Association of Device Industry Payments, Physician Supply, and Regional Utilization of Orthopedic and Cardiac Procedures

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ABSTRACT

BACKGROUND: Geographic variation in high-cost medical procedure utilization in the USA is not fully explained by patient factors but may be influenced by the supply of procedural physicians and marketing payments.

OBJECTIVE: To examine the association between physician supply, medical device–related marketing payments to physicians, and utilization of knee arthroplasty (KA) and percutaneous coronary interventions (PCI) within hospital referral regions (HRRs).

DESIGN: Cross-sectional analysis of data from the 2018 CMS Open Payments database and procedural utilization data from the CMS Provider Utilization and Payment database.

PARTICIPANTS: Medicare-participating procedural cardiologists and orthopedic surgeons.

MAIN MEASURES: Regional rates of PCIs and KAs per 100,000 Medicare fee-for-service (FFS) beneficiaries were estimated after adjustment for beneficiary demographics.

KEY RESULTS: Across 306 HRRs, there were 109,301 payments (value $17,554,728) to cardiologists for cardiac stents and 68,132 payments (value $40,492,126) to orthopedic surgeons for prosthetic knees. Among HRRs, one additional interventional cardiologist was associated with an increase of 12.9 (CI, 9.3–16.5) PCIs per 100,000 beneficiaries, and one additional orthopedic surgeon was associated with an increase of 20.6 (CI, 16.9–24.4) KAs per 100,000 beneficiaries. A $10,000 increase in gift payments from stent manufacturers was associated with an increase of 26.0 (CI, 5.1–46.9) PCIs per 100,000 beneficiaries, while total and service payments were not associated with greater regional PCI utilization. A $10,000 increase in total payments from knee prosthetic manufacturers was associated with an increase of 2.9 (CI, 1.4–4.5) KAs per 100,000 beneficiaries, while a similar increase in gift and service payments was associated with an increase of 14.5 (CI, 5.0–24.1) and 3.4 (CI, 1.6–5.2) KAs, respectively.

CONCLUSIONS: Among Medicare FFS beneficiaries, regional supply of physicians and receipt of industry payments were associated with greater use of PCIs and KAs. Relationships between payments and procedural utilization were more consistent for KAs, a largely elective procedure, compared to PCIs, which may be elective or emergent.

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INTRODUCTION

Regional variation in the use of healthcare services is well established [1,2]. For many common chronic conditions, there are both high-cost invasive procedural treatments (e.g., percutaneous coronary intervention [PCI] for coronary artery disease and knee arthroplasty for osteoarthritis) and lower-cost pharmaceutical and office-based treatments available. For most conditions, clinical guidelines recommend reserving the use of high-cost invasive procedures for more severe disease after failure to improve with other less-intensive treatments. Despite guidelines, numerous prior studies demonstrate that regional variation in procedural utilization is not fully explained by patient factors, suggesting that factors beyond clinical indication likely influence the decision to perform these procedures[3–7].

Studies from the 1990s and early 2000s have shown that supply-side factors, such as physician supply and physician characteristics, may influence the use of invasive procedures and healthcare delivery[8–11]. The creation of the Centers for Medicare and Medicaid Services (CMS) Open Payment Program has allowed for the study of another possible driver of procedure utilization, marketing payments from pharmaceutical and medical device manufacturers. Receipt of payments from pharmaceutical manufacturers has been associated with greater prescribing of marketed medications and increased requests by physicians to add drugs to hospital formularies[12–15]. However, less is known about the impact of medical device manufacturer payments. Device-related payments exceed pharmaceutical payments in overall and average value[16–20]. Medical devices differ from

pharmaceuticals in important ways. Unlike pharmaceuticals, they are not dispensed directly to patients but are used by clinicians to facilitate invasive procedures. Furthermore, the unit cost of an implanted medical device, such as prosthetics and coronary stents, is typically thousands of dollars. Recent research suggests marketing payments may influence brand selection of medical devices[21], but whether payments are associated with increased utilization of device-related procedures is unknown. Understanding this relationship, particularly in the setting of elective procedures, is important because overtreatment is associated with patient harm and health care waste[22].

Therefore, we linked CMS Open Payments data and procedural utilization data for physicians performing cardiac catheterizations, PCIs, and knee arthroplasties and participated in Medicare in 2018 in order to examine the association between medical device manufacturer payments, physician supply, and procedure utilization within healthcare referral regions (HRRs). We examined two procedures, PCI and knee arthroplasty, as they are among the most common and most expensive device-related procedures performed among Medicare beneficiaries, and prior work has shown wide regional variation in their use[5,8,9]. We hypothesized that both medical device–related payments and physician supply would be associated with higher rates of regional procedure utilization, with a stronger association for knee arthroplasties which are nearly always elective compared to PCIs which may be performed emergently or electively.

STUDY DATA AND METHODS

Overview

We conducted a retrospective cross-sectional analysis linking the following 2018 CMS databases: the Open Payments database and Physician & Other Practitioners—by Provider Public Use File, and Geographic Variation Public Use File[23–25].We examined the association between device-related marketing payments, physician supply, and rates of procedure utilization at the HRR level. HRRs are geographic areas defined by healthcare markets for tertiary care services such as receipt of advanced cardiovascular procedures and surgeries. We examined regional rather than individual utilization for three reasons. First, prior studies have demonstrated regional variation in procedural utilization. Second, individual physician procedure rates may be influenced by case-mix and degree of participation in Medicare. Third, marketing payments often target key opinion leaders whose influence may have downstream impacts on the clinical practice of peers or trainees which would not be captured by individual-level analyses[26–29]. This study reports only publicly available data and thus is not subject to federal human subject regulations for institutional review board review.

Regional Procedure Utilization

Procedure utilization data for PCIs and knee arthroplasties was obtained from the 2018 CMS Physician & Other Practitioners—by Provider Public Use File[30], which provides clinician-level aggregate counts of services and procedures provided to Medicare beneficiaries, grouped by Current Procedural Terminology (CPT) codes (Appendix A1). The database contains 100% final-action physician/supplier Part B non-institutional line items for the Medicare fee-for-service (FFS) population. We aggregated clinician-level procedures to HRRs based on clinician practice ZIP codes[31].

Physician Supply

To establish a measure of regional physician supply, we identified all cardiologists who performed at least 11 cardiac catheterizations or PCIs and all orthopedic surgeons who performed at least 11 knee arthroplasties on Medicare FFS beneficiaries using the 2018 CMS Physician & Other Practitioners—by Provider Public Use File[30]. We defined physician supply based on procedural performance, rather than specialty, to avoid misclassification of subspecialists who do not routinely perform the procedures of interest (e.g., orthopedists who specialize in other joint surgeries). We then calculated the number of specialists per 100,000 Medicare FFS beneficiaries for each HRR.

Medical Device Manufacturer Payments

To identify device manufacturers of interest, we first identified all coronary stents and knee prostheses listed in the Food and Drug Administration Product Code Classification Database[32]. We then linked products to manufacturers of each unique device using the Food and Drug Administration Global Unique Device Identification Database[33]. Each coronary stent and knee prosthesis manufacturer was then matched to the 2018 CMS Open Payments database by company name[23].

We identified all payments made by medical device manufacturers listed in the Open Payments database to interventional cardiologists and orthopedic surgeons identified from the Physician & Other Practitioners – by Provider Public Use File. We excluded research payments and payments for ownership and royalties, which reflect different types of financial relationships than marketing (e.g., income from patents).

Payments linked to product types other than medical devices (e.g., pharmaceuticals) were also excluded. We grouped payment types into two broad categories: gifts and services. Gift payments included entertainment, food/beverage, gift, travel/lodging, education, non-research grants, and charitable contributions. Service payments included consulting fees, honoraria, compensation for services other than consulting, and compensation for serving as faculty or

as a speaker for an accredited or non-accredited continuing education program, and space rental or facility fees. We calculated payments in each HRR per 100,000 Medicare FFS beneficiaries.

Covariates

We used the CMS Geographic Variation Public Use File to identify HRR-level demographics of Medicare FFS enrollees of all ages in the year 2018 including the number of FFS beneficiaries, percent eligible for Medicaid, average hierarchical conditioning category score, average age, percent female, and percent by race and ethnicity (non-Hispanic White, African American, Hispanic, and other)[34].

Statistical Analysis

We present descriptive characteristics on procedure utilization rates, physician supply, and medical device manufacturer payments nationally and across HRRs. Marketing payments are presented overall and stratified by type into payments for gifts and payments for services.

We used multivariable linear regression models fitted using ordinary least squares to analyze the association between procedural physician supply, medical device manufacturer payments, and procedure utilization rates in 2018 at the level of the HRR, including the aforementioned covariates. Then, we estimated the impact of differing quintiles of regional physician supply and of marketing payments on predicted procedural utilization by calculating post-estimation marginal means.

All regression model estimates are presented with 95% confidence intervals (CIs). All analyses were conducted between January 2020 and January 2023 using Microsoft Access and Stata-SE version 16.

RESULTS

The study population included 9,140 cardiologists performing PCIs and cardiac catheterizations, and 7,076 orthopedic surgeons performing knee arthroplasties across 306 HRRs. Of these, 7,634 cardiologists and 5,947 orthopedic surgeons received payments.

In 2018, the median annual PCI rate across HRRs was 650.2 (IQR, 491.7 to 852.2) per 100,000 Medicare FFS beneficiaries, with the highest utilizing HRRs clustered in the Midwest (Fig. 1A).

The median number of cardiologists performing PCIs per 100,000 Medicare FFS beneficiaries was 26.1 (IQR, 19.5 to 22.4) (Fig. 1B).

The median annual knee arthroplasty rate across HRRs was 874.7 (IQR, 719.4 to 1050.5) per 100,000 Medicare FFS beneficiaries with the highest utilizing HRRs clustered in the Midwest, Northwest, and Southwest (Fig. 2A). The median number of orthopedic surgeons performing knee arthroplasties per 100,000 Medicare FFS beneficiaries was 21.0 (IQR, 17.1 to 25.7) (Fig. 2B).

Among the 306 HRRs, there were 109,301 payments to cardiologists by cardiac stent manufacturers totaling $17,554,728. The median value of payments from cardiac stent manufacturers was $19,193 per HRR (IQR, $6,997 to $58,057) (Table 1). Within the top quintile of payments by cardiac stent manufacturers, the median value of payments was $110,610 (IQR, $79,161 to $153,012) per 100,000 Medicare FFS beneficiaries while the median value of the lowest quintile was $5,803 (IQR, $3,527 to $8,249) per 100,000 Medicare FFS beneficiaries (Fig. 1C).

There were 68,132 payments to orthopedic surgeons related to prosthetic knees totaling $40,492,126. The median value of payments from prosthetic knee manufacturers was $29,013 per HRR (IQR, $7,203 to $157,150) (Table 1). The median value of the top quintile of payments by knee prosthetic manufacturers was $259,979 (IQR, $201,212 to $320,774) per 100,000 Medicare FFS beneficiaries while the median value of the lowest quintile was $6,268 (IQR, $3,378 to $9,521) per 100,000 Medicare FFS beneficiaries (Fig. 2C). Across groups, gift-related payments had a higher median value than service payments (Table 1).

Association Between Physician Supply and Procedure Utilization

In multivariable regression models, increasing the supply of interventional cardiologists by 1 per 100,000 Medicare FFS beneficiaries in an HRR was associated with an increase in PCI utilization rate of 12.9 procedures (CI, 9.3 to 16.5) per 100,000 Medicare FFS beneficiaries (Table 2). Similarly, increasing the supply of orthopedic surgeons by 1 per 100,000 Medicare FFS beneficiaries in an HRR was associated with an increase in knee arthroplasty utilization rates of 20.6 procedures (CI, 16.9 to 24.4) per 100,000 Medicare FFS beneficiaries. Figure 3A shows the predicted mean number of PCIs per 100,000 Medicare FFS beneficiaries performed across HRRs if the supply of cardiologists for each HRR was at the median of each quintile for overall cardiologist supply. Figure 3B shows the same relationships for orthopedic surgeons and knee arthroplasties.

Association Between Medical Device Manufacturer Payments and Procedure Utilization

For PCIs, total payments from stent manufacturers were not significantly associated with an increase in procedure utilization (coeff, 3.4; 95% CI, – 2.9 to 9.6). Gift payments from stent manufacturers were associated with an increase in procedure utilization, but service payments were not (Table 2). An increase in gift payments from stent manufacturers to interventional cardiologists by

Distribution of percutaneous coronary interventions, cardiologist supply, and payments by medical device manufacturers of cardiac stents in 2018 to interventional cardiologists, by hospital referral region

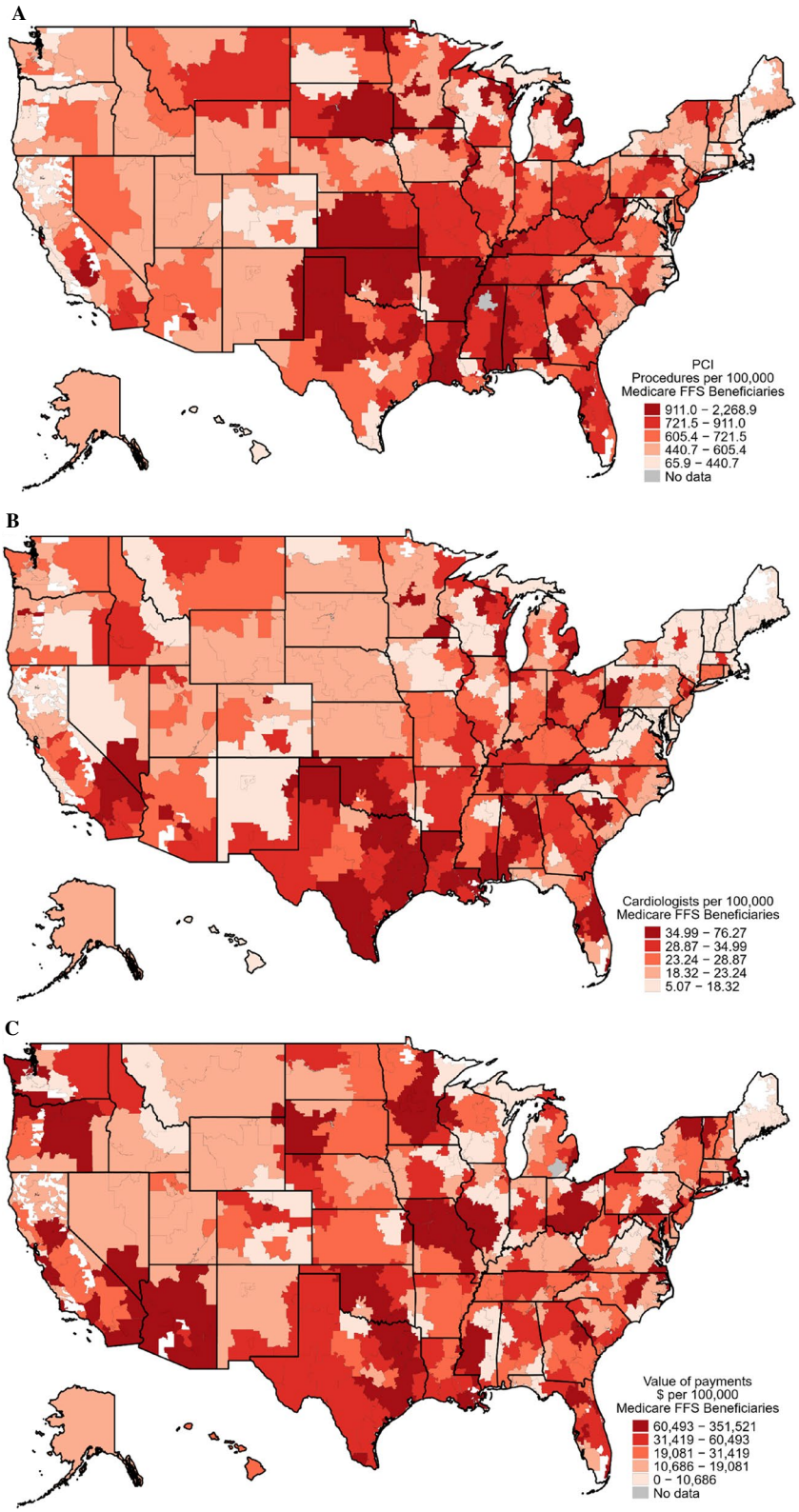

Figure 1 A Number of percutaneous coronary interventions per 100,000 Medicare FFS beneficiaries in each healthcare referral region. B Map showing number of cardiologists performing cardiac catheterizations per 100,000 Medicare FFS beneficiaries in each healthcare referral region. C Payments in $ per 100,000 Medicare FFS beneficiaries from medical device manufacturers of cardiac stents to cardiologists in each healthcare referral region. For all panels, darker red indicates higher quintile values.

Distribution of knee arthroplasties, orthopedic surgeon supply, and payments by medical device manufacturers of knee prosthesis in 2018 to orthopedic surgeons, by hospital referral region.

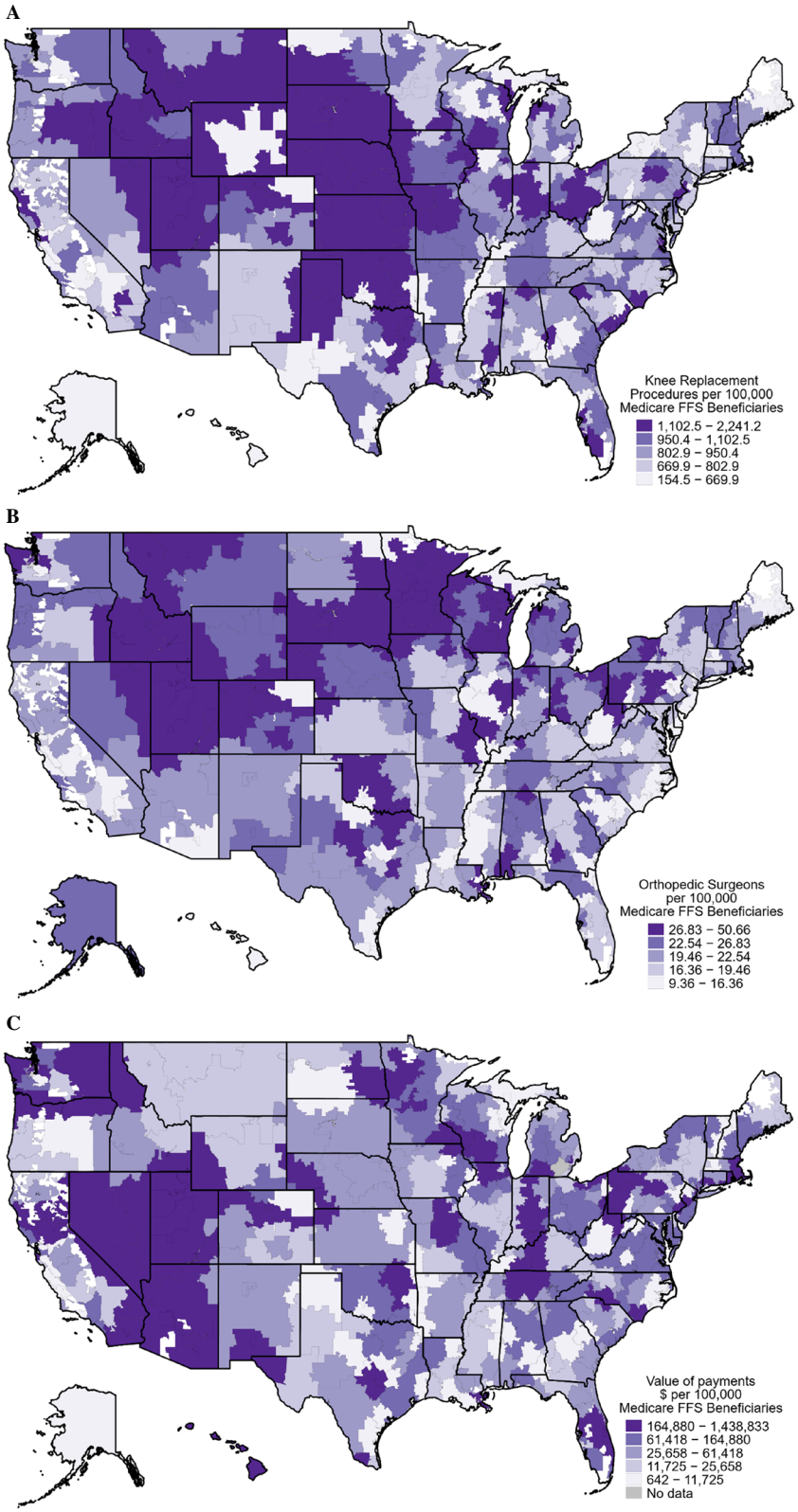

Figure 2 A Number of knee arthroplasties per 100,000 Medicare FFS beneficiaries in each healthcare referral region. B Map showing number of orthopedic surgeons performing knee arthroplasties per 100,000 Medicare FFS beneficiaries in each healthcare referral region. C Payments in $ per 100,000 Medicare FFS beneficiaries from medical device manufacturers of knee joints to orthopedic surgeons in each healthcare referral region. For all panels, darker purple indicates higher quintile values.

Table 1 Marketing Payments from Medical Device Manufacturers to Cardiologists and Orthopedic Surgeons in 2018

	Cardiac stent manufacturers	Prosthetic knee manufacturers
Total value of payments, $		
All	17,554,728	40,492,126
Gifts*	8,303,645	9,194,378
Services†	9,251,083	31,297,747
Median value of payments to HRRs, $ [IQR]		
All	19,193 [6,997 to 58,057]	29,013 [7,203 to 157,150]
Gifts	13,410 [63,36 to 28,069]	15,031 [5,406 to 37,576]
Services	2480 [0 to 23,952]	12,275 [0 to 122,150]
Median value of payments to HRRs, $ per 100,000 Medicare FFS beneficiaries [IQR]		
All	23,569 [12,146 to 48,759]	35,546 [15,253 to 128,079]
Gifts	18,760 [10,693 to 31,006]	19,241 [10,798 to 30,282]
Services	2408 [0 to 19,179]	14,283 [0 to 99,820]

*Gift payments include charitable contribution, entertainment, food/beverage, gift, travel/lodging, education, and non-research grants

†Service payments include consulting fee; honoraria; compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program; compensation for serving as faculty or as a speaker for an unaccredited and a non-certified continuing education program; and compensation for serving as faculty or as a speaker for an accredited or a certified continuing education program

$10,000 per 100,000 Medicare FFS beneficiaries was associated with an increase in PCI utilization rates of 26.0 procedures (CI, 5.1 to 46.9) per 100,000 Medicare FFS beneficiaries. Figure 3C shows the predicted number of PCIs performed across HRRs if the payments from stent manufacturers to each HRR was at the median of each quintile of overall industry payments from stent manufacturers.

For knee arthroplasties, all payment categories were associated with an increase in procedure utilization rates (Table 2). An increase in total payments from knee prosthetic manufacturers to orthopedic surgeons by $10,000 per 100,000 Medicare FFS beneficiaries was associated with an increase in knee arthroplasty utilization rates of 2.9 procedures (CI, 1.4 to 4.5) per 100,000 Medicare FFS beneficiaries. An increase in gift payments from knee prosthetic manufacturers by $10,000 per 100,000 Medicare FFS beneficiaries was associated with an increase in knee arthroplasty utilization rates of 14.5 procedures (CI, 5.0 to 24.1) per 100,000 Medicare FFS beneficiaries, while a similar increase in service payments was associated with a smaller increase in knee arthroplasty utilization rates of 3.4 procedures (CI, 1.6 to 5.2) per 100,000 Medicare FFS beneficiaries. Figure 3D shows the predicted number of knee arthroplasties performed across HRRs if the payments from knee manufacturers to each HRR was at the median of each quintile of overall industry payments from knee manufacturers.

Table 2 Association Between the Value of Medical Device Manufacturer Payments to Physicians, Regional Physician Supply, and Regional Utilization Of Procedures in 2018

	Change in regional procedure rate per 100,000 Medicare beneficiaries in a hospital referral region [95% CI]	
	Percutaneous coronary intervention	Knee arthroplasty
Medical device manufacturer payments		
$10,000 increase in total device-related payments per 100,000 Medicare FFS beneficiaries	3.4 [-2.9 to 9.6]	2.9 [1.4 to 4.5]
$10,000 increase in gift device–related payments per 100,000 Medicare FFS beneficiaries	26.0 [5.1 to 46.9]	14.5 [5.0 to 24.1]
$10,000 increase in service device–related payments per 100,000 Medicare FFS beneficiaries	1.7 [-6.2 to 9.6]	3.4 [1.6 to 5.2]
Procedural physician supply		
Increase of 1 physician per 100,000 Medicare FFS beneficiaries	12.9 [9.3 to 16.5]	20.6 [16.9 to 24.4]

Estimates derived from multivariate linear regression models in which the dependent variable was regional procedure rate per 100,000 Medicare FFS beneficiaries, the independent variable was total payments ($10,000s of dollars per 100,0000 Medicare FFS beneficiaries) from device companies to physicians, and controls at the HRR level included the physician supply (number of interventional cardiologists for percutaneous coronary interventions and orthopedic surgeons for knee arthroplasties) per 100,000 FFS Medicare beneficiaries, percent eligible for Medicaid, average HCC score, average age of Medicare FFS beneficiaries, percent female, percent non-Hispanic White, percent African American, and percent Hispanic

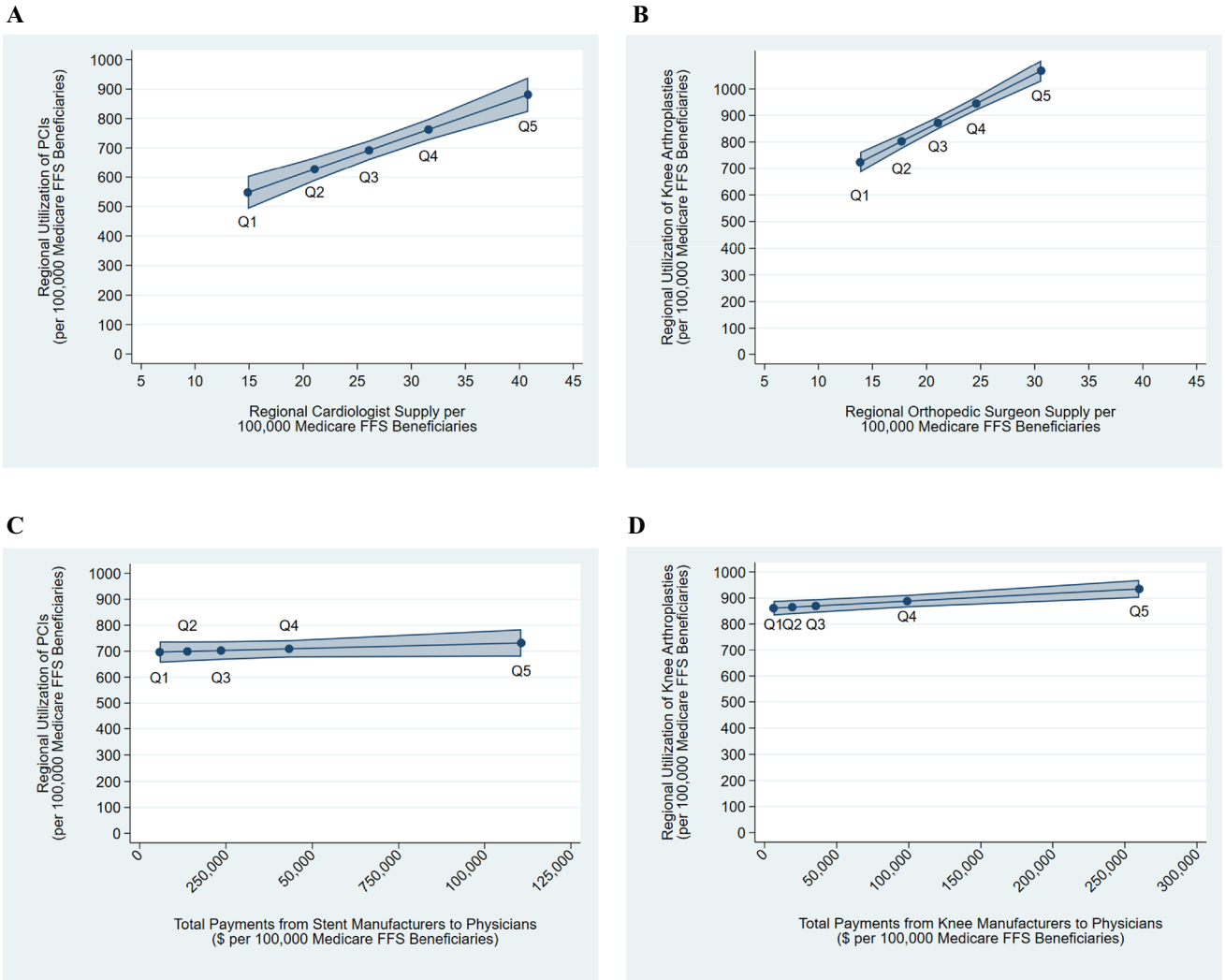

Figure 3 A Predicted regional utilization of percutaneous coronary interventions in an average HRR if the supply of regional cardiologists per 100,000 Medicare FFS beneficiaries was at each quintile value for overall cardiologist supply. B Predicted regional utilization of knee arthroplasties in an average HRR if the supply of regional orthopedic surgeons per 100,000 Medicare FFS beneficiaries was at each quintile value for overall orthopedic surgeon supply. C Predicted regional utilization of percutaneous coronary interventions in an average HRR if the total number of payments per 100,000 Medicare FFS beneficiaries from stent manufacturers to cardiologists in that region was at each quintile value for overall payments from stent manufacturers. D Predicted regional utilization of knee arthroplasties in an average HRR if the total number of payments per 100,000 Medicare FFS beneficiaries from knee manufacturers to orthopedic surgeons in that region was at each quintile value for overall payments from knee manufacturers. For all panels, Q1 represents the lowest quintile and Q5 represents the highest.

DISCUSSION

In this national study of cardiologists and orthopedic surgeons participating in Medicare, both regional supply of procedural physicians and receipt of device-related gift payments were associated with greater use of both knee arthroplasty and PCI. Medical device–related total and service payments were associated with increased rates of knee arthroplasty but not PCI. As knee arthroplasty is universally an elective planned procedure while PCI may be elective or urgent, one possible explanation is that while physician supply may have broad influence on the decision to perform procedures, marketing payments of all categories may be more likely to influence elective procedures.

The finding that greater regional physician supply is associated with greater procedure utilization is consistent with prior studies from the 2000s and earlier, which were

unable to account for the additional supply-side factor of industry marketing[10,11,35]. Procedural physician supply is highly variable; the HRRs with the highest supply have ten times as many physicians per capita than the HRRs with the lowest supply. Since our analyses adjusted for regional patient complexity and demographics, this finding may be evidence of supply-induced demand, or procedural physicians promoting procedural solutions rather than medical options. This finding could also reflect insufficient procedural physicians to meet demand in certain regions. To fully explore the implications of this finding, future research drawing on patient-level procedural information, including data on procedure urgency and appropriateness, is greatly needed.

This study provides one of the first analyses of the relationships between industry payments and medical device utilization. The observed financial relationships were consistent with prior literature showing that the values of industry payments to cardiologists and orthopedic surgeons are large, with median payments in 2019 of $725 for cardiologists and $509 for orthopedic surgeons, but highly variable with the top quartile of recipients in both groups receiving over $2000 in yearly payments[36,37]. Numerous prior studies have documented consistent associations between marketing payments and increased prescribing of marketed drugs across classes[38], at individual[13] and regional levels[12]. Additionally, one recent study found that patients were more likely to receive an implantable cardioverter-defibrillator made by the manufacturer that provided the largest payments to the operating physician; however, this study did not examine overall device utilization[21]. Our study is also consistent with a recent analysis of cardiologists which found that receipt of industry for antiplatelet drugs was associated with a small increase in rates of PCI use[39].

The relationships between marketing payments and procedural utilization were more consistent for knee arthroplasty than for PCI, which may be due to the fact that knee arthroplasties are largely elective. PCIs may be performed emergently, for acute coronary syndromes, or electively for stable angina. A multi-state study of trends in the rates of PCI from 2010 to 2017 found that 57% of PCIs were elective[40]. Furthermore, there are national guidelines outlining PCI indications which may lower the chance of individual decision-making[41,42]. In contrast, knee arthroplasties are nearly always elective and thus may be subject to more individual physician discretion than PCI. Furthermore, CMS' Local Coverage Determination for PCIs states that PCI is not indicated for patients who can be managed medically whereas the indications for knee arthroplasties are more broad[43,44]. Previous studies have mainly focused on gift-related payments[12,15]. The fact that our study finds a differential effect of service payments is interesting because they include consulting which can reflect legitimate financial relationships focused on product development. However, they can also represent hidden marketing relationships[45].

In conjunction with prior literature, our findings suggest that more discretionary medical decisions, such as choice of pharmaceutical or device brand or recommending an elective procedure, may be more likely to be influenced by industry marketing payments. Our study is not able to distinguish overuse from appropriate use and does not indicate that payments by medical device manufacturers lead to overuse of knee arthroplasty, as when appropriately used these procedures can provide important functional and symptomatic benefits for patients. However, invasive procedures pose both a high cost to the health system and important perioperative risks to patients, and consistent with practice guidelines should be reserved for patients who do not respond to more conservative therapies. Our findings indicate that supply-side factors, which may drive overuse of these procedures, warrant continued scrutiny from CMS and other payers. Restriction of gift-type marketing payments has been advised by the Institute of Medicine since 2009[46] and would be one step toward reducing the risk of undue industry influence. Monitoring regions and individual clinicians with high observed to expected ratios of elective procedures, as has been proposed for knee arthroplasties[47], and strengthening local coverage determinations are other potential strategies to curtail overuse.

This study is subject to several limitations. First, we studied procedures performed on Medicare FFS beneficiaries, and while older adults account for the majority of individuals in the USA receiving coronary stents and joint replacements, industry payments may have differential effects on care for patients with other insurance, including Medicare Advantage. We speculate that the direction of observed associations would be similar in the private insurance population given that physicians practice in a fee-for-service incentive structure for both Medicare and private insurance and that industry payments are not payer-specific. Physician supply could be a larger driver given that private insurers' payments for procedures are typically much larger than Medicare payments[48], though this may also be counterbalanced by payer controls such as prior authorizations. Second, as a cross-sectional analysis, we are unable to establish causality. Third, the utilization data available excludes reporting on physicians performing fewer than 11 procedures per year; thus, our findings do not generalize physicians with low volume in Medicare FFS. Fourth, while examining HRR-level outcomes allowed us to evaluate the regional association of payments and prescribing, which may account for the broader impact of speaking-related payments, we are unable to make individual-level inferences. Finally, we were not able to distinguish between PCIs which were done emergently versus those done electively.

CONCLUSION

Among Medicare FFS beneficiaries, regional supply of procedural physicians was associated with greater use of both knee arthroplasty and PCI. Medical device–related gift payments were associated with increased rates of both PCI and knee arthroplasty. Medical device–related total and service payments were associated with increased rates of knee arthroplasty but not PCI. To ensure optimal use of high-cost invasive procedures, payers and policy makers should consider measures that discourage supply-side factors that may lead to overuse while maintaining an adequate supply of procedural physicians to avoid shortages. The data that support the findings of this study are openly available. URLs are cited in references [23–25, 30–33] and [34]. The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials.

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Declarations

Conflict of Interest *The authors declare that they do not have a conflict of interest*

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