

Radical Cystectomy and Surgical Quality of Care

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Key Words

Bladder neoplasms, quality of care, radical cystectomy

Abstract

Defining surgical quality is an imperative and substantial undertaking before its measurement and ultimate improvement. This article defines quality of care and a rationale for its measurement. In the context of radical cystectomy for bladder cancer, we describe a conceptual model for measuring quality of care. Finally, we provide a framework for future research by presenting an overview of recent work pertaining to cystectomy and quality of care. (*JNCCN* 2005;3:37–42)

Studies of surgical practice patterns have clearly shown a substantial variation in surgical practice and outcomes. The notion that the delivery of surgical services; encompassing the preoperative, intraoperative, and postoperative management and decision-making—directly affects the outcome that patients experience and represents the basis for surgical quality of care. This review defines quality of care, establishes the rationale for measuring it, and highlights some of the work done in the setting of radical cystectomy for bladder cancer.

What is Quality of Care?

The Institute of Medicine (IOM) has defined quality of care as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current profes-

sional knowledge.”¹ For more than a decade, this widely accepted definition has provided a framework from which to develop quality initiatives. Despite its short length, the statement offers profound insight into the complexities of defining and measuring quality. The phrase “increase the likelihood of desired health outcomes” emphasizes that quality cannot be equated with outcome alone because, often, many uncontrollable disease-related factors ultimately determine a patient’s result. Furthermore, this definition clarifies the notion that quality is an ever-changing target. As medical evidence evolves and current professional knowledge changes, the metrics used to assess quality must also change. Finally, this statement reminds us that quality must be considered from both an individual and societal perspective. Improvements in quality delivered at the physician-patient encounter must also be extended to the population as a whole by ensuring that all patients have access to appropriate medical care. Despite this, surgeons have been slow to embrace these ideas and to develop accurate measures for assessing quality of care in the majority of surgical diseases.

Why Measure Quality?

Physician judgment alone is no longer sufficient to ensure the delivery of quality health care. Substantial variability occurs in the outcomes of a wide variety of surgical procedures, and a growing body of evidence suggests that the discrepancy between medical practice in an “ideal world” and that in the “real world,” the so-called quality gap, is substantial. A recent report from the IOM-sponsored National Roundtable on Health Care Quality of Health Care in America concluded the following:

Serious and widespread quality problems exist throughout American medicine. These problems, which may be classified as underuse, overuse, and misuse, occur in small and

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*large communities alike, in all parts of the country, and with approximately equal frequency in managed care and fee-for-services systems of care. Very large numbers of Americans are harmed as a direct result.*²

The quality gap is highlighted by recent work at RAND Corporation (Santa Monica, CA) which estimated that study participants from 12 metropolitan areas received only 55% of recommended care based on 439 quality of care indicators developed and validated by the investigators.³ Besides the natural desire to improve the quality of health services delivered and, ultimately, the patient's health outcomes, external forces apply pressure to measure and improve quality of care. With few exceptions, the surgical sciences have largely been isolated from the quality of care movement; however, consortiums of large corporations have been formed and have developed, by some standards, crude quality metrics (e.g., procedural volume standards) for a finite number of surgical procedures in an effort to reduce costs by improving health outcomes.⁴

In a similar context, initial efforts to measure health plan performance have been equally rudimentary. The Health plan Employer Data and Information Set (HEDIS) contains nine indicators of quality (five of which are based on disease prevention) from which adherence rates can be measured and used to make generalizations regarding the overall quality of care delivered. Such initiatives may prompt gaming of the system (health plan focus solely on services being measured), and it is unclear how well such a system will perform in measuring quality for serious acute and chronic conditions.⁵ Furthermore, the IOM's report suggesting that 98,000 preventable deaths occur annually as a result of medical errors⁶ captivated the attention of health care consumers. Collectively, this suggests that payers and patients are critically interested in quality of care delivered, are willing to reimburse based on quality,⁷ and are potentially inclined to use imperfect quality measures rather than none at all. Consequently, those within the surgical disciplines⁸ must develop quality of care indicators that can accurately characterize the quality of the actual care received rather than have grading (and potentially reimbursement) based on unfair standards.

How Can Quality be Measured?

Improvements in the quality of health services can only be realized after appropriate measurement of these

services. Without measurement, consumers can expect little change.⁹ The quality of care paradigm laid out by Donabedian¹⁰ has provided a framework in which quality can be evaluated. This conceptual model consists of three distinct elements: structure, process, and outcome.

Structural measures consist of parameters that reflect the health care setting or system in which services are delivered (such as hospital bed capacity), those that describe the provider (board certification), and those that describe the population (case-mix).¹¹ Certain structural measures are typically easy to ascertain (hospital volume of a certain procedure), and this feature has prompted their frequent use in a variety of large administrative datasets.^{12,13} Expediency notwithstanding, structural measures can be weakly correlated with what actually happens to patients (the processes of care), thus limiting their utility as the sole indicators of quality.¹⁴

Process of care measures include all elements of the interaction between the patient and health care professional (such as ordering a laboratory test). Process of care measures are particularly attractive from a measurement perspective because they can be based on solid evidence supporting their use, can be actionable, and their implementation can be directly linked to improvements in patient outcome.

The third distinct component of the quality of care paradigm is outcome. Outcomes include common benchmarks such as cost, morbidity, mortality, and length of hospital stay, in addition to disease-specific functional outcomes and patient satisfaction with care. Measurement of outcomes is particularly appealing to patients and surgeons as the ultimate indicators of quality, but the usefulness of outcomes measurement has several limitations. First, measuring outcomes alone does not permit developing methods to improve quality.¹⁵ Second, variation in outcomes can often be explained, to some degree, by factors outside the control of the health care provider (case-mix).¹⁴ Finally, measuring outcomes alone implies that improving quality is not possible if the outcomes of all providers are equal.¹⁶ These limitations notwithstanding, the utility of either process of care or structural measures as quality of care indicators must be based on the association with outcomes.⁵ Thus, it is essential that all three elements of the paradigm be considered to provide insight into quality of care.

Surgical Quality of Care

A distinction afforded to urology is that practice includes both medical management and surgical care. In surgery, efforts to define and measure quality have been limited to only a few procedures and have lagged behind those of the medical diseases (e.g., diabetes) for a variety of possible reasons, including lack of scientific evidence for processes of care and a lack of support for surgeon-investigators. However, public perception and recognition of the gap in quality has inspired health care purchasers to form large coalitions (e.g., the Leapfrog Group) to drive quality improvement using their considerable financial leverage. This coalition discourages, and in some cases de-selects specific hospitals that do not meet certain procedural volume standards for five high-risk surgical procedures.¹⁷ As a consequence of this and other potential financial stimuli⁷ and the recognition that indicators of quality are likely to be externally developed and implemented without the input of surgeons, providers of surgical care have rightly begun to focus on defining and measuring quality.

Quality of Care for Radical Cystectomy

Efforts to address the quality gap in bladder cancer have largely been directed at radical cystectomy, which is considered by most to be a high-risk surgical procedure. Evidence supporting this focus includes the relatively high postoperative morbidity (28%–34%)^{18,19} and mortality rates (3%–4%)^{18,20} at “centers of excellence” and the discrepancy in its use among older patients and patients in certain geographic locations.²¹ In the context of Donabedian’s¹⁰ paradigm, initial work in this realm has explored the relationship of structural measures with common outcome benchmarks (mortality and length of hospital stay) using administrative datasets. Among Medicare patients, those undergoing radical cystectomy at low-volume hospitals (less than two procedures per year) had a 5.5% adjusted mortality rate compared with 2.6% at very high volume hospitals (more than 11 procedures per year).¹² Furthermore, postoperative lengths of stay were significantly shorter at high-volume relative to low-volume centers (11.5 vs. 12.7 days).²²

The inverse relationship of hospital volume and mortality has also been shown for patients undergoing pelvic exenteration (including cystectomy) adjusted for cancer severity by linking Medicare claims

with data from the Surveillance, Epidemiology, and End Results (SEER) registry. In this study, the investigators noted 30-day mortality rates for low-volume institutions (1 to 5 procedures per year) to be 3.7% compared with 1.5% at high (11 or more procedures per year).¹³ These data suggest that, within the Medicare population, patients can significantly reduce the risk of dying after radical cystectomy by choosing hospitals that perform the procedure more often.

In this context, volume is not a direct quality indicator but probably a surrogate measure that reflects a broad array of factors, including patient selection, preoperative preparation, hospital services, composition of the surgical team, surgical and anesthetic expertise and judgment, and postoperative care.²³ For radical cystectomy patients, the hospital volume to mortality effect can only be partially attributed to surgeon volume, with 39% of the hospital volume effect attributable to higher surgeon volume.²⁴ Surgeons performing a single cystectomy annually showed surgical mortality rates of 5.5% compared with 3.1% among surgeons performing more than 3.5 procedures annually. Causality in this setting has not been established. It is unclear whether selective referral to hospitals and surgeons with good outcomes occurred (creating high volume centers) or whether hospitals and surgeons with good outcomes have become proficient by performing a greater number of cases (the concept of “practice makes perfect”).²⁵ Nonetheless, the data collectively suggest that a clear structure (surgical volume-outcome) relationship exists for radical cystectomy, although other structural qualities and processes (hospital and surgeon characteristics) responsible for the improved outcomes have yet to be studied. Until more research is completed, concentration of cystectomy cases to higher volume hospitals and surgeons may be warranted.²⁶

More recent evidence has further enlightened us regarding structural and process measures that appear to be important after radical cystectomy. An Intergroup trial conducted by the Southwest Oncology Group (SWOG 8710) has shown that negative margin status and 10 or more lymph nodes removed at cystectomy (both potentially processes of care) were independently associated with better survival. Furthermore, the data showed that patients were more likely to undergo an extensive lymph node and bladder dissection (as manifested by more subjects with negative margin status and 10 or more lymph nodes removed) at academic

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Table 1 Hypothetical Framework for Measuring Quality of Care Among Radical Cystectomy Patients

Structure of Care	Process of Care	Outcomes
System	Preoperative	Clinical Endpoints
Facility	Re-review of outside pathology slides	Length of hospital stay
Annual facility volume	Re-resection of high-grade T1 tumors	30-day mortality
Specialty mix	Staging evaluation	90-day mortality
Intensive care unit status (closed vs. open)	Use of neoadjuvant chemotherapy in appropriate patients	Morbidity
Availability of dedicated urologic oncology pathologist	Evaluation of functional status (continence, potency, bowel habits)	Cancer-specific survival
Availability of enterostomal therapist	Characterization of physiology (renal function, nutrition)	Need for subsequent surgery
Dedicated urology operating rooms and staff	Nutritional supplementation	Functional Endpoints
Provider	Time between diagnosis and cystectomy	Continence
Treating specialty	Expenditures	Potency
Years in practice	Referral to tertiary center for high-risk patients	Return to work
Specialty training		Satisfaction with care
Age	Intraoperative	Financial coverage
Gender	Blood loss	
Job satisfaction	Need for transfusion	
Surgeon volume	Ability to perform nerve-sparing	
Income	Number of lymph nodes sampled	
Economic incentives	Ability to perform multiple types of urinary diversion	
Functional results	Intraoperative consultation (major vascular or rectal injury)	
Historical mix of diversion types	Expenditures	
Preferences	Margin status	
Patient Characteristics	Postoperative	
Age	Use of validated clinical pathway	
Gender	Checking for ureteroileal stricture	
Disease severity (grade, stage)	Follow-up examinations and laboratory/radiologic evaluations	
Comorbidities	Referral to medical oncology for high-risk patients	
Health habits (smoking status)		
Preferences		
Income		
Insurance		
Education		
Race		

hospitals and by specialty-trained urologic oncologists.²⁷ Therefore, in a completely different setting than the aforementioned Medicare studies, the data support the notion that both the surgeon and the center in which the surgery is performed are relevant in determining outcome after radical cystectomy.

A potential limitation of available data is in the lack of adequate adjustment for case-mix. Available

comorbidity indices have been used in radical cystectomy patients but have not been responsive to increasing comorbidity as it relates to overall mortality.²⁸ This suggests that more discriminative and specific tools are necessary in these patients. To address this problem, the authors have used data from the National Surgical Quality Improvement Program (NSQIP) to identify preoperative structural qualities (case-mix)

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and intraoperative process measures that are associated with various outcome benchmarks.²⁹

The NSQIP is an ongoing prospective quality of care initiative at 123 Veterans Affairs Medical Centers nationwide. The significance of this work is threefold. First, it will establish responsive and accurate tools for characterizing and adjusting for case-mix after radical cystectomy, which will permit comparisons of outcomes across institutions (e.g., benchmarking). Second, it will facilitate patient counseling regarding outcome expectations based on individualized risk and identify those at high risk for adverse outcomes who may best be served at high-volume or regionalized cystectomy centers. Finally, it will identify potentially modifiable elements of structure (case-mix) that can be converted into novel processes of care that may be implemented to improve outcomes. Furthermore, the data will provide insight into a number of potential quality indicators that should be measured in this patient population. A hypothetical framework for measuring quality of care among radical cystectomy patients is presented in Table 1.

Summary

In summary, the available evidence suggests that the focus on quality of care in the context of radical cystectomy is still in its infancy and has centered primarily on structural measures characterizing the setting, the provider, and the patient population. Whether current outcome benchmarks such as in-hospital or 30-day mortality are appropriate or whether other standards need to be developed (90-day mortality) is still unclear. Furthermore, processes of care strongly associated with these outcomes need to be identified to facilitate quality of care initiatives. Future work should verify the face validity of these indicators using appropriate methodology and should concentrate on developing other novel indicators that can potentially be used to measure quality in these patients.

References

1. Medicare: A Strategy for Quality Assurance. Washington, D.C.: National Academy Press; 1990.
2. Chassin MR, Galvin RW. The urgent need to improve health care quality. Institute of Medicine National Roundtable on Health Care Quality. (Review; comment) *JAMA* 1998; 280:1000–1005.
3. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. (comment) *N Engl J Med* 2003;348:2635–2645.
4. Birkmeyer JD, Wennberg DE, Young M, Birkmeyer CB. Leapfrog Safety Standards: Potential Benefits of Universal Adoption. Washington, D.C.: The Business Roundtable; 2000.
5. Brook RH, McGlynn EA, Cleary PD. Quality of health care. Part 2: measuring quality of care. (comment) *N Engl J Med*. 1996; 335:966–970.
6. To Err is Human: Building a Safer Health System. Washington, D.C.: National Academy Press; 1999.
7. Epstein AM, Lee TH, Hamel MB. Paying physicians for high-quality care. *N Engl J Med* 2004;350:406–410.
8. Bass BL. Invited commentary: Measurement of quality in surgery: that's our job. *Surgery* 2004;135:576–578.
9. Donaldson MS, Nolan K. Measuring the quality of health care: state of the art. *Jt Comm J Qual Improv* 1997;23:283–292.
10. Donabedian A. Evaluating the quality of medical care. (Review) *Milbank Mem Fund Q* 1966;44(Suppl):1–206.
11. Tarlov AR, Ware JE Jr, Greenfield S, et al. The Medical Outcomes Study. An application of methods for monitoring the results of medical care. *JAMA* 1989;262:925–930.
12. Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. (comment) *N Engl J Med*. 2002;346:1128–1137.
13. Begg CB, Cramer LD, Hoskins WJ, Brennan MF. Impact of hospital volume on operative mortality for major cancer surgery. (comment) *JAMA* 1998;280:1747–1751.
14. Brook RH, McGlynn EA, Shekelle PG. Defining and measuring quality of care: a perspective from US researchers. (Review) *Int J Qual Health Care* 2000;12:281–295.
15. Kahn KL, Keely KL, Sheerwood MJ, et al. Comparing outcomes of care before and after implementation of the DRG-based prospective payment system. (comment) *JAMA* 1990;264:1984–1988.
16. Palmer RH. Process-based measures of quality: the need for detailed clinical data in large health care databases. (Review) *Ann Intern Med* 1997;127:1–8.
17. Birkmeyer JD, Dimick JB. Potential benefits of the new Leapfrog standards: effect of process and outcomes measures. *Surgery*. 2004;135:569–575.
18. Stein, JP, Lieskovsky G, Cote R, et al. Radical cystectomy in the treatment of invasive bladder cancer: long-term results in 1,054 patients. *J Clin Oncol* 2001;19:666–675.
19. Cookson MS, Chang SS, Wells N, Parekh DJ, Smith JA Jr. Complications of radical cystectomy for nonmuscle invasive disease: comparison with muscle invasive disease.[see comment]. *J Urol* 2003;169:101–104.
20. Ghoneim MA, el Mekresh MM, el Baz MA, el Attar IA, Ashamalla A. Radical cystectomy for carcinoma of the bladder: critical evaluation of the results in 1,026 cases. *J Urol* 1997;158:393–399.
21. Konety BR, Joslyn SA. Factors influencing aggressive therapy for bladder cancer: an analysis of data from the SEER program. *J Urol* 2003;170:1765–1771.

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22. Goodney PP, Stukel TA, Lucas FL, Finlayson EV, Birkmeyer JD. Hospital volume, length of stay, and readmission rates in high-risk surgery. (see comment). *Ann Surg* 2003;238:161–167.
23. Epstein AM. Volume and outcome—it is time to move ahead. (see comment) *N Engl J Med* 2002;346:1161–1164.
24. Birkmeyer JD, Stukel TA, Siewers AE, et al. Surgeon volume and operative mortality in the United States. *N Engl J Med* 2003;349:2117–2127.
25. Hannan EL, O'Donnell JF, Kilburn H Jr, Bernard HR, Yazici A. Investigation of the relationship between volume and mortality for surgical procedures performed in New York State hospitals. (comment). *JAMA*. 1989;262:503–510.
26. Dudley, R.A., Johansen, K.L., Brand, R., Rennie, D.J. & Milstein, A. Selective referral to high-volume hospitals: estimating potentially avoidable deaths. (comment) *JAMA* 2000;283:1159–1166.
27. Herr, H.W, Faulkner JR, Grossman HB, et al. Surgical Factors Influence Bladder Cancer Outcomes: A Cooperative Group Report. *J Clin Oncol* 2004;22:2781–2789.
28. Miller DC, Taub DA, Dunn RL, Montie JE, Wei JT. The impact of co-morbid disease on cancer control and survival following radical cystectomy. *J Urol* 2003;169:105–109.
29. Hollenbeck BK, et al. Factors associated with increased resource utilization following radical cystectomy. (Abstr #137) *J Urol* 2004:171.