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Medicare expenditures for elderly patients undergoing surgical clipping or endovascular intervention for unruptured cerebral aneurysms

Kimon Bekelis, M.D.^{1,2}, Dan Gottlieb, M.S.², Yin Su, M.S.², Nicos Labropoulos, Ph.D.⁴, George Bovis, M.D.⁵, Michael T. Lawton, M.D.⁶, and Todd A. MacKenzie, Ph.D.^{2,3,7,8,9}

¹Section of Neurosurgery, Dartmouth-Hitchcock Medical Center, Lebanon, NH

²The Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, NH

³Geisel School of Medicine at Dartmouth, Hanover, NH

⁴Department of Radiology, Stony Brook University Medical Center, Stony Brook, NY

⁵Department of Neurosurgery, Rush University Medical Center, Chicago, IL

⁶Department of Neurosurgery, University of California, San Francisco Medical Center, San Francisco, CA

⁷Department of Biomedical Data Science, Geisel School of Medicine at Dartmouth, Hanover, NH

⁸Department of Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, NH

⁹Department of Community and Family Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, NH

Abstract

Background—The cost difference between the two treatment options (surgical clipping and endovascular therapy) for unruptured cerebral aneurysms remains an issue of debate. We investigated the association of treatment method for unruptured cerebral aneurysms and Medicare expenditures in elderly patients.

Methods—We performed a cohort study of 100% of Medicare fee-for-service claims data for elderly patients, who underwent treatment for unruptured cerebral aneurysms from 2007 to 2012. In order to control for measured confounding, we used multivariable regression analysis with

Corresponding Author: Kimon Bekelis, M.D., Section of Neurosurgery, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03755, T. 6036505110, F. 6036504547, kbekeles@gmail.com.

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mixed effects to account for clustering at the HRR level. An instrumental variable (regional rates of endovascular treatment) analysis was used to control for unmeasured confounding by creating pseudo-randomization on the treatment method.

Results—During the study period, there were 8,705 patients, who underwent treatment for unruptured cerebral aneurysms, and met the inclusion criteria. Of these, 2,585 (29.7%) had surgical clipping, and 6,120 (70.3%) had endovascular treatment. The median total Medicare expenditures in the first year after the admission for the procedure were \$46,800 (IQR \$31,000 to \$74,400) for surgical clipping, and \$48,100 (IQR \$34,500 to \$73,900) for endovascular therapy. When we adjusted for unmeasured confounders, using an instrumental variable analysis, clipping was associated with increased 7-day Medicare expenditures by \$3,527 (95% CI, \$972 to \$5,736) and increased 1-year Medicare expenditures by \$15,984 (95% CI, \$9,017 to \$22,951).

Conclusions—In a cohort of Medicare patients, after controlling for unmeasured confounding, we demonstrated that surgical clipping of unruptured cerebral aneurysms was associated with increased 1-year expenditures in comparison to endovascular treatment.

Keywords

cerebral aneurysms; cost; clipping; endovascular therapy; instrumental variable; Medicare

INTRODUCTION

Optimal treatment selection for cerebral aneurysms has been an issue of debate in recent years.¹² Since the publication of the International Study for Aneurysm Treatment (ISAT),³ there has been a paradigm shift in the treatment of cerebral aneurysms, with an increasing focus on endovascular coiling as the preferred intervention for subarachnoid hemorrhage (SAH) patients.¹⁴ Additional investigations have supported that the results of endovascular intervention are at least non-inferior to open surgery for unruptured cerebral aneurysms,⁵ fueling an explosive growth of coiling in this population.¹ However, concerns have been raised that technologically advanced endovascular options carry a significant cost attributed to constantly evolving devices that outweighs the cost of clipping, which involves less expensive implants. With cost containment being a national priority,⁶ demonstrating the financial viability of new treatment options is crucial.^{7–17}

Several studies have analyzed the economic aspects of cerebral aneurysm interventions.^{18–23} However, the generalizability of their findings is limited, because most authors failed to adjust appropriately for measured or unmeasured confounders. Some are single center^{18–20} or international experiences,^{21–23} whereas others have utilized charges as a surrogate for cost,²⁴ and are therefore not reflecting the true financial impact of these procedures. Several investigators have focused only on hospitalization cost, which does not take into account the cost of possible future reintervention in endovascularly treated patients, or the cost of long-term care in patients experiencing complications.^{18,19,22–26} Analyses over longer periods have focused only on ruptured cerebral aneurysms.^{20,21} There is no prior investigation examining the comparative long-term cost of clipping and endovascular therapy, while appropriately controlling for unmeasured confounders.

We performed a national cohort study of Medicare patients with unruptured cerebral aneurysms investigating the association of treatment method and Medicare expenditures for elderly patients in the first year postoperatively. In order to control for unmeasured confounding, we used an instrumental variable (IV) approach, simulating pseudo-randomization on the treatment method.

METHODS

Data and cohort creation

This study was approved by the Dartmouth Committee for Protection of Human Subjects. The data was anonymized and de-identified prior to use and therefore no informed consent was required. We used 100% of Medicare Denominator file and corresponding Medicare inpatient and outpatient claims, Parts A and B, 2007–2012 (MedPAR, Carrier and Outpatient files) to select patients with unruptured cerebral aneurysm diagnosis. Aneurysm patients were identified based on one or more inpatient or outpatient diagnoses (*International Classification of Diseases, Ninth Revision* (ICD-9) diagnosis code 437.3) between 2007 and 2012 (including 2012). For cohort inclusion, patients were required to be (1) continuously enrolled in fee-for-service (FFS) Medicare Parts A, and B for 12 months before index diagnosis, (2) be age 65 or older at the time of index diagnosis, and (3) have no secondary insurance at any point during the study. The reason for exclusion of the last group (less than 11 patients) was that we did not have access to parts of these patients' care billed to other insurances or the amounts paid by other vendors. Therefore if these patients were included, their costs (since we could only access Medicare expenditures) would be artificially low and bias our analysis.

Intervention

We used ICD-9-CM codes to identify patients with unruptured cerebral aneurysms (ICD-9-CM code 437.3) who underwent clipping (ICD-9-CM code 39.51) or endovascular therapy (ICD-9-CM code 39.52 (should also have a code 88.41 and no 39.51 during the same hospitalization), 39.72, 39.75, 39.76 39.79) between 2007 and 2012.

Outcome variables

The primary outcome was 1-year total Medicare expenditures, starting on the admission day for the procedure. Secondary outcome was 7-day total Medicare expenditures, starting on the admission day for the procedure. These calculations included the exact amount paid for all billing claims (including imaging, angiography etc.) generated during this time frame.

Covariates

Age categories (65–69, 70–74, 75–79, 80–84, 85–99) were created, as well as five ethnicity and race categories (Asian, Black, Hispanic, Native American, and other, with white being the excluded variable). The enrollee's ZIP code was used to match to 2010 Census data on income and poverty. We included the ZIP-level poverty rate separately, from the income variable, to reflect the differing distribution of income within the ZIP code.

Comorbidities, diagnosed (in more than 2 outpatient and/or 1 inpatient encounters) at any time in the 12-month look-back (before the intervention), for which outcomes were adjusted (Supplemental Table I), included: hypertension, myocardial infarction, cardiac arrhythmia, congestive heart failure, hyperlipidemia, coagulopathy, hypertension, ischemic stroke, peripheral vascular disease, chronic obstructive pulmonary disease (COPD), other pulmonary disease, diabetes, obesity, alcohol abuse, malignancy, and dementia.

Each facility was identified with one of the 306 Hospital Referral Region (HRR) in the United States as used by The Dartmouth Atlas of Health Care. An HRR is a region served by a hospital or group of hospitals that offer cardiovascular and neurosurgical procedures, so that each HRR includes at least one tertiary care hospital. All ZIP codes in the United States were assigned to HRR on the basis of the migration patterns of hospital use among the elderly population. The endovascular therapy rate in each HRR was calculated by dividing the number of endovascular procedures in an HRR by the number of total interventions for unruptured cerebral aneurysms in the same location and time period.

Statistical analysis

To compare total Medicare expenditures between endovascular and clipping therapies we initially used multiple linear regression, adjusting for all the covariates listed above, to address known confounders. These models included a random intercept for HRR. In sensitivity analysis we repeated this approach after logarithmic transformation of expenditures. The results were similar and are therefore not reported further.

Patients have already been selected for clipping or endovascular treatment, which can affect the outcomes as well as the cost of these interventions. To overcome this confounding (the non-random selection of patients for either treatment) due to covariates not captured by Medicare analyses we employed an instrumental variable analysis.²⁷ This analysis uses the differences in practice patterns across regions to simulate the structure of a randomized trial, in an observational setting. This advanced observational technique has been used before by clinical researchers, to answer comparative effectiveness questions for different interventions. The goal is to simulate randomization, especially when the baseline functional characteristics of the patients are unknown (similar to our application).^{28–30} Instrumental variable analysis effectively compares similar patients that have already undergone clipping and coiling and doesn't reassign clipped patients to coiling and vice versa. Therefore this analysis doesn't imply that patients with surgically inaccessible aneurysms should undergo open procedures or the opposite.

Use of endovascular therapy varies widely across HRR. Patients tend to seek care for unruptured aneurysms close to their residence. Someone, who lives in an HRR where endovascular treatment is primarily offered, is more likely to receive this treatment. The IV approach depends on the assumption that HRR endovascular treatment rates affect the outcomes only by promoting the use of these treatments in the HRR (exclusion restriction criterion), and on the assumption that there are no variables that affect both the regional endovascular treatment rate and costs (no instrument-outcome confounders) besides those adjusted for as in the linear regression models above. HRR endovascular treatment rates were not correlated with average predicted cost within an HRR, based on covariates

controlled for in the regression models above ($r=-0.03$, $P>0.10$) suggesting case-mix balance between HRRs, and therefore there was no correlation of the instrument with the outcomes as per the model assumptions. A practical rule³¹ for employing an instrument is that the F-statistic (or chi-square for a binary exposure) for the association of the instrument and treatment exceeds 10. This value was 941 in our study, when using HRR endovascular treatment rates as an instrument for endovascular therapy. In sensitivity analysis, we used the differential distance of the patient's residence to facilities preferentially offering clipping versus endovascular intervention. Although the results were qualitatively the same, this second IV approach had minimal ability to discriminate between treatments, and resulted in high variance. Therefore, this was not used further.

We subsequently calculated the causal estimate of the differences in total Medicare expenditures between clipping and endovascular intervention, using a linear regression model with an IV analysis, in 2-stage least squares approach (2SLS), as previously described in the literature.⁵²⁸⁻³⁰ HRR endovascular treatment rate was used as an instrument for endovascular intervention, and we additionally adjusted for all other covariates listed above. In sensitivity analysis we excluded patients with less than a year of follow up from our models. The direction of the observed associations did not change and therefore these results are not reported further.

Given that we had 6,120 patients undergoing endovascular intervention and 2,585 clipping, we had an 80% power to detect a difference in cost as small as 4.0%, at an α -level of 0.05 assuming a lognormal distribution with mean of \$48,000 and IQR of \$32,000 to \$72,000. Patients with missing data (3% of poverty and income) were excluded from further analysis. All probability values were the result of two sided tests. SAS version 9.4 (SAS Institute, Cary, NC), and the 64-bit version of R.2.12.2 (R Foundation for Statistical Computing) were used for statistical analysis.

RESULTS

Patient characteristics

From 2007–2012, there were 8,705 Medicare patients who underwent treatment for unruptured cerebral aneurysms, and met the inclusion criteria for the study. Of these, 2,585 (29.7%) underwent surgical clipping, and 6,120 (70.3%) endovascular therapy. The respective distribution of exposure variables between the two methods of treatment can be found in Table 1. Figure 1 demonstrates the distribution of endovascular treatment rates per HRR.

7-day total Medicare expenditures

The median total Medicare expenditures in the first 7-days after admission for the procedure were \$27,500 (IQR \$22,000 to \$35,200) for surgical clipping, and \$31,300 (IQR \$24,800 to \$39,700) for endovascular therapy.

As demonstrated in Table 2, clipping was associated with decreased 7-day expenditures by \$5,241 (95% CI, -\$5,950 to -\$4,532) in the unadjusted analysis. Adjusting for measured confounders with a logistic regression model (Table 2) demonstrated a similar association

(Adjusted difference $-\$4,865$; 95% CI, $-\$5,607$ to $-\$4,124$). However, when we adjusted for unmeasured confounders, using an instrumental variable analysis, clipping was associated with increased 7-day Medicare expenditures by $\$3,527$ (95% CI, $\$972$ to $\$5,736$).

1 year total Medicare expenditures

The median total Medicare expenditures in the first year after admission for the procedure were $\$46,800$ (IQR $\$31,000$ to $\$74,400$) for surgical clipping, and $\$48,100$ (IQR $\$34,500$ to $\$73,900$) for endovascular therapy.

As demonstrated in Table 2, there was no association of treatment method and 1-year expenditures by (difference $\$352$; 95% CI, $-\$1,807$ to $\$2,511$) in the unadjusted analysis. Adjusting for measured confounders (Table 2) demonstrated that clipping was associated with increased 1-year expenditures by $\$2,993$ (95% CI, $\$757$ to $\$5,228$). When we controlled for unmeasured confounders, using an instrumental variable analysis, clipping was associated with increased 1-year Medicare expenditures by $\$15,984$ (95% CI, $\$9,017$ to $\$22,951$).

DISCUSSION

Among Medicare patients undergoing treatment for unruptured cerebral aneurysms, we identified an association of surgical clipping with increased Medicare expenditures at 7-days and 1-year after the day of admission for the intervention, in comparison to endovascular therapy. In recent years, the pendulum has swung dramatically in favor of endovascular intervention for unruptured cerebral aneurysms. However, the comparative cost of the two techniques in this population remains an issue of debate.

Prior investigations have demonstrated conflicting results regarding the short-term cost of elective clipping and coiling. Some single center studies have demonstrated that the hospitalization cost of clipping was lower in comparison to coiling.¹⁸¹⁹²²²³ However, in a retrospective analysis of the Nationwide Inpatient Sample, Hoh et al²⁴ showed that clipping was associated with higher hospitalization charges in comparison to coiling for both ruptured and unruptured aneurysms. Bekelis et al,²⁵²⁶ in a national study utilizing the same database developed a predictive model of hospitalization cost for these patient populations. Cost calculations based on the NIS are crude and mostly derived from charges, and therefore do not reflect the true cost of the interventions. In addition, the available data refer to the acute hospitalization only, and do not allow the study of the long-term financial impact of these procedures. The lack of adjustment for center effects (clustering), and rigorous control for unmeasured confounders (the fact that patients were non-randomly selected for either treatment), significantly limit the interpretation of the results of these investigations.

Long-term economic analyses of these groups have only been performed in ruptured aneurysms. Maud et al²⁰ utilized a commercial database in order to assess the cost-effectiveness of clipping and coiling in the setting of SAH. However, the cost calculations in this study were based on assumptions and extrapolation of data from other investigations, and do not represent the exact costs incurred during the procedures. Therefore, it is questionable whether these findings give a true picture of the economic impact of the two

procedures. In addition, participation in this database was voluntary, and therefore it is likely that hospitals incentivized to achieve higher quality standards would be overrepresented. This self-selection introduces significant unmeasured confounding, which the authors did not account for. Internationally, the investigators of the ISAT study reported no difference in the cost of clipping or coiling among patients participating in the study, which was conducted mainly in Europe.²¹

Our study purposefully addresses many of these methodologic limitations. First, we created a cohort of almost all elderly patients in the United States, giving a true picture of national practice. Second, we used advanced observational techniques to control for confounding. The prior selection of patients for either procedure will undoubtedly bias the outcomes and therefore the comparative cost of the two procedures. We utilized an instrumental variable analysis to account for such bias. This approach simulates the effect of randomization on treatment by controlling for unknown confounders (i.e. aneurysm size and location). In contrast to prior studies, which lacked long-term cost analysis, we modeled our primary outcome as 1-year expenditures to account for possible future reintervention in some patients, or the cost of long-term care in patients experiencing complications. Lastly, our cost calculations are based on exact Medicare expenditures for each patient longitudinally overtime. This provides an accurate reflection of the true financial impact of those procedures, contrary to prior investigations focusing on charges or estimates.

This analysis provides insight in the economic aspects of the available treatments for cerebral aneurysms. However, we are lacking the granularity to identify the exact components contributing to the total yearly cost of either procedure.⁵ More detailed analyses can be performed by the creation of large, long-term registries, with such efforts currently being underway.³² These can integrate quality of life outcome measures (such as the modified Rankin scale), or patient satisfaction metrics to reach meaningful conclusions about cost-effectiveness.

Our study has several limitations common to administrative databases. First, this is an observational study. We used multiple techniques (multivariable regression, HRR random effects, IV analysis), to account for known and unknown confounders. To the extent that HRR endovascular treatment rate is a good instrument, the possibility of residual confounding is small. Our first stage F-statistic was consistent with a strong instrument,³¹ and it is unlikely that the regional rate of endovascular treatment will be associated with costs in any other way, than the choice of treatment. Second, coding inaccuracies can affect our estimates. However, coding for procedures is rarely inaccurate, given that it is a revenue generator, and is under scrutiny by payers.

Third, claims data do not provide metrics on the postoperative neurologic status of the patients (i.e. modified Rankin score), chronic pain, or quality of life. Therefore we cannot analyze the difference of clipping and endovascular intervention, in regards to these measures. Fourth, findings among this older, American population (patients over 65 years are eligible for Medicare coverage) may not be generalizable to younger or otherwise dissimilar populations. Although our results accurately reflect the cost of cerebral aneurysm treatment for Medicare, we cannot generalize these results for other payers or private

insurance. In addition, the elderly is not an entirely representative population for elective aneurysm treatment, since many cranial surgeons tend to not offer open surgical treatment for patients over 70 years of age. Fifth, we have no information on aneurysm size, location, and details of treatment, which can affect expenditures. However, the use of an IV analysis is expected to simulate a randomized trial, and control for such unknown confounders. Sixth, a one year horizon cannot capture all retreatment events with endovascular therapy. If a longer time frame was feasible the results might have been more favorable for the long term cost of surgery. Lastly, causal inference is hard to establish based on observational data, even when using an IV analysis.²⁷

Conclusions

The cost difference between the two treatment options (surgical clipping and endovascular therapy) for unruptured cerebral aneurysms remains an issue of debate. We investigated the association of treatment method for unruptured cerebral aneurysms and Medicare expenditures in elderly patients. In a cohort of Medicare patients, after controlling for unmeasured confounding, we demonstrated that surgical clipping of unruptured cerebral aneurysms was associated with increased 1-year expenditures in comparison to endovascular treatment. This analysis demonstrates that the upfront implant cost associated with endovascular therapy is justified.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Percent of Medicare beneficiaries treated for unruptured cerebral aneurysms using endovascular treatment (2007–2012). Each blue dot represents the percent of Medicare beneficiaries who were treated for cerebral aneurysms with endovascular therapy in one of 306 hospital referral regions in the U.S. Red dots indicate the regions with the 5 lowest and 5 highest rates. The names of the latter can be found on the left. (Bekelis K, Goodney RP, Dzebisashvili N, Goodman DC, Bronner KK. *Variation in the Care of Surgical Conditions: Cerebral Aneurysms*. Lebanon, NH, 2014, reproduced with permission)

Table 1

Patient characteristics

	Clipping	Endovascular therapy	Z-value
Age, mean (SD)	70.5 (4.0)	72.7 (5.5)	-2.3
Male gender	625 (24.3%)	1630 (26.6%)	-18.6
African-Americans	169 (6.6%)	431 (7%)	-0.8
Income [*]	\$46,900 (17,000)	\$46,000 (17,100)	-2.3
Poverty [*]	233 (9%)	483 (7.9%)	-3.7
Comorbidities[¶]			
Hypertension	1354 (52.6%)	2356 (53.1%)	-0.5
Hyperlipidemia	531 (20.6%)	1339 (22.8%)	-2.3
Chronic obstructive pulmonary disease	76 (3.0%)	156 (2.5%)	1.1
Myocardial infarction	328 (12.7%)	983 (16.0%)	-3.9
Cardiac arrhythmia	139 (5.4%)	535 (8.7%)	-5.3
Coagulopathy	19 (0.7%)	65 (1.1%)	-1.4
Renal insufficiency	66 (2.6%)	258 (4.2%)	-3.7
Congestive heart failure	67 (2.6%)	309 (5.0%)	-5.1
Pulmonary disease [§]	75 (2.9%)	147 (2.4%)	1.4
Obesity	19 (0.7%)	46 (0.8%)	-0.01
Alcohol abuse	Ø	14 (0.2%)	Ø
Dementia	17 (0.7%)	82 (1.3%)	-2.7
Ischemic stroke	263 (10.2%)	754 (12.3%)	-2.8
Diabetes	332 (12.9%)	918 (15.0%)	-2.5
Peripheral vascular disease	265 (10.3%)	923 (15.1%)	-5.9
Malignancy	162 (6.3%)	484 (7.9%)	-2.6

SD: Standard Deviation

Output represents crude numbers and percentages in parentheses

^{*} The enrollee's ZIP code was used to match to 2010 Census data on income and poverty.[¶] Based on 12-month look-back before the date of the procedure[§] Non COPD

Ø Output suppressed to comply with the reporting rules of Medicare, which do not allow printing of output involving less than 11 patients

Table 2

Correlation of clipping with outcome measures

Models	1-year expenditures [#]		7-day expenditures [#]	
	Adjusted difference (95% CI)	P-value	Adjusted difference (95% CI)	P-value
Crude	\$352 (–\$1,807 to \$2,511)	0.750	\$–5,241 (–\$5,950 to –\$4,532)	<0.001
Multivariable regression *	\$2,993 (\$757 to \$5,228)	0.009	–\$4,865 (–\$5,607 to –\$4,124)	<0.001
Instrumental variable analysis [¶]	\$15,984 (\$9,017 to \$22,951)	<0.001	\$3,527 (\$972 to \$5,736)	0.004

95% CI: 95% Confidence Interval

* Mixed effects; Includes patient's HRR as a random effect variable

[¶]HRR endovascular treatment rate (fraction of endovascular treatment of total procedures performed) was used as an instrument of choice of treatment[#]Analyses based on linear regression