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Certificate-of-Need State Laws and Total Knee Arthroplasty

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ABSTRACT

Background: Many states in the United States have certificate-of-need (CON) programs designed to restrain health care costs and prevent overutilization of health care resources. The goal of this study was to characterize the associations between CON regulations and total knee arthroplasty (TKA) by comparing states with and without CON programs.

Methods: Publicly available data were used to classify states in to CON or non-CON categories. The 100% Medicare Standard Analytical Files from 2005 through 2014 were then used to compare primary TKA procedure volumes, charges, reimbursements, and distribution of procedures based on facility volumes between the groups. Adverse events such as infection and emergency room visits after TKA were also evaluated.

Results: Although CON status was associated with lower per capita utilization of TKA, the annual incidence of TKA appears to have increased over time more rapidly in states with CON laws compared with non-CON states (overall increase of 5.6% vs 2.3%, $P < .01$). When normalized to the Medicare population, the incidence of TKA increased 2.0% in CON states, whereas it actually decreased 7.2% in states without CON regulations ($P = .011$). Average reimbursement (and thus Medicare spend) was 5% to 10% lower in non-CON states at all time points ($P < .0001$). In non-CON states, relatively more TKAs appear to be performed in lower volume hospitals. Examination of adverse events rates did not reveal any strong associations between any adverse outcome and CON status.

Conclusion: CON programs appear to have influenced the delivery of care for TKA. Although our data suggest that these laws are associated with lower per capita utilization of TKA and the use of higher-volume facilities, we were unable to detect any strong evidence that CON regulations have been associated with improved quality of care or have limited growth in the utilization of this procedure over time. Confounding population and geographic factors may influence these findings and further study is needed to determine whether or not these programs have served their purpose and should be retained.

Healthcare expenditure in the United States continues to escalate at a rapid pace. The role of government intervention in controlling these rising health care costs has been vigorously debated for decades. While some have called for increased regulation, others have argued for more competition. Certificate-of-need (CON) regulations were implemented over 50 years ago in the United States as a way to try to constrain the cost increases in healthcare [1]. CON programs were designed with the intent of aligning the supply of facilities and services with public need. Advocates felt that costs could be controlled by limiting excess capacity and unnecessary expansion of health care facilities. Under CON, health facilities are required to obtain approval from a designated state governmental agency before significant capital expenditures or changes of services could occur.

Despite the importance of this issue and the ongoing debate, there has been little examination of the role of government regulations in the practice of orthopedic surgery and virtually no evidence in the published literature to inform this debate. Given that total knee arthroplasty (TKA) is the most common inpatient surgery for Medicare beneficiaries and cost Medicare more than $7 billion in 2014 for hospitalizations alone [2], it is particularly important to investigate the impact of CON on this patient population.

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The purposes of the present study were to characterize the effects of CON regulations on TKA by (1) examining and comparing trends in procedure volumes in states with CON regulations and those without, (2) comparing trends in reimbursement between states with CONs and states without, (3) evaluating distribution of procedure volumes between high-volume, midvolume, and low-volume facilities between CON and non-CON states, and (4) comparing adverse event and complication rates after TKA between states with and without CON regulations.

Materials and Methods

Study Design and Setting

The PearlDiver Patient Records Database (www.pearldiverinc.com, Fort Wayne, IN), a for-fee insurance-based patient records database, was used for the present study. The database consists of several separate private insurers and a Medicare database with procedural volumes and patient demographics for patients with International Classification of Diseases, 9th Revision (ICD-9), diagnoses and procedures or Current Procedural Terminology codes. Data obtained are anonymous, and thus this study was deemed exempt by the authors' institutional review board. Data for the present study were derived from the Medicare database within PearlDiver, which contains approximately 55 million individual patients records from 2005-2014. The Medicare data contained within the database is the complete 100% Medicare Standard Analytical File, indexed and reorganized to allow for patient tracking over time among other benefits.

Study Subjects

The goal study population were patients who underwent isolated primary TKA. The database was first queried for all patients who fit these criteria using ICD-9 procedure code 81.54 (TKA). Patients who underwent subsequent contralateral TKA were counted only once for whichever surgery occurred first.

The state in which each patient had their surgical procedure performed is provided within the Medicare data. Each patient was grouped according to which state their procedure was performed.

CON Status

The presence or absence of CON laws governing inpatient or outpatient surgical procedures during the study period for each of the 50 United States and the District of Columbia was determined using data provided by the National Conference of State Legislatures website [3]. Patients in states with CON regulations during the study period covering both inpatient and outpatient operating rooms (ORs) formed the study group (n = 25 states, including AK, CT, DE, FL, GA, HI, IL, IA, KY, ME, MD, MA, MI, MS, NV, NH, NY, NC, RI, SC, TN, VT, VA, WV, and DC). Patients in states without CON laws, or with CON laws which did not cover ORs during the study period formed the control group (n = 20 states, including AZ, AR, CA, CO, ID, IN, KS, LA, MN, NE, NM, ND, OH, OK, PA, SD, TX, UT, WI, and WY). Three states had CON laws covering only outpatient or ambulatory ORs but not inpatient ORs and 3 states had CON laws which covered only inpatient ORs. Patients with procedures performed in these 6 states were excluded from the analysis.

Variables and Outcome Measures

The number of TKA procedures for CON states and non-CON states was determined from the standard database output. The incidence of TKA procedures was also determined by normalizing the number of procedures performed to the total number of Medicare patients in each group each year for the CON states and non-CON states. This normalization thus gave us a per capita rate of TKA in the Medicare population. These data were compared between groups both as overall incidences and as a change in normalized incidence from the index year (2005).

The overall and yearly average costs for TKA procedures were compared between CON and non-CON states by examining both per-patient procedural charges and per-patient procedural reimbursements.

The facilities in which the TKA procedures were performed are also reported in the Standard Analytical File data. For each study year, the number of procedures performed at all facilities which performed a TKA procedure was determined and categorized into low-volume (<50 procedures per year), midvolume (50-99 procedures per year), and high-volume (100 procedures or more per year) facilities. As we are unaware of a consensus as to what should be considered “low”, “mid,” or “high” volume, these cut-offs were determined by examining the facility breakdowns from the present data set to provide fairly equal distributions between groups.

Several postoperative complications after TKA were compared between CON and non-CON states. These included in-hospital death within 1 year, emergency room (ER) visit within 30 days postoperatively, admission to a hospital within 30 days postoperatively, infection within 6 months, and stiffness within 1 year. Mortality is reported within the database as a hospital discharge code; thus, patients who die at home without admission to an ER or hospital are not captured in this analysis. The other outcome measures were determined using ICD-9 and Current Procedural Terminology codes.

Statistical Analysis

Comparisons of overall procedure volumes and incidences were performed using Student *t* test and chi-squared analyses. Trends in procedure volumes and incidences were compared using linear regression analyses. Comparisons of charges and reimbursements were performed using Student *t* tests. Yearly comparisons of high-volume, midvolume, and low-volume facilities between CON and non-CON states were performed using chi-squared tests. Comparisons of postoperative complication rates were performed using a logistic regression analysis to control for confounding variables, including patient demographics (age, sex, body mass index) and numerous medical comorbidities (tobacco use, alcohol abuse, inflammatory arthritis, depression, diabetes mellitus, hyperlipidemia, hypertension, peripheral vascular disease, congestive heart failure, coronary artery disease, chronic kidney disease, chronic lung disease, chronic liver disease, thyroid disease, hypercoagulable state, and current hemodialysis use). Statistical analyses were performed in both SPSS version 24 (Aramonk, NY) and Microsoft Excel (Microsoft, Redmond, WA).

Results

Incidence

We identified 1,247,485 patients in CON states and 1,182,708 patients in non-CON states who underwent TKA over the period studied (2004-2014). The overall normalized incidence of TKA was higher in non-CON states compared with CON states (Fig. 1). However, the incidence of TKA was observed to steadily decrease over time in non-CON states, whereas the incidence slowly increased in CON states ($P = .011$; Fig. 2).