# Downstream effects of regionalization: reconciling our predictions with the volume-outcome paradigm

### Daniel C. Parker<sup>1</sup>, Nikhil Waingankar<sup>2,3</sup>

<sup>1</sup>Department of Urology, The University of Oklahoma Health Sciences Center & The Stephenson Oklahoma Cancer Center, Oklahoma City, OK, USA; <sup>2</sup>Department of Urology, <sup>3</sup>Department of Population Health Science and Policy, Icahn School of Medicine at The Mount Sinai Hospital, New York, NY, USA

*Correspondence to:* Nikhil Waingankar, MD, MSHP. Department of Urology, Icahn School of Medicine at The Mount Sinai Hospital, 25-10 30th Ave, Astoria, New York, NY 11102, USA. Email: nikhil.waingankar@mountsinai.org.

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Introduction

In the United States, there has been widespread recognition among health care quality improvement experts that a strong relationship exists between the volume of particular surgical cases performed and the outcomes experienced by patients electing to undergo such procedures (1,2). Volume, in this sense, can represent both the degree of experience and referral nature of the operator as well as the readiness and capacity of the hospital organization where she/he chooses to perform the surgery. Mortality and morbidity are the most commonly used measurements of comparison when discussing patient outcomes between surgeons or hospitals, although other metrics exist (3). The volume-outcome relationship, then, is a macro-economic phenomenon that is intuitively congruent with what we, as surgeons, know from our own experience learning the art: that surgery and care of surgical patients are taskoriented specialties; skills accomplishing these tasks improve with repetition and practice; skills can atrophy without maintenance of aptitude; objectives become more proficiently achieved as experience accumulates.

No contemporary discussion of the volume-outcome effect in surgical patients can begin without reference to the work of Birkmeyer and colleagues who, in the early 2000s, published two landmark manuscripts confirming the existence of an inverse relationship between operative mortality and hospital (4) as well as individual surgeon (5) volume for certain index procedures in a large population of Medicare patients. As a prime urologic example of the principles established by Birkmeyer, numerous studies have tested the volume-outcome effect on radical cystectomy for bladder cancer due to its oncologic complexity and because of the narrow technical margins that separate outcomes of patients receiving intricate urinary diversions. Reintervention rates (6), cost (7), and patient satisfaction (8) are all metrics [aside from mortality (9)] associated with surgeon and hospital volume that impact cystectomy outcomes.

Less clear is how our predictions of the downstream manifestations of the volume-outcome relationship have corresponded to actual patient outcomes over time. Regionalization, a strategy whereby select health care resources are siphoned to pre-defined high-volume centers and operators, is one effect that has been noted across multiple specialties (10). Other downstream implications of the volume-outcome paradigm concern the timeliness, efficiency, and equitability of care delivered across geographic regions and demographic populations. For each of these effects, health policy that encourages patients to seek scarce resources from centralized, highvolume providers carries the potential to create severe supply/demand imbalances.

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Are patient outcomes congruent with our predictions? One article in this month's *Journal of Urology*, entitled *The Association Between Mortality and Distance to Treatment Facility in Patients with Muscle Invasive Bladder Cancer* finds somewhat counterintuitive results (11). For example, our prediction might be that in a system which incentivizes the centralization of surgery for muscle invasive bladder cancer (MIBC), patients will simply wait longer and travel farther to receive therapy from high-volume surgeons. Since timeto-cystectomy impacts overall survival (12), we would further expect that mortality would correspondingly rise as the distances to treatment and wait times increase. But as Ryan *et al.* have shown, the reality may be more complex than predicted.

#### Regionalization: a downstream effect of volumeoutcome

Avedis Donabedian's conceptual framework for analyzing the quality of health care delivery can be used as a template to explain why regionalization results from systems which organize services around high-volume providers (13). In the Donabedian model, the origin of any patient outcome can be traced to underlying health system structure and care delivery processes. Through self-generated experience or selective referral (14), high-volume providers of any given service will acquire and hone the necessary structure and process measures to make delivery of that service more efficient. Good patient outcomes, in the Donabedian model, are a reflection of a provider's ability to attain this optimization.

A relatively recent method has also emerged by which healthcare consumer bases can be grown and herded toward centralized providers: the leveraging of healthcare purchasing power. For example, the Leapfrog Group a consortium of large corporations whose aim is to impact the outcomes and affordability of healthcare delivery by promoting safety and quality initiatives—has become a large national purchaser of healthcare services. Because of its industrial influence, Leapfrog can direct its nearly 40 million subscribers to organizations which satisfy transparently published quality metrics; purchasers can thus shop for high value care, and patients are centralized to high-performing hospitals.

An alternative mechanism of centralization is through direct policy and/or governmental guidelines. For example, in the nationalized healthcare setting, the United Kingdom's National Institute for Health and Care Excellence (NICE) defines geographic as well as cost boundaries for the acquisition of services, particularly for urologic pelvic surgery.

An established literature foundation exists confirming that trends towards centralization of various urologic procedures is occurring, most notably for radical cystectomy (9,15,16). Data from Fox Chase Cancer Center analyzing the New York, New Jersey, and Pennsylvania tri-state area between 1996-2009 reported a significant concentration effect of cystectomy services at very high-volume institutions (defined as >32 cystectomies per year) resulting from a 23% decrease in the number of providers offering the procedure in that region. Concomitantly, a 22% annual increase in the number of patients receiving cystectomy at very high-volume hospitals was observed during the study period (17). After adjustment for confounding factors, receipt of radical cystectomy at very high-volume institutions was significantly associated with decreased odds of mortality (OR =0.33) relative to very low-volume hospitals (0-2/year).

The data for regionalization's positive effect on clinical outcomes notwithstanding, concerns over potential detrimental impacts on access to care have been raised. For muscle-invasive bladder cancer patients, any socioeconomic force which delays definitive therapy in the form of neoadjuvant chemotherapy and radical cystectomy portends a worse prognosis for the patient (12). Tomaszewski and colleagues reported data from a National Cancer Database (NCDB) analysis during 2003-2010 of more than 22,000 patients with MIBC noting that 14% experienced a 3-month treatment delay due to transitions of care between hospitals, presumably toward regionalized centers (18). A contemporary trend analysis revealed that both the frequency of care transitions and the treatment delays related to them increased significantly over the study period. This study also implicates regionalization as a factor in disparate access to care on the basis demographic and socioeconomic factors related to cystectomy, as African-American patients and patients with Medicaid or without insurance were more likely to experience treatment delays during care transitions. Similarly, Smaldone et al. identified that the elderly, African-American patients, and those on Medicaid were more likely to be treated at non-regionalized centers (17).

The preceding discussion raises a logistical question that has implications for health services distribution: how far is too far? Does a threshold distance to centralized care exist beyond which patients are more likely to be "left behind"

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from an outcomes standpoint? Based on the above evidence, our intuitive prediction would favor a positive relationship between distance to care and outcomes such as mortality. This so-called distance bias was also the hypothesis shared by Ryan *et al.* in their article examining this question in this month's *Journal of Urology* (11).

## **Distance bias: the relationship between distance to care and outcomes**

The Association Between Mortality and Distance to Treatment Facility in Patients with Muscle Invasive Bladder Cancer is a well-conceived, thoughtful, and well-analyzed manuscript in which the authors queried the NCDB between 2004-2012 for patients with MIBC (n=34,729), with a subanalysis performed for those who underwent radical cystectomy (n=11,059). Using Zip Code data, estimated distances were calculated from the patients' approximate home location to the address of the treatment facility. Clinicopathologic data were collected on a host of variables including receipt of neoadjuvant chemotherapy and hospital volume for the radical cystectomy subgroup. Most patients (total cohort: 58%; radical cystectomy cohort: 42%) lived a short distance from their treatment facility, defined as less than 12.5 miles. The radical cystectomy cohort, however, had a larger proportion (22%) of patients who received treatment >50 miles from their zip code than the overall cohort (11.8%).

The most interesting, and perplexing, of the results reported was that the primary covariate of interest (distance traveled to treatment facility) was not associated with mortality. In fact, increased distance traveled to treatment facility was associated with a decrease in mortality for all patients. Interestingly, for the cystectomy patients, receipt of neoadjuvant chemotherapy also improved with greater distance traveled to treatment.

Indeed, these results are counter to our predictions when considered under the framework of distance to care, but when viewed in the context of regionalization to more efficient centers, the outcomes make sense. In a subgroup analysis of the radical cystectomy cohort (supplementary tables provided online), those patients who were traveling the farthest for care sought treatment at high-volume institutions. For institutions on the receiving end of these patients, this is precisely the intended consequence that practicing the selective referral theory of regionalization hopes to achieve: a center of excellence with a reputation that corrals consumer volume. For select patients with muscle invasive bladder cancer, receipt of care at centers of excellence trumps the risk of disease progression due to treatment delay.

Though it is our opinion that the results from this study are perfectly expected when viewed through the context of the Donabedian model, some questions regarding regionalization raised by this study remain to be answered and should be the focus of further research. First, the distance bias phenomenon has not been uniformly demonstrated for all procedure types. Indeed, Etzioni and colleagues utilized the National Surgical Quality Improvement Program to analyze outcomes in the context of distance traveled to the Mavo Clinic and found the opposite effect as noted here (i.e., patients who traveled less had better outcomes) (19). Moreover, Casey and associates found that while regionalization is indeed in progress in the New York area, a subset of patients exist that travel an excess distance to low volume centers despite having a high volume center close by, indicating that barriers in access to care exist beyond travel time or distance (20). Future analysis on regionalization must consider these unobserved variables that impact access to care, and must also be considered in the context of geographic provider density and disease incidence (21).

Next, while multivariable analyses generally produce hazard ratios that favor receipt of care at high-volume institutions for radical cystectomy, these relative survival differences must be considered alongside the absolute differences, which are quite small. In our data examining the effect of surgeon and hospital volume on shortterm mortality following radical cystectomy, the absolute differences in adjusted 30- and 90-day mortality between hospitals with more than 30 cases per year and those with fewer than 5 cases per year was only 0.9% and 2.3%, respectively (9). On a policy level, these small absolute survival advantages in favor of regionalization need to be weighed against the risks of undergoing surgery at lowvolume centers and the cost of losing low-volume providers entirely from the pool of available safety nets for patients who cannot obtain access to a center of excellence.

Unrealized challenges may also await regionalized health care delivery systems. As more patients gravitate towards centralized providers, such resources may become overwhelmed leading to greater wait-times and shifts in the intensity of care that regionalized centers are capable of providing. Furthermore, the structural and procedural nuances that separate highly efficient hospitals from average or low-volume centers for bladder cancer remains

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to be elucidated. Clarification of these factors may aid in improving care at safety net hospitals that still see a low annual volume of MIBC patients. Other potential areas for investigation include improvements in transfer protocols for patients who seek regionalized care, bolstering of patient navigation to improve pre-treatment communication among teams (22), and the implementation of health information technology to bridge the travel distance gap for those with poor access to regionalized, high-quality care (23).

#### Conclusions

In summary, a positive volume-outcome relationship exists for care delivered to patients with muscle invasive bladder cancer. As Ryan *et al.* found in their study on travel distance, regionalization tends to improves outcomes. Patients who travel to bladder cancer centers of excellence likely have a survival benefit despite an increased risk of modest treatment delays. However, delays during care transitions, disparities in access to care, and safety net hospital structural and procedural metrics must be addressed moving forward.

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#### Footnote

*Conflicts of Interest*: The authors have no conflicts of interest to declare.

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