < 0.001 and 95% CI: 11.7–29.2.

### Multivariate analysis

As we can see in Table 5, in the section of mobility, none of the factors analyzed showed statistical significance. In personal care, we did find an association between significant problems and having stoma complications (p = 0.049; 95% CI: 0.001–0.37). The presence of limitations in daily activities were associated with female sex, with a p = 0.019 (95% CI: 0.078–0.834). The stoma complications were also associated with the presence of pain/discomfort (p = 0.002; 95% CI: 0.17–0.71), and with anxiety/depression (p = 0.029; 95% CI: 0.03–0.59). Furthermore, the anxiety/depression section was also associated with adjuvant treatment with chemotherapy (p = 0.045; 95% CI: 0.01–0.84).

As for the overall assessment of the quality of life, we found a statistically significant association with adjuvant chemotherapy (p = 0.40; 95% CI: −29.1 to −0.7) and the complications associated with the stoma (p < 0.001; 95% CI: −30.7 to −11.5).

### Discussion

The WHO defines quality of life as the perception that an individual has of their place in existence, in the context of the culture and system of values in which they live and in relation to their expectations, standards and concerns. It is a very broad concept, but that we can reduce when we talk about the quality of life related to health. Here we include aspects such as functional capacity, symptoms, self-perceived health, social and psychological welfare, cognitive function, daily activities, and satisfaction with the care received. This makes it necessary to identify the factors that influence the quality of life of our patients since the results obtained in other populations may not apply to them.

One of the limitations of the study is the failure to include patients with orthotopic diversions, since the type of diversion might influence the quality of life. This is due to the small number of orthotopic diversions performed in the period of time analyzed and to the selection of younger patients and with better functional status. There are few studies that showed improved quality of life in patients with neobladders versus those with ileal conduit, and they lack an assessment before surgery, so the results could be biased by choosing patients in better condition to perform neobladders.

In the Spanish population, 2 studies have been published examining the quality of life in patients with radical cystectomy. Conde et al. used a non-validated questionnaire of 45 questions. They found better quality in patients with neobladders in areas such as urinary continence, ability to travel, less anxiety, and better information about its diversion. However, the number of patients with ileal conduit is scarce, with a significant percentage of urine leaks (83 vs. 23% in our series), and problems with the skin of the stoma (60 vs. 35% in our study). They found no differences in the perception of body image; in both types of diversion the patients feel less attractive, more insecure, they do not get naked as naturally, and they have equally decreased physical contact with others.

Salinas et al. used the SF-36 questionnaire in patients with skin stoma (ileal conduit and cutaneous ureterostomy) and internal diversions (bladder substitution and ureterostomy). No differences were found in the quality of life between the different types of diversion. A better outcome was shown indeed in younger patients, without associated chronic diseases, lower tumor stages, social

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Complications associated with the stoma.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. cases</td>
</tr>
<tr>
<td>Urinary infections</td>
<td>20</td>
</tr>
<tr>
<td>Retraction of the stoma</td>
<td>6</td>
</tr>
<tr>
<td>Peristomal dermatitis</td>
<td>21</td>
</tr>
<tr>
<td>Parastomal hernia</td>
<td>6</td>
</tr>
<tr>
<td>Excessive production of mucus</td>
<td>5</td>
</tr>
<tr>
<td>Bleeding</td>
<td>10</td>
</tr>
<tr>
<td>Stenosis of the stoma</td>
<td>4</td>
</tr>
<tr>
<td>Urine leaks</td>
<td>14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Results of EuroQol-5-D-3L, indicating in number of patients in each section of the questionnaire.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mobility</td>
</tr>
<tr>
<td>Without problems</td>
<td>45</td>
</tr>
<tr>
<td>Some problems</td>
<td>14</td>
</tr>
<tr>
<td>Relevant problems</td>
<td>0</td>
</tr>
</tbody>
</table>
classes IV (skilled manual worker) and VI (housewife) and with fewer postoperative complications. As in our study, the patients with more postoperative complications have worse quality of life, although in the study by Salinas, complications associated with the stoma are not specified. However, we found no association between quality of life and age, associated disease, tumor stage, educational level, occupational activity, or income.

The EuroQol-5D-3L questionnaire offers different advantages; it is short and easy to fill in, with an administration time of approximately 2–3 min. This is important, because our patients are usually older, and this simplicity has a positive impact on the quantity and quality of the data collected, reducing the number of lost or wrong responses. As a disadvantage, within its dimensions, there is no assessment of body image. The patients with radical cystectomy have impaired perception of their body image that improves over time as they adapt to new habits. Despite what one might assume, this impairment is not greater in patients with skin stoma when compared with those who have undergone a neobladder. When we analyze the factors that influence the quality of life, we find that none of them is related to mobility. It is probably due to the fact that no patient had major problems in this dimension. The female sex is associated with the limitations in performing daily activities, which might be associated with greater participation in housework.

In patients with stages T3–T4 or lymph node involvement, adjuvant chemotherapy is indicated. We use a combination of cisplatin and gemcitabine or, alternatively, carboplatin and gemcitabine. In these patients, we found a relationship with mood disorders and an overall decrease in their quality of life. These results do not correspond either with the tumor stage or with the presence of recurrence. Therefore, we assume that the treatment with chemotherapy causes the patient to have a more negative view of their disease.

The complications related to the stoma are the most important factor in the quality of life of our patients. They are associated with problems in personal care, with the presence of pain/discomfort and anxiety/depression and poorer overall quality of life. Within these, retraction, stenosis,

Table 4 Univariate analysis of each of the 5 dimensions of the EuroQol 5-D-3L questionnaire.

<table>
<thead>
<tr>
<th></th>
<th>Mobility</th>
<th>Personal care</th>
<th>Daily activities</th>
<th>Pain/discomfort</th>
<th>Anxiety/depression</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20 vs 44%</td>
<td>12 vs 11%</td>
<td>32 vs 88%</td>
<td>24 vs 55%</td>
<td>40 vs 88%</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>p = 0.11</td>
<td>p = 0.93</td>
<td>p = 0.005</td>
<td>p = 0.03</td>
</tr>
<tr>
<td><strong>ASA</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>19 vs 26%</td>
<td>11 vs 8%</td>
<td>38 vs 39%</td>
<td>27 vs 30%</td>
<td>41 vs 52%</td>
</tr>
<tr>
<td>II</td>
<td></td>
<td>p = 0.48</td>
<td>p = 0.93</td>
<td>p = 0.26</td>
<td>p = 0.46</td>
</tr>
<tr>
<td>III–IV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Employment status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Retired</td>
<td>25 vs 0%</td>
<td>12 vs 0%</td>
<td>40 vs 50%</td>
<td>29 vs 25%</td>
<td>49 vs 25%</td>
</tr>
<tr>
<td>Active</td>
<td></td>
<td>p = 0.24</td>
<td>p = 0.82</td>
<td>p = 0.42</td>
<td>p = 0.6</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elem-basic.</td>
<td>26 vs 14%</td>
<td>13 vs 7%</td>
<td>40 vs 42%</td>
<td>33 vs 14%</td>
<td>53 vs 28%</td>
</tr>
<tr>
<td>Int-univ.</td>
<td></td>
<td>p = 0.34</td>
<td>p = 0.53</td>
<td>p = 0.36</td>
<td>p = 0.25</td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1000 €</td>
<td>27 vs 17%</td>
<td>13 vs 8%</td>
<td>52 vs 21%</td>
<td>38 vs 13%</td>
<td>58 vs 30%</td>
</tr>
<tr>
<td>&gt;1000 €</td>
<td></td>
<td>p = 0.36</td>
<td>p = 0.54</td>
<td>p = 0.05</td>
<td>p = 0.1</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With a partner</td>
<td>23 vs 25%</td>
<td>12 vs 8%</td>
<td>31 vs 75%</td>
<td>27 vs 33%</td>
<td>44 vs 58%</td>
</tr>
<tr>
<td>Without a partner</td>
<td></td>
<td>p = 0.9</td>
<td>p = 0.67</td>
<td>p = 0.02</td>
<td>p = 0.005</td>
</tr>
<tr>
<td><strong>Stage</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Localized</td>
<td>18 vs 33%</td>
<td>13 vs 9%</td>
<td>39 vs 42%</td>
<td>26 vs 33%</td>
<td>39 vs 61%</td>
</tr>
<tr>
<td>Advanced</td>
<td></td>
<td>p = 0.19</td>
<td>p = 0.11</td>
<td>p = 0.89</td>
<td>p = 0.75</td>
</tr>
<tr>
<td><strong>Adjuvant chemotherapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>17 vs 36%</td>
<td>10 vs 15%</td>
<td>35 vs 52%</td>
<td>30 vs 31%</td>
<td>35 vs 73%</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>p = 0.1</td>
<td>p = 0.52</td>
<td>p = 0.42</td>
<td>p = 0.6</td>
</tr>
<tr>
<td><strong>Recurrence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>22 vs 33%</td>
<td>13 vs 0%</td>
<td>41 vs 33%</td>
<td>30 vs 16%</td>
<td>45 vs 66%</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>p = 0.56</td>
<td>p = 0.34</td>
<td>p = 0.85</td>
<td>p = 0.43</td>
</tr>
<tr>
<td><strong>Stoma complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>21 vs 25%</td>
<td>4 vs 16%</td>
<td>34 vs 44%</td>
<td>4 vs 44%</td>
<td>21 vs 63%</td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td>p = 0.77</td>
<td>p = 0.15</td>
<td>p = 0.45</td>
<td>p = 0.003</td>
</tr>
</tbody>
</table>

The significant associations are in italic and underlined.
and prolapse of the stoma stand out, which may affect up to 25–30% of the patients.\textsuperscript{2,14} They are a common cause of reoperation and they significantly affect the patient’s lifestyle. Another common problem is the appearance of peristomal dermatitis, which relates to the leakage of urine due to poor adaptation of the external collecting device. It is important to consider that the stoma is the only part of the diversion that the patient can see and has to care for. Therefore, we must be very careful when we build a stoma, preoperatively assessing its correct location, as well as in each of the steps of the surgical technique, thereby reducing the incidence of these complications and improving the quality of life of our patients.

## Conclusions

The quality of life in patients with cystectomy and ileal conduit for bladder cancer is mainly affected by the presence of complications associated with cutaneous stoma. These affect personal care and they are associated with pain or discomfort and mood disorders (anxiety and depression), as well as a decrease in overall quality of life. Other factors include adjuvant chemotherapy (anxiety/depression and overall quality of life) and female sex (limitation in daily activities).

## Conflict of interest

The authors declare that they have no conflict of interest.

## References