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Published in:
Urologia Internationales

DOI:
10.1159/000319369

Publication date:
2011

Original Paper

Urologia Internationalis

Urol Int 2011;86:11–18
DOI: 10.1159/000319369

Received: March 19, 2010
Accepted after revision: July 7, 2010
Published online: October 7, 2010

Quality of Care Indicators for Muscle-Invasive Bladder Cancer

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Key Words
Bladder cancer · Cystectomy · Quality of care

Abstract
Objective: To define a set of quantifiable quality of care indicators (QIs) to measure the standard of care in our institute given to patients with muscle-invasive bladder cancer (MIBC). ***Patients and Methods:*** Possible QIs were defined and selected by a multidisciplinary project group from recent literature, guidelines, and/or consensus within the project group. In a retrospective study a baseline for each QI was assessed and compared to a predefined benchmark. ***Results:*** Four categories of QIs were selected: (1) care management, (2) accessibility and time management, (3) professional competence, and (4) patient factors. A list of 26 QIs was created. In the retrospective study, it became evident that 22 QIs failed to reach their benchmark, because of (1) an inadequate process of care (n = 5), (2) insufficient care given (n = 14), and (3) data not retrievable in retrospective study design (n = 2). Adjustments were made in the different processes of care in order to improve quality of care. ***Conclusions:*** In the face of a complete lack of a QoC registration system for MIBC, we listed 26 quantifiable QIs, to measure QoC in our own institute. Our process of care did not meet 22 of the benchmarks, after which adjustments were made. This QoC registration method is a first step in defining applicable quality of care indicators, for implementation in the clinical practice.

Introduction

A quality of care (QoC) registration system or guidelines on how to improve and measure QoC with regard to the treatment of patients with muscle invasive bladder (MIBC) cancer do not exist. Therefore, it has not been shown that the use of a strict protocol or a multidisciplinary approach improves outcomes in terms of mortality and morbidity rates. As the definition of QoC states, it is the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge [1]. To describe this optimal QoC for patients with MIBC, quality of care indicators (QIs) can be used. There is currently much discussion on QIs, how to define and measure them. And more importantly, how to demonstrate that these QIs do indeed alter the course

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of the disease in the long-term. Given the definition of QoC, a broad range of parameters or QIs must be selected to adequately describe the quality of care given in an certain institution. By defining these indicators, insight can be gained in the multiple elements of the provided care. Next a benchmark must be established to define minimal requirements for optimal care. After comparing the results per indicator with this benchmark, elements that are in need of improvement may be identified. The purpose of this study was to define the set of quantifiable QIs for use in our hospital and compare this set and the associated benchmarks with care provided in previous years in our institute.

Patients and Methods

Developing Quality of Care Indicators

Defining the QIs was done through a multidisciplinary approach using the Delphi method [2]. The project group included an academic urologist, a urologist of a large teaching hospital, a psychologist, an oncologic surgeon, and a urological research-physician. First, an inventory was made of resources that could serve as guidelines for defining and extracting QIs, i.e. guidelines on MIBC [3, 4], indicators formed by other project groups specialized in QIs [5], (inter-)national literature, and expert opinion (i.e. the project group). Next, based on this inventory a list of potential indicators was made divided in different categories of QIs regarding the diagnosis, treatment and counseling of patients with MIBC [5]. For each category, indicators were discussed within the project group using the Delphi method. After defining the final QIs, benchmark values were formulated for each individual QI, using a systematic Pubmed search of the medical literature from 2001 until 2007. For each indicator, a question was formulated; e.g. for complication rate: what is the mean complication rate in recent literature? This search was limited to publications in the English language with an abstract. The final value of the benchmark was based on this literature study and/or consensus within the project group.

Retrospective Study Design and Data Collection

Secondly, a retrospective study was performed to establish baseline values for each QI and to compare these with the preset benchmark. The study was approved by the local ethics committee. Inclusion criteria were radical cystectomy for MIBC, followed by an ileal conduit or an orthotopic bladder substitution at the St. Elisabeth Hospital, Tilburg, The Netherlands, between January 2001 and January 2006. The patients were identified using the Hospital information system and the Pathological Anatomical National Automated Archive. Data concerning the QIs was collected by one research-physician, using both in- and outpatient medical records. Clinical and logistic information (i.e. appointments and date of surgery) were obtained from the files. A prospective complication registration system was used since 2004 [6].

Results

Quality of Care Indicators

Four quality related categories were formulated: (1) care management, (2) accessibility and time management, (3) professional competence, and (4) patient factors. 'Care management' consists of indicators based on the principles of basic care for patients who will undergo a cystectomy. 'Accessibility and time management' concerns the waiting periods for diagnostic tests, results, and treatment. 'Professional competence' indicators relate to the skills of the hospital staff (e.g. urologists, nurses) taking care of the patient. The 'patient factors' category includes factors relating to co-morbidity and psycho-social factors. A list of 26 QIs was divided across the four categories, including mortality and complication rates (table 1). For each individual QI, a benchmark value was established (table 1). Clarification on different QIs per category is provided below when needed.

Care Management Indicators

For this category, the benchmark for all indicators was set at 100%. The structured multidisciplinary uro-oncology consultation was implemented in 2007 and is attended by an urologist, a radiotherapist, a medical oncologist, and a radiologist. Recently, a psychologist also attended.

Accessibility and Time Management Indicators

Bladder cancer is found in two subsets of patients. Patients referred with hematuria and patients with nonspecific symptoms (i.e. abdominal pain or frequent urinary infections). It is only possible to make a time path for reference and diagnostic management for the first group, since the second group is too diverse in its presentation. For macroscopic hematuria, it is our regional policy to see the patient within 24 h, for microscopic hematuria within 14 days [7]. For the indicator 'time from TURBT (transurethral resection bladder tumor) until cystectomy', the target is set at a maximum of 12 weeks for a cystectomy. This standard is based on findings from several studies showing that a delay in surgery greater than 12 weeks is associated with an advanced pathological stage and increased mortality [8–10]. Only one study found that a reasonable delay from the last TURBT to a cystectomy is not independently associated with stage progression or with decreased survival [11].

Professional Competence Indicators

Operating time is defined as the time needed to perform a lymph node dissection, cystectomy, and bladder

Table 1. Quality of care indicators and the defined benchmark

Category	Description of final indicator	Benchmark
Care management		
1	outpatient consultation between surgeon and patient	100%
2	preoperative multidisplinary consultation	100%
3	postoperative multidisplinary consultation	100%
4	preoperative consultation stoma nurse	100%
5	postoperative consultation stoma nurse	100% for ileal conduit, optional for neobladder
6	informed consent	100%
7	preoperative consultation anesthesiology	100%
Accessibility and time management		
8	interval reference hematuria–1st consultation	macroscopic <24 h microscopic <14 days
9	interval 1st consultation–cystoscopy for hematuria	≤10 days
10	interval cystoscopy–TURBT	≤21 days
11	interval TURBT–pathology result known by patient	≤10 days
12	interval TURBT–cystectomy	≤12 weeks
13	interval cystectomy–pathology result know to patient	≤10 days
Professional competence		
14	operating time	Bricker: 80% ≤300 min neobladder: 80% ≤360 min
15	lymph node dissection	100%
16	number of lymph nodes per dissection	80% ≥10 nodes
17	frozen section ureters	100%
18	positive margins cystectomy	total <10%; pT3–4 <15%; salvage <20%
19	transfusion rate	50%
20	packed cells per admission per patient	<4
21	length of hospital stay	Bricker: 80% ≤14 days neobladder or Indiana pouch: 80% ≤21 days
22	complication rate	≤64%
23	mortality rate	≤4%
24	readmission within 90 days after cystectomy	≤12%
Patient factors		
25	comorbidity registered in chart	100%
26	preoperative psychosocial screening	100%

TURBT = Transurethral resection bladder tumor.

reconstruction. Taking into account that a substantial amount of the patients have had previous abdominal procedures and will need more operating time, our target was set to 80% of the ileal conduit patients to be operated within 300 min and 80% of the orthotopic neobladder patients to be operated within 360 min [12, 13]. The norm for performing a standard lymph node dissection is set at 100%, which is also a requirement in the recent Dutch Guideline, which states that all cystectomies should be performed with at least a standard lymph node dissection [14]. Progression-free as well as overall survival may be correlated with the amount of lymph nodes removed during the dissection, but interindividual differences in the number of lymph node counts by pathologists make it hard to establish a standard [4]. Herr et al. [15] suggested that at least 10–14 lymph nodes should be removed; therefore, we set the number of nodes per dissection at a minimum of 10. We set the standard at 100% for frozen section evaluation of the surgical margins of the ureter, although the updated EAU guideline states that only in case of a patient with CIS a frozen section should be performed. A standard percentage for positive cystectomy margins was adopted from Herr et al. [15], i.e. the percentage of positive margins in all cases should be less than 10%, in pT3–4 tumors less than 15% and for the salvage cystectomy less than 20%.

The mean hospital stay is highly variable according to differences in local protocols. Hospital stays between 6

Table 2. Patient characteristics according to type of diversion

	Ileal conduit		Orthotopic neobladder		Total		p value
	n	%	n	%	n	%	
Gender							
Male	36	88	8	73	44	85	
Female	5	12	3	27	8	15	≤0.218
Pathology tumor category							
No tumor (T0)	3	7	2	18	5	10	
Organ-confined (≤T2)	14	34	9	82	23	44	
Non-organ-confined (≥T3)	24	59	0		24	46	≤0.005
Nodal status							
Negative	30	73	9	82	39	75	
Positive	11	27	2	18	13	25	≤0.556
Age, years							
Mean (SD)	65	8.3	57	11.1	64	9.5	≤0.006
Previous treatments (other then TURBT)							
Radiotherapy	1	2	0	0	1	2	≤0.601
Chemotherapy	1	2	0	0	1	2	≤0.601
Iridium	3	7	0	0	3	7	≤0.355
ASA score							
1–2	26	63	11	100	37	72	
≥3	15	37	0	0	15	29	≤0.05
Total	41		11		52		

and 22 days are described [13, 16]. Our benchmark is based on our own protocol, where the patient is assumed to be able to perform his own stoma care 14 days postoperatively, i.e. to discharge 80% of patients within 14 days [17]. For a patient with an orthotopic neobladder we set the benchmark at 80% hospital discharge within 21 days, as after 2 weeks the transurethral catheter is removed, and the patient can be trained for continence.

Comparing retrospective-based complication studies, rates are reported to vary from 9 to 44% [18, 19]. In a study with a prospective complication registration system, the rate was 64% (90 days after surgery) [20]. Due to the accuracy of prospective registration, our target is set at a maximum of 64%. When mortality rates are compared, again major differences in rates are found, varying from 0.7 to 8.1% [13, 16, 18, 20–26]. This variation is mostly explained by the difference in case mix and case load per hospital and per surgeon. However, when comparing case loads and mortality rates, it appears that different definitions are used. Various definitions of low-volume hospitals have been used, ranging from hospitals performing <2 to <11 cystectomies per year [13, 16, 18, 20–26]. High volume hospitals are variously defined as hospitals performing ≥3 to ≥34 [13, 16, 18, 20–26]. As the mean for the 30-day mortality rate found is around 4%, this was set as target value.

Patient Factors

Co-morbidity plays a key role in defining a patient's ASA classification and this indicator is set for a target of 100%. The American Society of Anesthesiologists' (ASA) physical status classification serves as a guide to predict the anesthetic/surgical risks. One reason for a multimodality approach for the patient with MIBC is the substantial amount of time that is required for thorough psychological counseling, due to the psychosocial and sexual implications of diagnosis and treatment [27]. As a consequence, preoperative psychological screening is a mandatory indicator. If the screening suggests that the patient is in need for extra social or psychological help, this is started preoperatively and will be continued during the hospital stay.

Retrospective Baseline Study

From 2001 to 2006, 58 patients underwent radical cystectomy for invasive bladder cancer. Fifty-two had MIBC (44 men, median age 64). Patient characteristics according to type of diversion are shown in table 2. One patient

Table 3. Final quality of care indicators and results of the baseline study

Category	Indicator (benchmark)	Results of the baseline study
Care management		
1	outpatient consultation between surgeon and patient (100%)	–
2	preoperative multidisplinary consultation (100%)	–
3	postoperative multidisplinary consultation (100%)	–
4	preoperative consultation conduit nurse (100%)	62%
5	postoperative consultation conduit nurse (100%)	60%
6	informed consent (100%)	69%
7	preoperative consultation anesthesiology (100%)	–
Accessibility and time management		
8	interval reference hematuria–1st consultation (macroscopic <24 h, microscopic <14 days)	–
9	*interval 1st consultation–cystoscopy hematuria (≤10 days)*	*median 10 (range 3,700)*
10	interval cystoscopy–TURBT (≤21 days)	median 23 (range 109)
11	interval TURBT–pathology result known by patient (≤10 days)	median 14 (range 25)
12	*interval TURBT–cystectomy (≤12 weeks)*	*median 6 (range 25)*
13	*interval cystectomy–pathology result known by patient (≤10 days)*	*median 9 (range 22)*
Professional competence		
14	operating time (Bricker: 80% ≤300 min; neobladder: 80% ≤360 min)	Bricker: mean 273 (70% ≤300) neobladder: mean 348 (54% ≤360)
15	lymph node dissection (100%)	92%
16	number of lymph nodes per dissection (80% ≥10 nodes)	46% >3 nodes per side
17	frozen section ureters (100%)	10%
18	positive margins cystectomy (total <10%; pT3–4 <15%; salvage <20%)	total = 23%; pT3–4 = 23%; salvage = 50%
19	transfusion rate (50%)	89%
20	packed cells per admission per patient (<4)	median 4 (range 31)
21	hospital stay (Bricker: 80% ≤14 days; neobladder or Indiana pouch: 80% ≤21 days)	Bricker: median 16 (34% ≤14) neobladder: median 22 (45% ≤21)
22	*90 days postoperative complication rate (≤64%)*	*54%*
23	30 days postoperative mortality rate (≤4%)	5.8% (3 patients)
24	readmission within 90 days after cystectomy (≤11.5%)	12%
Patient factors		
25	comorbidity registered in chart (100%)	–
26	preoperative psychosocial screening (100%)	–

Italics = On or above target; normal = below target. Below target due to: (1) inadequate process of care (n = 6: QI2, 3, 7, 16, 17, 26), (2) insufficient care given (n = 14: QI1, 4, 5, 6, 10, 11, 14, 15, 18, 19, 20, 21, 22, 24), and (3) data not obtained due to retrospective nature of study (n = 2: QI8, 25).

had preoperative T3GIII tumor, with no sign of lymph node invasion on the CT scan. One patient had preoperative cT1GIII, and was found to be pT2GIII after the cystectomy. One patient had recurrent CIS and showed to be pT3GIII after cystectomy. The pT0 (10%) tumors were all pT0 after the cystectomy, but were all T2GIII found by transurethral resection. The postoperative group for >pT2 was very high, as it included 3 salvage cystectomies, and 4 patients with preoperative pT2GIII N^+. 66% of the pT2 tumors found by TURT where upstaged. The 25 patients with an upstaged tumor included 44% pT3N0 (n = 11), 12% pT4N0 (n = 3), 16% pT2N+ (n = 4), 16% pT3N+ (n = 4), and 12% pT4n+ (n = 3). Baseline results are shown in table 3. After comparing the results per indicator with the benchmark, it was evident that 22 QIs failed to reach the benchmark. In as many as 7 indicators, a baseline could not be obtained, and 15 QIs were below the benchmark. Because the study was retrospective, QI1 and QI8 were not available in the charts. A structured pre- and postoperative multidisciplinary meeting for all oncological patients did not exist in our institution between 2001 and 2006 (QI2–3). The same issue occurred for indicator 7. The median perioperative blood transfusion rate was two packed cells and during the rest of the hospital stay a

median of 1.5 packed cell was given. The 30-day mortality rate was 5.8%, i.e. 3 patients of the 52, all receiving an ileal conduit. Since a psychosocial screening has only recently been implemented in the clinic, no baseline was available. To improve the QoC in our institute, adjustments were made in the treatment protocol. In the category 'care management', a pre- and postoperative structured multidisciplinary consultation is implemented in which all patients with MIBC are discussed. And a pre- and postoperative visit to a specialized stoma nurse and preoperative visit to the outpatient clinic of the anesthesiologist is made mandatory. In the 'accessibility and time management' category, a strict time protocol is implemented at the outpatient clinic and ward. For the 'professional competence' category, the following changes are implemented: centralization of all cystectomies from the region Tilburg to one hospital and performed by a fixed team of 2 urologists and a standardized extended lymph node dissection (proximal border: aortic bifurcation) was performed in all patients. A new transfusion protocol was introduced hospital-wide. In the category 'patient factors', the mandatory preoperative psychological screening is implemented.

Discussion

QoC registration systems or guidelines on how to improve and measure QoC with regard to MIBC are nonexistent. In the face of a complete lack, we listed 26 quantifiable QIs to measure QoC in our own institute. The QIs were measured in a retrospective study of 52 cystectomy patients. For 22 indicators, the benchmark was not reached. Three main reasons account for this: (1) inadequate process of care (e.g. no structured multidisciplinary consultation; n = 5), (2) insufficient care given (e.g. mortality rate too high; n = 14), and (3) data not obtained due to retrospective nature of study (e.g. interval hematuria–1st consultation clinic; n = 2). In respect to the process of care, a structured pre- and postoperative multidisciplinary meeting for all oncological patients did not exist in our institution between 2001 and 2006 (QI2–3). However, patients with complex pathology were discussed in a weekly multidisciplinary oncologic meeting. The same issue occurred with QI7, stating how many patients had a preoperative visit to the anesthesiologist' clinic. During the studied period, an outpatient anesthesiologist clinic did not exist, but the anesthesiologist consultation was performed the day before surgery.

To improve the QoC in our institute, the following adjustments were made in the treatment protocol:

A structured multidisciplinary consultation was implemented in 2007 after the final indicators were developed. In the same period, a consultation with a specialized stoma nurse and to the outpatient clinic of the anesthesiologist was established for all patients.

QI14 (operating time) did not reach the benchmark. In 46% of the neobladders, the operating time exceeded 360 minutes, and in 30% of the incontinent ileoconduit the 300 minutes operating time were surpassed. It is clear that this should be improved.

Because increasing the number of surgeries performed by a single surgeon and increasing the volume per hospital leads to lower mortality and morbidity rates [13, 16, 18, 20–26], a fixed team of 2 urologists started performing all cystectomies in our clinic. At the same time all patients are getting an extended lymph node dissection requiring extra time. Furthermore, centralization of all cystectomies in the region Tilburg to the St. Elisabeth Hospital was established. Our mortality rate of 6% is comparable to the English study from McCabe (6.7%). However, in their study, the mean mortality rate dropped from 6.7 to 4.2% when surgeon volume went to 8 cases or higher a year [26]. As our mean surgeon volume was 2.5 cases a year, this could be a major reason for our higher mortality rate. Mortality rates were shown to be related to caseloads in studies from high volume centers in the USA [16, 23]. The third adjustment in the category Professional competence that was made is a standardized extended lymph node dissection for all patients.

Blood loss and transfusion rates are marginally described in the literature [13, 28]. Our transfusion rate between 2001 and 2006 was high (89%), and in need of improvement. Our hospital implemented a new transfusion protocol (6–5–4 rule) in 2006, e.g. all physicians and nurses have been trained and instructed to determine when an anemic patient according to his ASA classification and symptoms qualifies to get a blood transfusion. This method has reduced the transfusion rate by 49% hospital wide.

A prospective study is in progress to see if all the adjustments that have been made will result in the desired improvement of QoC resulting in more QIs reaching their benchmark.

Although this exercise has proven its value to our clinic, critical notes can be made on both the development of the QIs as for the baseline measurement. One concerns the Delphi method of reaching topic-specific consensus. The limitation is that it is only as appropriate and relevant as the expert panel involved. Also, when using this meth-

od for QIs for international purposes, an international panel from cancer centers of expertise would be a more appropriate choice. Lastly, our project group included urologists, psychologists, oncologic surgeons and research physicians, but did not include pathologists, radiotherapists and radiologists.

Also the QIs were not derived from one specific guideline in which the level of evidence influences the choice for QIs, e.g. the most important QIs having evidence that adherence to them improves survival. With the current levels of evidence in bladder cancer this high benchmark is hard to define. This means that the stronger QIs are the ones that could potentially be influencing survival, e.g. those relating to a delay in treatment and the quality of cystectomy and lymph node dissection, whereas QIs related to patient satisfaction are softer in nature.

Prognostic factors like pathologic stage, tumor grade, mean nuclear area, and lymphatic invasion are independent factors of overall and disease-free survival. We made a distinction between outcome parameters and quality of care parameters in defining the QIs; a QoC indicators should be able to change by team effort. Prognostic factors, such as tumor grade cannot be influenced.

A prospective study for the baseline study would have had the advantage that the upcoming prospective results would have been comparable.

Currently, QIs are often defined following (inter)national guideline developments with the aim to evaluate if it can be measured that implementation does indeed change practice and improve QoC. Our QIs were defined at the same time as the Dutch guideline on MIBC was developed. Our purpose of defining QIs was to see if they change practice and improve our QoC, not if the guideline can alter the course of disease.

QIs are developed to improve and guide one's own process of care and are above all being used solely by hospitals and medical professionals. This in contrast to performance indicators, which should be seen as external measurements developed by Dutch insurance companies to evaluate the performance of a care institution or hospital. In the Netherlands, there is an ongoing debate between the insurance companies and the hospitals about the use of performance indicators. When a target of a performance indicator has not been reached, this could lead to financial consequences, i.e. the hospital not getting paid for the treatment provided. So when QIs are being used in clinical practice, awareness must be raised to prevent indicator motivated actions, i.e. interventions only to reach the QIs target. The purpose of QIs is to bring quality of care to a higher standard.

Ultimately QoC indicators should be used as surrogate measures for (1) oncologic outcomes (cancer specific and overall survival), (2) patient quality of life outcomes, and (3) healthcare expenditures. Before QOC indicators are generally implemented and standardized into oncologic practice, it is imperative to document correlation between QoC and above-mentioned outcome factors.

Conclusions

In the face of a complete lack, we listed quantifiable QIs to measure QoC in our own institute for patients with MIBC, not only by assessing hospital mortality and morbidity, but with a more extensive set of outcome parameters. For each indicator a benchmark was established, based on recent literature and guidelines. In a retrospective study, a baseline measurement was set which was compared to the benchmark to get insight in the multiple elements of the provided care. Twenty-two QIs failed to reach the target and these dictated the necessary improvements. After making adjustments in our process of care, a follow up study will be initiated to evaluate the QIs in a prospective fashion. This QoC registration method is a first step in defining applicable quality of care indicators, for implementation in clinical practice.

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