Quality of Life in Elderly Patients with Urological Malignancies – A Review of Standard Questionnaires

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Abstract

Quality of life (QOL) is a very complex subject and is difficult to measure in elderly patients. Only a few tools have been validated in this population: the Medical Outcome Study Short Form 36 (SF-36) and the European Organisation for Research and Treatment of Cancer (EORTC) questionnaire QLQ-C30 with addition of the QLQ-ELD15 module. Other tools have been studied in genito-urinary tumours: the Functional Assessment of Cancer Therapy (FACT)-General (FACT-G) and specific tools adapted for use in patients with kidney and bladder cancers. Moreover, different tools must be used in different clinical settings, such as localised or castration-refractory prostate cancers.

Thus, there is an unmet need for both standardisation and co-ordination of QOL evaluation tools in genito-urinary cancers. The availability of good QOL tools would enable an increase in the efficiency of decision-making in these cancers where comparisons between the side effects of the different treatments are difficult.

Keywords

Oncogeriatry, elderly, genito-urinary cancers, quality of life, prostate cancer, bladder cancer, renal cancer, quality-of-life questionnaires

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The quality of life (QOL) of the sick is a very complex concept. Different definitions have been proposed: "Quality of life is the subjective evaluation of life as a whole"; and "Quality of life refers to patients’ appraisal of and satisfaction with their current level of functioning compared to what they perceived to be possible or ideal". The World Health Organization (WHO) has defined health as "A state of complete physical, mental and social wellbeing and not merely the absence of disease." In the cancer setting, quality of life is measured to evaluate the consequences of the disease itself and of management interventions. Generally, QOL assessment in elderly cancer patients follows the same rules as in the younger population. Nevertheless, in the elderly, cancer is often associated with other chronic conditions (heart, pulmonary, neurological or neuro-psychological diseases) that also affect QOL. These chronic conditions are associated with a global impairment of elderly patients’ health status that is better evaluated by the Comprehensive Geriatric Assessment (CGA) procedure.

Clinical research on QOL has rarely focused on elderly cancer patients; specific instruments have been developed but is not yet validated in this population. Quality of life can be assessed by either generic or highly specific instruments. The Medical Outcome Study Short Form 36 (SF-36), for instance, has been designed to measure the general impact of a wide range of medical conditions on QOL as a whole and the questionnaire has already been validated in the geriatric population. On the other hand, since the cancer-specific questionnaire of the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 has been developed, several other questionnaires specifically designed for particular types of cancers have been validated. Recently, a specific module for the assessment of QOL in elderly cancer patients, the QLQ-ELD15 questionnaire, has been published, though is not yet validated. We will review the background information on genito-urinary (GU) cancers and their clinical settings and the standard QOL questionnaires available for elderly cancer patients, namely the EORTC QLC-QC30 and SF-36 questionnaires and their use in elderly patients with GU cancers. Thereafter, we will review the current knowledge on QOL in elderly patients with specific GU cancers (prostate, bladder and renal cancers). As regards prostate cancers, we will focus on localised, hormone-sensitive (HSCP) and castration-resistant (CRCP) diseases. PubMed searches have been performed to retrieve the literature on the different tools available and to count the number of articles published in the different settings and to select those that seem relevant. We have searched the terms ‘quality of life’, ‘prostate cancer’, ‘bladder cancer’, ‘kidney or renal cancer’, ‘elderly’ and the different tool names used within the titles and/or titles and abstracts of the articles.

Genito-urinary Cancers in the Elderly

The characteristics of GU cancers and their clinical settings are shown in Table 1. Some observations deserve attention: the majority of prostate cancer patients are elderly, as are bladder cancer patients. The objectives of treatment vary with the type of cancer and the clinical setting. The majority of patients with prostate cancer have localised disease, for which treatment is curative; some patients...
with indolent prostate cancer may even not require radical treatment impacting QOL. On the contrary, metastatic prostate cancer is never curable and improving QOL is clearly the objective of palliative treatment. The prognosis of bladder cancer is poor in case of infiltrating disease that requires aggressive radical treatment with major QOL impact; metastatic disease is treated by chemotherapy, with only marginal results and major complications. Renal cancer is generally curable; only a few patients are likely to receive targeted drugs, which have a major impact on QOL. Finally, although many studies have focused primarily on the side effects of treatment, few have addressed the question of QOL assessment.

**Standard Quality of Life Questionnaires in Cancer Patients**

A number of QOL studies in cancer patients have used SF-36 or similar QOL scales, along with the Activity of Daily Living (ADL) index and other cognitive and functional measures, together with CGA. A correlation between self-rated Kaofsky Performance Status (KPS) and SF-36 has been shown. The EORTC Quality of Life Group has developed a QOL assessment tool combining a core module (QLQ-C30) and additional modules focused on different types of cancer. The QLQ-C30 tool has been shaped for use in patients involved in clinical trials. It is noteworthy that few elderly patients enter clinical trials. Therefore, the QLQ-C30 questionnaire has been designed and validated on populations of younger patients. On the other hand, the generic SF-36 questionnaire has been used in a broad range of populations. Previous studies have shown that the SF-36 is reliable and suitable for use with older adults. The Functional Assessment of Cancer Therapy (FACT)—General (FACT-G) is a 28-item questionnaire. Its ability to discriminate patients on the basis of stage of disease, performance status rating (PSR) and hospitalisation status supports its sensitivity. It has also been demonstrated that this sensitivity may change over time. The validity of measuring separate areas, or dimensions, of QOL is supported by the differential responsiveness of subscales when applied to patients with different physical, functional, social and emotional wellbeing. A PubMed search using the terms ‘FACT-G’ and ‘QLQ-C30’ yielded 20 articles, but only one of these focused specifically on elderly patients, though not patients with genito-urinary cancers, but with breast cancer. The authors examined all the studies published between 2000 and 2010 that also used other scales like SF-36 and the Hospital Anxiety and Depression Scale (HADS). The study did not compare the different scales for efficiency. The authors concluded that issues related to baseline co-morbidities in the frail elderly, the adverse effects of novel chemotherapeutic agents or targeted drugs and treatment compliance should receive more attention for evaluations of QOL in elderly breast cancer patients. The Schedule for the Evaluation of Individual Quality of Life (SEIQoL) was first developed in internal medicine and thereafter refined to allow respondents to identify the areas of life that they considered most important, to rate their level of functioning or satisfaction with each area and to indicate their relative importance to overall QOL. The five domains covered were family, relationship, health, friends and social life. This scale was compared with SF-36 and the Sickness Impact Profile (SIP) (an evaluation scale assessing 14 domains: functioning, cognitive, emotional, etc.), in the specific setting of amyotrophic lateral sclerosis. The validity of the SEIQoL-DW was rated higher than that of the other two scales. The SIP was associated with higher emotional distress in patients than the SEIQoL-DW, with a similar trend for the SF-36. The QOL-relevant domains most frequently mentioned in the SEIQoL-DW were family, health and profession.

### Table 1: Comparative Characteristics of Genitourinary Cancers in the Elderly

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Prostate**</th>
<th>Bladder**</th>
<th>Kidney**</th>
</tr>
</thead>
<tbody>
<tr>
<td>New cases per year</td>
<td>375,000</td>
<td>137,000</td>
<td>100,000</td>
</tr>
<tr>
<td>Deaths per year</td>
<td>90,000</td>
<td>51,000</td>
<td>45,000</td>
</tr>
<tr>
<td>Median age at diagnosis**</td>
<td>72 years</td>
<td>73 years</td>
<td>64 years</td>
</tr>
<tr>
<td>Median age at metastasis**</td>
<td>82 years</td>
<td>75 years</td>
<td>69 years</td>
</tr>
<tr>
<td>Specific clinical settings</td>
<td>HSPC</td>
<td>Superficial (S)</td>
<td>Localised Metastatic</td>
</tr>
<tr>
<td></td>
<td>CRPC</td>
<td>Infiltrating (I)</td>
<td>Metastatic</td>
</tr>
<tr>
<td>Outcome of localised disease</td>
<td>80 %</td>
<td>5 = 85 %</td>
<td>1 = 50 %</td>
</tr>
<tr>
<td>Outcome of metastatic disease</td>
<td>HSPC = 24 months</td>
<td>CRPC = 20 months</td>
<td>14 months</td>
</tr>
<tr>
<td>Major treatments for localised disease</td>
<td>Prostatectomy</td>
<td>Radiotherapy</td>
<td>Cystectomy</td>
</tr>
<tr>
<td>Major side effects</td>
<td>Impotence</td>
<td>Incontinence</td>
<td>Impotence</td>
</tr>
<tr>
<td>Major treatments for metastatic disease</td>
<td>HSPC = castration</td>
<td>CRPC = chemotherapy</td>
<td>Chemotherapy</td>
</tr>
<tr>
<td>Major side effects</td>
<td>HSPC = impotence</td>
<td>Multiple</td>
<td>Multiple (fatigue, hypertension, neurotropia)</td>
</tr>
</tbody>
</table>

**Number of new cases in Europe according to GLOBOCAN 2008.**

**Median age according to the Surveillance Epidemiology and End Results database in the US.**

CRPC = castration refractory prostate cancer; HSPC = hormone-sensitive prostate cancer.

Interestingly, the SEIQoL-DW has been studied in prostate cancer but not in elderly patients. In conclusion, although numerous QOL questionnaires have been developed in cancer patients, only a few have been used in the elderly and more precisely in elderly GU cancer patients.

### Comparison Between Quality of Life Scales in Elderly Patients

We recently published a study comparing QLQ-C30 and SF-36 in a population of 87 male GU cancer patients aged 68–86 years (median 76 years). These patients were also evaluated for pain (Visual Analog Scale [VAS] graded from zero to 10), KPS, ADL, Instrumental ADL (IADL) and depression (Geriatric Depression Scale [GDS]). Internal consistency reliability was high (α = 0.7), except for SF-36 cognitive function (α = 0.62) and QLQ-C30 general health status (α = 0.57). QLQ-C30 and SF-36 appear similarly reliable for QOL assessment in this population. However, cognitive function and functional status, two factors likely to influence the level of self-assessed QOL, are poorly taken into account whereas they are correctly explored by the CGA procedure. Our findings suggest that neither QLQ-C30 nor SF-36 is suitable to explore functional status, although it is a crucial aspect of QOL in elderly cancer patients. The EORTC QLQ-ELD15 questionnaire adds 15 issues (five conceptual scales) to the core of QLQ-C30. This scale requires psychometric validation. The five conceptual scales are: functional independence, relationship with family and friends,
worries about the future, autonomy and burden of illness. Functional independence is assessed using four items: difficulty with steps or stairs, joint stiffness/pain, gait and help with household chores. This does not qualify as a reliable, validated screening test for dependence, contrary to the ADL and IADL scales. Other domains are not defined as classically carried out in geriatric practice: none of the issues, for instance, screen for cognitive impairment (which causes loss of autonomy) and depression. Nevertheless, when adding the items evaluating functional independence (items one to four) in the QLQ-ELD15 and items one to five of the QLQ-C30 we observe that they explore the whole field of dependence, based on patients’ self-evaluation. However there has been no cross-evaluation with the ADL and/or IADL scales currently used in geriatric oncology and performed by the clinician. There is a consensus that patients should assess QOL themselves; but, on the other hand, functional status and other domains of geriatric assessment may be better estimated by clinicians than by patients. In our study, we have analysed the correlation between the five QOL items evaluating functional independence and the geriatric functional scales ADL and IADL commonly used to assess patient functional status. No correlation with either QOL instrument (QLQ-C30 or SF-36) was observed. Such a comparison should also be undertaken using the augmented questionnaire QLQ-ELD15. In the next paragraph, other QOL questionnaires used in prostate cancer patients will be reviewed, such as the Prostate Cancer Specific Quality of Life Instrument (PROSQOL), a composite instrument based on nine linear analogue self-assessment (LASA) scales and a pain intensity and analgesic score, the FACT-G and Prostate module (FACT-P), which has been adapted to different languages and the University of California Los Angeles (UCLA) QOL prostate cancer index (UCLA-PCI), but none has been adapted for use in elderly cancer patients nor validated in this population.

Quality of Life Studies in Prostate Cancer and Specific Questionnaires – The Case of Elderly Patients

Prostate cancer is the GU cancer in which QOL has been studied most often; nevertheless, the specific situation of elderly patients is infrequently addressed. A PubMed search of titles with the terms ‘quality of life’ + ‘prostate cancer’ yields 493 references. When searching both the titles and abstracts, the result is 2,167, whereas adding the term ‘elderly’ reduces the number of articles to 76. An important observation is that the question of QOL in prostate cancer patients is completely different according to the clinical status of the disease, as shown in Table 1. In localised disease, the objective of treatment is cure and complications are the major indicators for QOL evaluation. This is reflected in the construction of the QOL questionnaires currently used in this clinical setting. The EORTC has proposed to supplement the QLQ-C30 with an additional questionnaire specifically designed for prostate cancer patients. This questionnaire adds 25 items exploring different domains and encompassing the whole spectrum of treatment complications in patients with localised prostate cancer: urinary symptoms (eight items), incontinence (one item), bowel symptoms (four items), hormonal treatment-related symptoms (six items), sexual activity (two items) and sexual functioning (four items). It has been used in 26 of the articles identified by PubMed. The UCLA-PCI is a composite questionnaire that includes the 36 items of the SF-36 scale and 20 specific items focused on prostate cancer treatment complications, combined with socio-demographic items. This index has been used in 58 of the articles retrieved by PubMed. It is noteworthy that it performs well in the population of older men with and without prostate cancer. It has demonstrated good psychometric properties and appears to be well understood and easily completed. The SF-36 scale has been used in 56 studies published on prostate cancer. This scale does not include specific items investigating specific complications; however, a study of the combination of the SF-36 scale and of the Expanded Prostate Cancer Index Composite (EPIC) has been recently published. Furthermore, only two studies concerned elderly prostate cancer patients. In localised disease, patient health status is generally good. The reason why only a limited number of patients with health impairments are studied in these articles is that trials generally use stringent inclusion criteria; therefore the patients are assigned to the group of fit or vulnerable patients according to the current classification used in geriatric oncology and more specifically for cancer patients. In elderly prostate cancer patients, the evaluation of health status is important and demonstrates that impairments in different domains are frequent. In a prospective survey of geriatric problems in a population of elderly patients with prostate cancer, we observed that in 60 patients aged 70–92 years (median: 78 years), only 33 % were fully independent and 67 % had no signs of depression, but 45 and 20 % were at risk of malnutrition or were malnourished, respectively and 45 % had abnormal cognitive function. Moreover, all patients had three or more co-morbidity conditions. This indicates that QOL is impacted by other problems than cancer and cancer treatment; at the least dependence, malnutrition, co-morbidities and cognitive impairment are important. In localised prostate cancer treatment, the impact of age by itself and of co-morbidities on complication rates has been widely studied. It has been demonstrated that age and co-morbidities (as measured by the Charlson score) are independent prognostic factors for complications: incontinence, impotency and gastrointestinal symptoms due to either prostatectomy or radiotherapy or brachytherapy. Specific QOL studies have used QOL questionnaires such as QLQ-C30 and QLQ-PR25 in patients treated by brachytherapy and external beam radiotherapy, but none has yet combined the three EORTC questionnaires QLQ-C30, QLQ-PR25 and QLQ-ELD15.

In the setting of metastatic HSPC and CRPC, several QOL studies have been performed. Recent studies carefully addressed the question of the impact of androgen deprivation therapy (ADT) on physical function, QOL and cognitive function. To measure QOL, the authors used the SF-36 scale. To measure physical function, they used three tests: six-minute walk, grip strength and timed get-and-go. To measure cognitive function, they used a battery of 14 neuropsychological tests. Three groups of patients were studied: patients with non-metastatic prostate cancer starting ADT, the same patients but without ADT, and controls. Median age was 69 years (range 50–87 years), meaning that half of the patients were elderly; however, these patients were fit (few co-morbidities). The conclusions were that ADT has adverse effects on physical function but not on cognitive function. Interestingly, results of self-reported physical function tested with the SF-36 scale were consistent with objective measurements. Nevertheless, none of these patients had significant abnormalities when using the ADL or IADL indexes. None of the other self-reported QOL items of the SF-36 scale and mini-mental status measures was abnormal. In this study, SF-36 appears to be a good tool to explore functional status. No similar study was conducted using the EORTC QOL tools. An interesting recent article studied the relationship between QOL and hypogonadism in cancer patients (except prostate cancer): QOL was measured by the FACT-P questionnaire; median age was 62 years. The study revealed...
a direct relationship between alteration of QOL (both global and sexuality items) and values of serum androgen levels, particularly bioavailable testosterone. This study did not directly target elderly prostate cancer patients treated by ADT, but results indicate that FACT-P is a good tool in this setting.

The question of CRPC was addressed early (over 15 years ago) in the development of active treatments, namely chemotherapy. PROSQUAL, an index based on pragmatic indices measuring response to medical treatment in CRPC, has not been adapted for use in elderly prostate cancer patients. Nevertheless it has established for the first time the impact of a chemotherapeutic agent, mitoxantrone, on patients with CRPC. All items of the LASA scales were significantly in favour of the mitoxantrone plus prednisone arm when compared with prednisone only. The trial design included a concomitant evaluation using the EORTC QLQ-C30 with a specific module other than the QLQ-CR25. Overall there were no significant differences in QOL changes according to treatment between the two scales. The only disadvantage of PROSQUAL was that it was relatively weak for evaluating urinary problems and family relationship; its advantage was that it was quick, simple and valid. Similar conclusions were drawn in subsequent trials testing chemotherapeutic drugs using other indexes such as the FACT-P scale. Finally, more recent trials have limited the evaluation of QOL aspects to the measurement of pain, possibly due to the fact that overall survival impact has become the principal objective of such trials.

Quality of Life in Elderly Patients with Bladder Cancer

Few studies have been published on the QOL consequences of intravesical treatment for superficial bladder tumours. Standard questionnaires such as SF-36 have been used in only a few studies: the scores evaluating physical, social and role – emotional functioning decrease after the first transurethral resection and increase thereafter when transurethral resection is repeated four or more times. Other investigators have developed specific questionnaires to study the QOL outcome of these patients. More studies have addressed the question of QOL consequences of radical treatments in patients with infiltrating bladder cancers using different questionnaires. The FACT questionnaire adapted for bladder cancer (FACT-BL) was used in 82 patients undergoing radical cystectomy and 177 patients receiving conservative treatment. There were no differences in general QOL scores between treatment groups and between the two urinary diversion groups, but patients undergoing cystectomy had worse sexual function scores. QOL scores for patients receiving conservative treatment tended to decrease with increasing age. The SF-36 questionnaire was used to compare the QOL associated with ileal conduit and with continent orthotopic neobladder. No significant difference was found in scale scores between treatment groups. Scale scores for role – physical functioning, social functioning and role – emotional functioning in both groups were significantly lower than the population norm. Patients with a neobladder who were 65 years old or older had significantly lower scores for role – physical functioning and role – emotional functioning than younger patients. Nonetheless, in elderly patients with no additional morbidity, orthotopic neobladder replacement can be superior to ileal conduit. Both types of diversion seem to result in acceptable scores for most aspects of QOL, including urinary symptoms and continence rate. These figures may be helpful in the pre-operative counselling of elderly patients with bladder cancer. Other clinicians have developed the 36-item Bladder Cancer Index, which is a robust, multidimensional measure of bladder cancer-specific health-related QOL exploring urinary, bowel and sexual health domains. It is the first validated instrument available to assess health outcomes across a range of local treatments commonly used for bladder cancer. The current literature does not allow the conclusion that one form of urinary diversion is superior to another based on QOL outcomes. Future studies should attempt to incorporate prospective data collection, longer-term follow-up and validated disease-specific QOL instruments. Several studies have assessed the QOL of patients with infiltrating bladder cancer treated by conservative treatment. One of these studies involved the concomitant use of SF-36, International Prostate Symptom Score (IPSS) and EPIC. No significant difference was found between groups according to IPSS. The QOL score of conservative treatment was lower than that of the control group of superficial bladder tumours when using SF-36, but there was no significant difference except body pain. There was a trend towards diminished physical and role – physical functioning in the conservative treatment group. The EPIC scores for urinary function, especially storage and voiding symptoms and bowel function, were significantly lower in the conservative treatment group. Multivariate analysis showed that body pain and bowel function were associated with the type of treatment. The EORTC QLQ-C30 index was also used to evaluate bladder preservation and functional quality after concurrent chemoradiotherapy for muscle-invasive bladder cancer. Concurrent chemoradiotherapy allowed bladder preservation with tumour control at eight years in 67 % of the patients. QOL and quality of bladder function were satisfactory for 67 % of patients. Conversely, few results are available on the QOL of patients treated by chemotherapy for advanced or metastatic disease. The only trial involving QOL evaluation was based on the EORTC QLQ-C30 questionnaire: Vinflunine demonstrated a survival advantage in second-line treatment for advanced urothelial cancer. It did not induce a decrease in health-related QOL as compared with best supportive care. By four-month follow-up there was a positive change in the global health status score in the study arm, whereas the control arm (best supportive care) showed continuous decrements from baseline values.

Quality of Life in Elderly Patients with Kidney Cancers

Only a few studies have addressed the question of QOL in renal cancer. An interesting approach was proposed under the auspices of the Kidney Cancer Association (KCA). The authors studied a composite QOL index involving demographics, medical history, the Watts Sexual Function Questionnaire (WSFQ), the SF-12 Health Survey, the Centre for Epidemiologic Studies Depression scale (CES-D) and the Revised Dyadic Adjustment Scale (RDAS). Overall, the total WSFQ scores, as well as the four domain scores (desire, arousal, orgasm and satisfaction), were similar in men and women and were lower than in female breast cancer and male hypertensive populations reported in the literature, indicating relatively worse sexual function. While most patients remained sexually active in non-distressed relationships, many reported depressive symptoms and sexual functioning was presumably worse than in comparable chronically ill populations. A recently published review explored the impact of new targeted drugs on the QOL of patients treated for advanced kidney cancer. The authors conclude that assessment of the impact of the disease and of its treatment on health-related QOL may influence the choice of treatment, highlighting the importance of incorporating patient-reported outcomes in clinical trials. Only one randomised trial designed to demonstrate the activity of a targeted drug, Sorafenib,
in metastatic kidney cancer has included a specific study of QOL outcome.26 Symptoms were measured by the FACT-Kidney Cancer Symptom Index (FKSI) and QOL by the FACT-G. At baseline and over time, there were no differences in mean FACT-G or FKSI scores between the sorafenib and placebo groups. FKSI single-item analysis showed that Sorafenib-treated patients reported significantly fewer symptoms and concerns (e.g. cough, fever, shortness of breath, ability to enjoy life, worry that condition will get worse) than patients receiving placebo. Only concern about treatment side effects favoured placebo. Total FKSI score at baseline predicted overall survival.

Practical Conclusions
A wide spectrum of QOL tools have been evaluated in different GU cancer trials and studies. Only a few have been specifically studied in elderly patients. To date, the only scales validated in the setting of elderly patients are the QLQ-ELD15 scale and more importantly, the SF-36 scale. However, the QOL scales most frequently used in GU cancers are FACT-G (and the FACT-P module), the EORTC QLQ-P25 scale and PROQOL. These tools have essentially been developed in young patients. Therefore, we recommend that, in elderly patients with GU cancer, the standard scale to be used is to evaluate elderly prostate cancer patients is clearly the EORTC QLQ-C30 plus PRQ-P25 scale. The addition of QLQ-ELD15 remains to be validated in this setting. For patients with bladder cancer or kidney cancer, no validated tool is currently available. In younger patients, the best choice would be to use the FACT-G and the EORTC QLC-C30 questionnaires. However, a health status evaluation is mandatory included in the global approach to measure the QOL in elderly patients and therefore should be performed through the collaboration of geriatricians with urologists and oncologists27 and the practice of CGA.

Perspectives
The major question that should be addressed in the future is the availability of tools for use in the elderly. Therefore, there is an urgent need to validate the tool composed of EORTC QLQ-C30 plus QLQ-P25 and QLQ-ELD15 for exploring the QOL of elderly prostate cancer patients. In bladder cancer, a specific tool should be developed to evaluate QOL in patients who receive curative treatment. This tool should be based on the Q-LC-30 questionnaire and a specific questionnaire focused on bladder function. In kidney cancer, the most important objective is to evaluate the QOL of metastatic patients who receive target treatments. These tools should contain the basic items of the EORTC QLC-C30 questionnaire and additional information on the side effects of targeted treatments.
Quality of Life in Elderly Patients with Urological Malignancies


