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Estimating the Learning Curve of a Novel Medical Device: Bipolar Sealer Use in Unilateral Total Knee Arthroplasties

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A B S T R A C T

Background: The use of cost-effectiveness analysis for medical devices has proven to be challenging because of the existence of the learning effects in the device-operator interactions. The need for the relevant analytical framework for assessing the economic value of such technologies has been recognized. **Objectives:** To present a modified difference-in-differences (DID) cost-effectiveness methodology that facilitates visualization of a new health technology's learning curve. **Methods:** Using the Premier Perspective database (Premier Inc., Charlotte, NC), we examined the impact of physicians adopting a bipolar sealer (BPS) to control blood loss in primary unilateral total knee arthroplasties on hospital lengths of stay and total hospitalization costs when compared with two control groups. In our DID approach, we substituted month-from-adoption for the calendar-month-of-adoption in both graphical representations and ordinary least-squares regression results to estimate the effect of the BPS. **Results:** The results clearly demonstrated a learning curve associated with the adoption of the BPS technology. Although the reductions in length of stay were immediate, the first postadoption year costs increased by $1335 (extrahospital controls) to $1565 (within-hospital controls). Importantly, and also consistent with a learning curve hypothesis, these initial higher costs were offset by subsequent cost savings in the second and third years postadoption. **Conclusions:** The presented modified DID approach is a suitable and versatile analytical tool for economic evaluation of a slowly diffusing medical device or health technology. It provides a better understanding of the potential learning effects associated with relevant interventions.

Keywords: bipolar sealer, economic evaluation, learning curve, medical technology, total knee replacement.

Introduction

With the growing pressure on the health care industry to reduce costs and improve quality, medical device manufacturers are increasingly obligated to demonstrate the economic value of their technologies [1]. Although most researchers agree on the general methods of cost-effectiveness analysis of health technologies [2,3], the unique methodological challenges associated with the evaluation of medical devices remain to be analytically addressed and standardized [4–6]. One of the main challenges, particularly relevant for the product launch of surgical innovations, is the existence of a "learning curve"—the time taken and/or the number of procedures an average practitioner needs to be able to perform a procedure independently with an acceptable outcome [7]. For most devices, the observed clinical outcome is a function of both the effectiveness of the device and the skill and expertise of the surgeon, as well as other aspects such as team experience/skills and their interplay [5,6,8,9]. This implies that it is particularly useful to conduct a cost-effectiveness analysis after the approval of the device by the Food and Drug Administration [10]. Because these analyses typically rely on the use of retrospective data, and because physicians are often at different stages of device adoption at any point in time, characterizing the learning curve can be difficult. Yet any misspecification of the learning curve can limit the informative value and robustness of findings and lead to misguided decision making. Although existing studies emphasize the need for a relevant methodological framework, no analytical solution has been proposed [8].

In this study, we presented a modified difference-in-differences (DID) cost-effectiveness methodology that facilitates visualization of a new technology's learning curve. Specifically, we substituted month-from-adoption for the calendar-month-of-adoption in both our graphical representation and our regression analyses. The motivation for this approach is that it allows for an intuitively sensible and graphically intelligible analysis of any technology that institutions might actually adopt at various times. In our application, we used patient-level data to examine the impact on hospital length of stay (LOS) and total cost of

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adopting a bipolar sealer (Aquamantys, Medtronic Advanced Energy, Portsmouth, NH) in primary unilateral total knee arthroplasties (TKAs) when compared with two control groups.

The bipolar sealer (BPS) delivers radiofrequency energy and saline simultaneously to a surgical field to provide hemostasis or sealing across an exposed tissue or bone surface. The BPS is an example of a device whose performance is greatly influenced by surgeon experience and training with the product. Moreover, this is a technology that has been adopted more slowly than might have been expected given its merits [11]. Hence, an understanding of the learning curve associated with its adoption is best achieved with our modified DID analysis.

Clinical Background

TKA is a common orthopedic procedure associated with the risk of bleeding-related complications in high-risk subpopulations (e.g., those with multiple comorbidities or on anticoagulant therapy). When bleeding occurs, it can be a risk factor for the development of postoperative anemia, additional hospitalization costs, and increased postdischarge medical care [12–20]. With demand for this procedure growing over the past two decades [21–23], opportunities to reduce postoperative complications, improve medical resource utilization, and minimize the associated costs have become increasingly relevant [24,25].

Receipt of a transfusion is associated with a number of serious complications, including immunosuppression and various infectious and noninfectious complications [16–18,26–32]. Hospitalizations for TKA with a bleeding-related complication and/or blood product transfusion are, on average, 1.3 days longer than those without such complications (4.9 vs. 3.6 days) [17].

The BPS uses patented Transcollation® technology (Medtronic, Dublin, Ireland), a combination of radiofrequency energy and saline that provides hemostatic sealing of soft tissue and bone during surgery. It permanently seals blood vessels through a biomechanical process that transforms and shrinks fibrous collagen into vessel walls. When used during TKA, the BPS provides benefits for both surgeons and patients—reducing transfusion rates by minimizing intra-operative blood loss, and maintaining hemoglobin levels compared with electrocautery [33]. The device is intended for, but not limited to, endoscopic and open abdominal, orthopedic, spine, and thoracic surgery. There are no contraindications for the use of the BPS in TKA.

Methods

Three Analytic Questions

We sought to estimate the impact of the adoption of the BPS on average cost and length of hospital admission from three perspectives. The three questions constitute an implicit inquiry into the reliability of the overall findings.

First, when compared with a control group of similar patients treated by similar surgeons in similar nonadopting hospitals, does a surgeon's adoption of the BPS correlate with significant practice-level changes (hypothesized reductions) in average LOS and costs over time? Is there an apparent learning curve associated with the use of the BPS?

Second, when compared with a control group of similar patients treated by similar surgeons in the adopting physician's hospital, does a surgeon's adoption of the BPS correlate with significant practice-level changes (hypothesized reductions) in average LOS and costs over time? Is there an apparent learning curve associated with the use of the BPS?

Third, do the observed learning curve outcomes appear to be because surgeons used the BPS on more- or less-difficult patients? That is, did the procedures with the BPS have higher or lower LOS and costs when compared with the adopting surgeons' procedures that did not use the BPS?

Data Source and Study Measures

We analyzed the Premier Perspective comparative database (Premier Inc., Charlotte, NC) to assess hospital LOS and costs among patients undergoing primary unilateral TKA with or without the use of the BPS. Premier is an all-payer hospital administrative data set that covers more than 20% of all inpatient discharges in the United States. The database contains complete billing and coding history, including patient characteristics, for more than 300 million patient encounters collected from more than 2000 community-based hospitals that participate in Premier's health care alliance [34]. Data for the period January 2008 to June 2012 were used for the analysis.

The primary end points were total patient LOS and the hospital's reported estimate of their total (direct plus overhead) cost for all inpatient services provided during the admission. We removed the reported costs of the implanted prostheses, both because these are theoretically unrelated to risk of transfusion and LOS and because omitting the widely varied costs of the implants prevents the implant selection in a hospital (or by a surgeon) from affecting the analysis. The use of the BPS is not linked to any implant or another product. All financial values were adjusted to 2012 US dollars using the "inpatient hospital services" component of the "all urban consumers" component of the consumer price index.

We created an analytic data set to include all primary unilateral TKA (*International Classification of Diseases, Ninth Revision, Clinical Modification* procedure code 81.54) procedures (both BPS and non-BPS) performed on adult patients by the BPS-adopting surgeons. The use of the BPS was identified using the patient billing files. The list of the terms identifying the BPS is available in Appendix Table 4 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.03.002. Patients with multiple listings (bilateral TKA) or a total hip arthroplasty procedure performed during the same hospitalization were excluded, as were revision and partial TKA procedures.

To limit any potential bias from the low volume of TKA procedures on both hospital level and surgeon level, we imposed the following requirements:

1. We looked only at those hospitals that performed 54 or more total TKA procedures over the 54-month study period (January 2008–June 2012).
2. Within these hospitals, we looked only at experienced adopters, more specifically, the adopters who performed at least 30 total TKA surgeries with the use of BPS (an "intent to treat" criterion led to including observations if the surgeon performed 30 or more TKAs with the BPS over 30 months, but subsequently stopped using the BPS).
   After applying these exclusion criteria, there were 17 hospitals with at least one surgeon identified as an eligible (i.e., not low-volume) surgeon performing TKAs. The time of adoption varied both on surgeon and hospital levels (the first BPS adoption occurred in June 2008; the last adoption occurred in December 2011).
3. To adequately establish pre-adoption trends, we required that for any given adopting surgeon, at least 6 months of pre-adoption data must be available.
4. We excluded any procedure performed during the month of the BPS adoption.

Given the variability in the adoption times of the BPS, we specified the analyzed data set to be limited to the maximum of