

Correlation of Postoperative Epidural Analgesia With Morbidity and Mortality Following Total Knee Replacement in Medicare Patients

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Abstract

It is unclear whether perioperative epidural analgesia is associated with a decrease in mortality in patients who undergo orthopedic procedures.

We examined 35,878 patients' data obtained from a random sample of Medicare beneficiaries who underwent elective total knee replacement. Division of patients into 2 groups was based on presence or absence of billing for postoperative epidural analgesia. Outcomes assessed were death and major morbidity 30 days after surgery.

Multivariate regression analysis revealed no between-groups difference in mortality 30 days after surgery. Postoperative epidural analgesia was not associated with lower incidence of mortality or major morbidity in Medicare patients who underwent elective total knee replacement.

Although the overall effect of intraoperative neuraxial (spinal and epidural) anesthesia on perioperative mortality is unclear,^{1,2} a systematic review of the literature indicates that patients who undergo orthopedic procedures with intraoperative neuraxial (vs general) anesthesia have a significantly lower 30-day mortality rate in part because of reduced odds of deep venous thrombosis and pulmonary embolism.³ However, it is not clear whether postoperative epidural analgesia might

influence perioperative mortality in these patients. Despite the potential physiologic benefits of epidural anesthesia,⁴ few studies have specifically examined the effect of postoperative epidural analgesia on postoperative mortality.

A prospective randomized controlled trial (RCT) is the ideal design for determining causality between an intervention (epidural) and an outcome (death), but a study designed to evaluate the effect of postoperative epidural analgesia on patient mortality in a relatively lower risk surgical procedure (eg, total joint replacement) may require more than 1 million subjects.⁵ An alternative method is to use large databases, such as the database of Medicare claims, to examine the correlation of perioperative epidural anesthesia and analgesia on mortality after total knee replacement (TKR).

We previously used administrative databases to examine the effectiveness of postoperative epidural analgesia on morbidity and mortality in Medicare patients who underwent a mix of surgical procedures,² and we have currently performed a subgroup analysis of these data to specifically examine TKR.

METHODS AND MATERIALS

Our institutional review board does not require approval to use an established database for research as long as the data are de-identified. A 5% nationally random sample of the 1997–2001 Medicare population was obtained and used for the analysis. Medicare database patients who were older than 65 and who underwent TKR were identified from part B using the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* codes for TKR (81.54) and revision TKR (81.55). Patients eligible for inclusion had an inpatient record for the procedure. Emergency surgical cases were excluded. Division of eligible patients into 2 groups was based on presence or absence of *Current Procedural Terminology* code 01996 (daily management of epidural analgesia). The methodology of our current analysis is similar to that of our prior analyses.² Data on major morbidity 30 days after surgery were obtained from part B for each group based on the presence of *ICD-9-CM* diagnosis codes. Number of deaths 30 days after surgery was also determined. Deyo modification of the Charlson index, a comorbidity measure based on diagnosis subgroups and

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Table I. Demographic and Other Baseline Data (Medicare 1997–2001)

	No Epidural (n = 30,181)	Epidural (n = 5697)	P
Sex			.88
Male	10,516 (35%)	2040 (36%)	
Female	19,665 (65%)	3657 (64%)	
Race			>.99
Caucasian	27,863 (92%)	5306 (93%)	
African American	1576 (5%)	272 (5%)	
Other	742 (2%)	119 (2%)	
Age (y)			.99
65-69	7515 (25%)	1435 (28%)	
70-74	9264 (31%)	1803 (32%)	
75-79	8078 (27%)	1477 (25%)	
80-84	3984 (13%)	742 (13%)	
>85	1340 (4%)	240 (4%)	
No. of inpatient days (mean, SD)	4.5 (2.6)	4.5 (2.5)	>.99
No. of intensive care unit days (mean, SD)	0.1 (1.0)	0.1 (1.0)	>.99
Charlson index (mean, SD)	0.1 (0.4)	0.1 (0.4)	>.99

developed by Elixhauser, was calculated for both groups.^{6,7} Multivariate regression analysis incorporating sex, race, age, comorbidities (for both modified Charlson and Elixhauser indices separately), hospital size, hospital teaching status, and hospital technology status was performed to determine whether the presence of postoperative epidural analgesia had an independent effect on mortality or major morbidity. Multivariate logistic models were developed separately for death at 30 days and for each complication at 30 days. Logistic regression equations were calculated with SAS 8.02 software (SAS Institute, Cary, NC). The χ^2 test was used to analyze differences in proportions of sex, race, and age; the *t* test was used to compare lengths of hospital stay and illness severity measures between the groups. All 30-day morbidity and mortality data are reported as odds ratios (ORs) with 95% confidence intervals (CIs).

RESULTS

From the 5% random sample of 1997–2001 Medicare claims data, we identified 35,878 patients who underwent TKR. Of these, 5697 (15.9%) received postoperative epidural analgesia, and 30,181 (84.1%) did not. Demographic data, length of hospital stay, length of intensive care unit stay, and illness severity data are shown in Table I. There were no differences between the groups with regard to any of these parameters.

Thirty days after surgery, unadjusted mortality rates were 0.44% and 0.37% for the no-epidural and epidural groups, respectively, and the overall rate (combined no-epidural and epidural groups) was 0.43%. In addition, unadjusted rates for all morbidity-related events were 0.73% and 0.95% for the no-epidural and epidural groups, respectively, and the overall rate (combined no-epidural and epidural groups) was 0.76%.

Adjusted data from the multivariate regression analysis incorporating such factors as sex, race, age, and comorbidities are shown in Table II. There was no significant difference in the 2 groups' mortality rates after 30 days (OR, 0.83; CI, 0.49–1.40; *P* = .47). There were increased odds of cardiac dysrhythmias, pneumonia, and somnolence in the epidural group 30 days after surgery.

DISCUSSION

In this study of a 5% national sample of 1997–2001 Medicare patients who underwent TKR, we found no significant difference in 30-day mortality rates between those who had received postoperative epidural analgesia and those who had not. Presence of postoperative epidural analgesia was associated with a surprising increase in odds of cardiac dysrhythmias, pneumonia, and somnolence in the epidural group 30 days after surgery. With its total of 35,878 patients, equivalent to approximately 718,000 subjects (604,000 without epidural analgesia plus 114,000 with epidural analgesia) for a 100% sample, our study is one of the largest to examine the correlation of postoperative analgesia on mortality after TKR.

Our findings are similar to those found in other observational trials^{1,8} but are at odds with the largest meta-analysis of RCTs.³ Although the issue of regional versus general anesthesia is controversial, reconciling the differences may be possible. Patients who underwent TKR may have been relatively healthy (eg, low Charlson index), and a unimodal intervention (eg, epidural analgesia) would unlikely have been able to influence a complex outcome (eg, death), despite the many physiologic benefits (decreased perioperative stress response, increased venous blood flow, improved perioperative pain control) of postoperative epidural anesthesia.⁴ Also, it is possible that epidural catheters were removed early in the postoperative period because

Table II. Adjusted Association Between Postoperative Epidural Analgesia and Outcome 30 Days After Surgery

Outcome at 30 Days	Odds Ratio	95% Confidence Interval	P
Death	0.82	0.49-1.40	.47
Acute myocardial infraction	0.56	0.17-1.83	.34
Cardiac dysrhythmias	2.16	1.21-3.87	.01
Heart failure	0.71	0.16-3.13	.66
Pneumonia	2.65	1.06-6.61	.04
Deep venous thrombosis	1.79	0.66-4.90	.26
Pulmonary embolism	1.62	0.69-3.76	.27
Sepsis	0.45	0.06-3.67	.46
Acute renal failure	1.60	0.33-7.77	.56
Acute cerebrovascular event	2.31	0.20-26.46	.50
Somnolence	13.21	1.14-153.51	.04
Any adverse event	1.53	1.11-2.12	.01

of concerns about concurrent thromboprophylaxis,⁹ and patients may not have received the full physiologic benefit of epidural analgesia, which may require infusion over a longer period. Finally, most RCTs have focused on comparing intraoperative epidural versus general anesthesia and have not been appropriately designed to discern a difference in outcomes with respect to postoperative epidural analgesia alone.

Our 30-days-after-surgery unadjusted mortality rate of 0.43% mirrors the rates found in other large retrospective reviews (0.1%-0.7%).¹⁰⁻¹⁶ The mortality rates are accurate, as death was captured in the Medicare claims database by checking the date-of-death field in the Medicare beneficiary enrollment file, obtained from the Social Security Administration.¹⁷ However, our individual morbidity rates are slightly lower than the rates in other retrospective sources (eg, 0.1% for pulmonary embolism after 30 days vs 0.4%-1.6%^{10,11}) and much lower than the rates in prospective trials (eg, 0.7% for deep venous thrombosis vs 7%-42%¹⁸⁻²⁰). Our overall morbidity rate of 0.8% was also lower than the rates reported in other trials (2.2%-21.8%).^{11,21} RCTs and systematic reviews indicate that postoperative epidural analgesia generally is associated with *decreased* risk for cardiac dysrhythmias,²² pneumonia,²³ and somnolence,²⁴ so we were surprised at and cannot fully explain the increase in these morbidities 30 days after surgery with epidural analgesia.

The discrepancies in our morbidity rates reflect some of the limitations inherent in using the Medicare claims database and other databases, which were created mainly for administrative/billing and not for research. Although mortality data are generally robust for the Medicare claims data set, morbidity rates (as in our data) may not be accurate, as retrospective extraction of complications from databases may be beset by ambiguities in coding, misclassification, and uncoded factors, such as disease severity,²⁵ such that rates of complications and comorbid conditions may be underreported in databases.^{26,27} However, there are several advantages in using databases in this type of analysis. A prospective RCT conducted to determine the efficacy of postoperative epidural analgesia on perioperative mortality

after TKR (a relatively low-risk procedure) would not be feasible because of the extremely large sample sizes (>1 million patients⁵) and the costs and time required to undertake this type of project.

CONCLUSIONS

We analyzed Medicare patients who had undergone elective TKR, stratified them according to presence or absence of postoperative epidural analgesia, and found no difference in 30-day mortality rates between patients who received postoperative epidural analgesia and those who did not. In addition, we unexpectedly found postoperative epidural analgesia associated with increased odds of cardiac dysrhythmias, pneumonia, and somnolence 30 days after surgery. These results should be interpreted with caution, in part because of some of the methodologic issues in database analysis. Whether to use postoperative epidural analgesia should be decided on an individual basis after assessing patient preferences^{28,29} and the risks³⁰⁻³² and benefits³³ of the technique.

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