Radical Prostatectomy: Does Higher Volume Lead to Better Quality?

Arnold L. Potosky, Joan L. Warren

Over the past decade, the U.S. health care system has witnessed rapid and dramatic changes in the financing and organization of health services. These shifts have been accompanied by extensive public policy discussions over whether cost containment can be achieved while preserving the quality of health care. Health care providers and researchers have recognized that there is insufficient knowledge about “quality” care that can be used to guide decisions that providers and patients must make in everyday clinical practices.

Measuring outcomes is widely considered an essential component of quality assessments because good outcomes usually reflect high quality in the process of care. Much of the health services literature is devoted to investigations of how the process and structure of health care delivery are associated with health outcomes. Patients who receive care in hospitals that perform a high volume of procedures have been shown in several studies (1–5) to have outcomes that are superior to those for patients undergoing procedures in institutions that perform a lower volume.

In this issue of the Journal, Yao and Lu-Yao (6) investigate the relationship between the hospital volume of radical prostatectomy for clinically localized prostate cancer and selected postsurgical outcomes. To our knowledge, this is the first study to assess the volume–outcome relationship for radical prostatectomy. Approximately 180,000 men in the United States are diagnosed with prostate cancer each year (7), and an estimated 60,000 annually undergo radical prostatectomy as initial therapy for clinically localized prostate cancer. About half of these procedures are performed on men 65 years old or older. Focusing on this age group using Medicare claims data, Yao and Lu-Yao demonstrate that men undergoing radical prostatectomy in hospitals performing a higher volume of procedures had a lower risk of re-admissions, serious complications, and 30-day postsurgical mortality. While these results are clearly presented, they also raise questions about methods, interpretation, and application of volume–outcome studies.

The Medicare claims data offer the advantages of being readily available and inexpensive, covering almost the entire population over age 65 years, and having nearly complete follow-up. These data have become increasingly used by researchers for examining the process and outcomes of care. However, because the Medicare Program covers persons aged 65 years and older, the volume of procedures in the age group under 65 years cannot be measured. Thus, hospitals may be inaccurately classified if the volume in the elderly population correlates poorly with total volume.

Other deficiencies of administrative claims for assessing quality of care have been previously well documented (8). These issues include the accuracy and completeness of diagnostic codes, differences in data quality across hospitals, and problems with establishing the timing of events. This makes it particularly difficult to differentiate some complications, such as congestive heart failure, from existing comorbidities.

There are methodologic challenges when assessing the relationship between volume and outcomes. It is essential to adequately risk-adjust to ensure that observed outcomes are due to hospital volume rather than to underlying differences in the health status of the patient population. Yao and Lu-Yao (6) adjusted for age and comorbidities from inpatient episodes occurring 12 months prior to surgery. This adjustment provides control for some, but not likely all, baseline risk differences. Second, there may be other unmeasured factors that may be important determinants of outcomes. The study by Yao and Lu-Yao did not assess surgeon volume or referral patterns, which may be as important a determinant of outcomes as hospital volume (3,9,10). A surgeon’s level of skill not only might have an impact on short-term outcomes but also might be reflected in the ability to achieve clear margins, which has ramifications for the patient remaining free of disease.

Despite these methodologic challenges that may limit causal inferences, the results reported by Yao and Lu-Yao (6) remain convincing for an apparent association between hospital volume and selected outcomes following radical prostatectomy. If one accepts the validity of these results, what are the implications for clinical practice? Volume–outcomes studies have been cited in support of concentration of cancer care in high-volume, specialized “centers of excellence” (11).

It is debatable whether the current evidence about outcomes for radical prostatectomy is sufficient to mandate such policies. In the study by Yao and Lu-Yao (6), the observed risk of 30-day mortality is quite small (about 0.5%), and the relative risks of outcomes across volume groups were fairly modest. Although these risk ratios were found to be statistically significant in a cohort of 100,000 cases, are they clinically meaningful and sufficient by themselves to dictate where patients should go to receive the procedure? There may be other factors that are relevant when choosing a hospital for major surgery (e.g., continuity of care and convenient access for patients and their caregivers).

Another challenge for applying volume–outcomes results to clinical practice is determining an operational definition of high volume that is useful for identifying better quality. Yao and Lu-Yao (6) divided hospitals arbitrarily into quartiles of volume, raising the question: What is the minimum volume level necessary to achieve good outcomes? Defining the appropriate volume threshold and establishing a clinically meaningful difference are closely related but complex and often subjective issues.

Affiliation of authors: Applied Research Program, Division of Cancer Control and Population Sciences, National Cancer Institute, Bethesda, MD. Correspondence to: Arnold L. Potosky, Ph.D., National Institutes of Health, Executive Plaza North, Rm. 313, 6130 Executive Blvd. MSC 7344, Bethesda, MD 20892-7344 (e-mail: potsosky@nih.gov).

1906 EDITORIALS
The outcomes reported by Yao and Lu-Yao (6) are not necessarily those of highest relevance for describing the quality of care for clinically localized prostate cancer, which has a prolonged natural history and a high 10-year survival (12). The outcomes that may matter most to prostate cancer patients who choose to undergo radical prostatectomy are their chances of long-term survival and other quality-of-life end points, such as urinary and sexual functioning.

Assessing the importance to clinical practice of the volume–outcomes effects reported for radical prostatectomy should be considered within the context of other pressing questions about treatment for clinically localized prostate cancer. There have been no definitive randomized trials completed that have established the efficacy of radical prostatectomy, and there is a considerable amount of uncertainty and disagreement about the advantages of surgical removal compared with those of other therapeutic strategies for clinically localized prostate cancer (13–15). While the mortality benefit is unproved, there is a substantial detrimental effect of radical prostatectomy on urinary and sexual function (16,17). For radical prostatectomy, determining whether high volume is equivalent to better quality, in the broadest terms most meaningful to patients, cannot be clearly resolved until more clinical studies are completed, most notably the ongoing randomized trial comparing prostatectomy with observation (18).

Should men choose to undergo radical prostatectomy, it may be prudent to seek high-volume providers to minimize the risk of short-term postsurgical mortality. However, until more research is available on the long-term outcomes of prostatectomy compared with those of other treatment strategies, perhaps the best indicator of quality of care for men with clinically localized prostate cancer may be the extent to which they are fully informed of their treatment options and any associated long-term outcomes.

REFERENCES