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WILEY
The Role of Industry Influence in Sinus Balloon Dilation: Trends Over Time

Shekhar K. Gadkaree, MD ©; Vinay K. Rathi, MD; Esther Gottschalk, MD; Allen L. Feng, MD ©; Katie M. Phillips, MD; George A. Scangas, MD ©; Ralph Metson, MD

Objective: Balloon dilation (BD) is a controversial alternative to conventional sinus surgery. The role of industry on practice patterns remains unknown. The aim of this study was to determine whether industry payments from BD manufacturers influence practice patterns for otolaryngologists and evaluate how these payments change over time.

Methods: Retrospective cohort study using Medicare Provider Utilization and Payment (PUP) Data and Center for Medicare and Medicaid Services Open Payments (OP) general payment datasets. A total of 294 otolaryngologists identified in the PUP dataset who performed BD procedures from January 1, 2013, to December 31, 2015, were cross-referenced in the OP dataset from January 1, 2014, to December 31, 2016, for BD manufacturer payments. Payments to surgeons performing BD stratified by amount, type, and number of procedures performed were primary outcome measures.

Results: Of the 294 otolaryngologists reporting BD procedures, 223 (76%) received payments from a company that manufactures BD devices. Receipt of $2,500 in BD payments was associated with performance of one additional BD procedure, and consulting fees were most positively associated with performing additional BD procedures (P = 0.006). The providers receiving the most in BD payments were more likely to continue to receive the most in payments, regardless of number of BD procedures performed. Performing more BD procedures did not correlate with decrease in other sinus procedures.

Conclusion: Payments to otolaryngologists from manufacturers of sinus BD devices are associated with the performance of an increased number of such procedures. Surgeons should consider the impact of interactions with industry when evaluating patients for BD procedures.

Key Words: Industry influence, balloon dilation, balloon sinuplasty.

Level of Evidence: 4.

INTRODUCTION

Since the introduction of balloon dilation (BD) technology into the sinus surgery marketplace in 2005, the indications and relative benefits of this technique have been widely debated.1–3 A small number of studies have examined the safety and efficacy of sinus BD. In particular, the industry-sponsored Confirm SAFety and Efficacy of Sinuplasty in the PaRanasal Sinuses (CLEAR) trials found no adverse events and sustained sinus patency rate of over 80% up to 2 years.4,5 Although these studies established the safety of BD, prospective trials comparing the benefits of BD to conventional FESS are limited.4–6

Criticisms of BD include the potential for postoperative mucocele formation and osteitis, as well as its additional cost with unclear benefits.1,5,4,7 These criticisms are particularly difficult to assess due to limited follow-up times and relatively low case volumes. Given that the absolute benefit over standard of care treatment has not been well established, the impact of industry influences in BD procedures is of particular interest.

The impact of industry payment in influencing physician behavior has been well documented, with even small gifts affecting clinical decision making.8–11 Increased contact with and payment from industries may lead to increased physician loyalty to particular brands of new technologies and manifest itself as increased utilization of industry products. Several studies have demonstrated that increasing usage of new medications and technologies is associated with increasing industry payments across medical subspecialties.12–14 Particularly for new technologies such as BD, close contact with industry representatives may be required to better understand and apply the technology. Credentialing courses are sponsored by BD companies, and industry representatives have frequent contact with physicians who are utilizing BD both inside and outside of the operating room. The role of BD industry influence in otolaryngology has been recently described in a cross-sectional study by
Eloy et al., showing a positive correlation between industry payments to sinus surgeons and BD procedures performed.15

The aim of the current study was to examine the impact of specific categories of industry payments to providers performing BD and identify any association between receipt of these payments and number of BD procedures performed. In addition, longitudinal trends in BD payments and procedures in otolaryngology were compared to those of other medical and surgical subspecialties in relation to industry influence.

MATERIALS AND METHODS

This study was conducted from the Medicare Provider Utilization and Payment (PUP) Data from January 1, 2013, to December 31, 2015; and the Open Payments General Payment (OP) dataset was conducted from January 1, 2014, to December 31, 2015; and the Open Payments General Payment (PUP) Data from January 1, 2013, to December 31, 2015; and the Open Payments General Payment (PUP) Data from January 1, 2013, to December 31, 2015. The PUP database provides claims data for Medicare beneficiaries who receive services and procedures from healthcare providers enrolled in the fee-for-service program. Otolaryngologists identified in the PUP database were then cross-identified in the OP dataset. The OP dataset reports payments from drug and device companies to physicians and stratifies payments by type, amount, and company.16 Payments to otolaryngologists associated with CPT codes 31295 (dilation of maxillary sinus ostium, e.g., BD), 31296 (dilation of frontal sinus ostium, e.g., BD), and 31297 (dilation of sphenoid sinus ostium, e.g., BD).17 This study was exempt from institutional review board approval because the databases involved in this analysis are publicly available.

Procedures performed from the PUP database were tracked from 2013 to 2015, with payment data from the OP database tracked from 2013 to 2016 because procedure data was unavailable for 2016. The number and amount of BD procedures performed per year were obtained from the PUP database. The number of yearly frontal sinusotomies (31276), ethmoidectomies (31255), maxillary antrostomies (31256), and sphenoidotomies (31287) were recorded from the PUP database as comparison. Because there was a high degree of colinearity between these variables in that these procedures are often performed together, frontal sinusotomy, ethmoidectomy, maxillary antrostomy, and sphenoidotomy were combined into a single variable representing "other procedures" for regression analysis. In the database, each payment was listed according to the company making that payment and stratified according to the payment type: 1) education, 2) consulting, 3) food and beverage, 4) travel and lodging, 5) accredited speaker, 6) nonaccredited speaker, 7) entertainment, 8) gift, 9) grant, 10) honoraria, 11) ownership or investment, 12) royalty or license, 13) faculty speaker, and 14) charitable contributions. Research payments were also examined but excluded for the purposes of analysis because only three otolaryngologists received research payments in the study population. For each otolaryngologist, the following information was collected: total payment amount, number of payments, payments stratified by payment type, payments stratified by company, and number of procedures performed. Payments were classified as either BD payments (from a company that offered BD technology) or non-BD payments.

Statistical analysis was performed using Stata 12.0 (StataCorp LP, College Station, TX).18 Chi-squared tests were used to compare quartiles of procedures performed and payment quartiles. Multiple linear regression was used to compare the absolute number of procedures performed and payment received. When assessing the relative contribution of each payment type to procedures involved, BD payment categories were included in a multiple linear regression model to examine for associations that remained significantly associated with number of procedures. P values of less than 0.05 were considered statistically significant.

RESULTS

Two hundred and forty-eight of the 294 (84.4%) otolaryngologists identified in this study received some type of industry payment in 2014. The total amount paid to otolaryngologists in this study by all industry companies was $908,506. The median payment amount was $506 per otolaryngologist. Of the 294 otolaryngologists, 223 (76%) received payments from a company that provides balloon sinuplasty equipment totaling $753,007 (Table

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TABLE I.


<table>
<thead>
<tr>
<th>Industry Payments to Otolaryngologists Associated With Balloon Dilation Procedures (2014)</th>
<th>Overall (N = 294)</th>
<th>Any Industry Payment (N = 248)</th>
<th>Received Any BD Payment (N = 223)</th>
<th>Only BD Company Payments (N = 223)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total amount paid (USD)</td>
<td>908,506</td>
<td>908,506</td>
<td>904,144</td>
<td>753,007</td>
</tr>
<tr>
<td>Number of payments</td>
<td>5,268</td>
<td>5,268</td>
<td>5,138</td>
<td>2,978</td>
</tr>
<tr>
<td>Number of otolaryngologists</td>
<td>294</td>
<td>248</td>
<td>223</td>
<td>223</td>
</tr>
<tr>
<td>Minimum payment amount (USD)</td>
<td>0</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>1st quartile payment amount (USD)</td>
<td>86</td>
<td>187</td>
<td>242</td>
<td>110</td>
</tr>
<tr>
<td>Median payment amount (USD)</td>
<td>330</td>
<td>506</td>
<td>563</td>
<td>270</td>
</tr>
<tr>
<td>3rd quartile payment amount (USD)</td>
<td>1,313</td>
<td>1,660</td>
<td>2,261</td>
<td>1,153</td>
</tr>
<tr>
<td>Maximum payment amount (USD)</td>
<td>215,344</td>
<td>215,344</td>
<td>215,344</td>
<td>193,031</td>
</tr>
<tr>
<td>Interquartile range (USD)</td>
<td>1,228</td>
<td>1,473</td>
<td>2,019</td>
<td>1,043</td>
</tr>
</tbody>
</table>

BD = balloon dilation; USD = U.S. dollar.
The median payment amount was $270 per otolaryngologist. Food and beverage payments comprised the majority of overall payments (86%) for total and BD-only payments (85%). The median payment for food and beverage was $242 from BD companies (Table II). Travel and lodging was the second most common payment type, comprising 5% of all payments, with a median payment amount of $1,199 (Fig. 1A). Although these two payment categories were most common in frequency, consulting fees comprised 67% of the overall payment amount (median payment amount of $4,200) and 80% of the BD company-only payments, of which the median payment amount was $3,612 (Fig. 1B). Forty percent of the study population received over 75% of their overall industry payments from BD companies alone.

On linear regression modelling, a higher number of BD procedures performed by specific otolaryngologists was significantly associated with higher payments from the BD industry to these physicians ($P < 0.001), as shown in Figure 2. Multivariate analysis demonstrated that for every $2,500 increase in BD payment amount, one extra BD procedure was performed. Thirty-eight otolaryngologists (13%) received over $2,500 in payments from BD companies. Given this association between overall BD payments and number of BD procedures performed, overall BD payments were stratified into payment types and compared. Food and beverage payments, consulting, and education payments all had positive associations with BD procedures. However, on multivariate regression controlling for all payment types, consulting fees alone remained significantly associated with number of procedures performed ($P = 0.006), as shown in Table III.

Seventy-seven percent of otolaryngologists who received payments in 2014 also reported payments in 2015. Fifty-four percent of these individuals performed less BD procedures in 2015 as compared to 2014. Of those who received BD company payments in 2014, 52% received an increased sum of industry payments from BD companies in 2016, with 47% of otolaryngologists receiving an over 20% increase in amount of BD payments from BD companies.

### Table II.

<table>
<thead>
<tr>
<th>Category</th>
<th>Overall BD Payments Only</th>
<th>BD Payments Only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Amount (USD)</td>
<td>Number of Payments</td>
</tr>
<tr>
<td>Consulting</td>
<td>608,388</td>
<td>289</td>
</tr>
<tr>
<td>Food and beverage</td>
<td>142,423</td>
<td>4,548</td>
</tr>
<tr>
<td>Travel and lodging</td>
<td>75,761</td>
<td>204</td>
</tr>
<tr>
<td>Education</td>
<td>30,566</td>
<td>37</td>
</tr>
<tr>
<td>Honoraria</td>
<td>29,101</td>
<td>32</td>
</tr>
<tr>
<td>Nonaccredited speaker</td>
<td>20,246</td>
<td>45</td>
</tr>
</tbody>
</table>

BD = balloon dilation; SD = standard deviation; USD = U.S. dollar.

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### A Balloon Dilation by Payment Volume

(Percentage of Total Payments)

<table>
<thead>
<tr>
<th>Category</th>
<th>Education</th>
<th>Consulting</th>
<th>Food and Beverage</th>
<th>Travel/Lodging</th>
<th>Speaking Fees</th>
<th>Honoraria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5%</td>
<td>10%</td>
<td>15%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>

### B Balloon Dilation by Payment Amount

(Median Payment Percentage)

<table>
<thead>
<tr>
<th>Category</th>
<th>Education</th>
<th>Consulting</th>
<th>Food and Beverage</th>
<th>Travel/Lodging</th>
<th>Speaking Fees</th>
<th>Honoraria</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4%</td>
<td>21%</td>
<td>63%</td>
<td>1%</td>
<td>2%</td>
<td>1%</td>
</tr>
</tbody>
</table>

Fig. 1. Payments from BD companies. (1A) Number of payments from BD companies for each payment category as a percentage of overall number of BD payments (2014). (1B) Median payment amount from BD company for each payment category type as a percentage of overall BD median payment amount (2014).

BD = balloon dilation.

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industry payments in 2016 as compared to 2014. In those individuals who had a 20% increase in number of BD procedures performed from 2014 to the following year, only 16% had an increase in BD payments in that time period. Thirteen percent (10 of 75) of this subgroup had no industry payments prior to their boost in BD usage and then had BD payments the following year. Those who receive high amounts of BD payments were likely to continue to receive high amounts of industry payment, with 76% of those who were in the top quartile of BD payments in 2014 remaining in the top two quartiles of BD payments in 2016 (Fig. 3A). Although the highest BD procedure performers in 2013 remained the highest BD performers in 2014, this trend was not sustained into 2015. There was no significant correlation between number of BD procedures performed and number of non-balloon procedures, as defined as the aggregate number of frontal sinusotomies, ethmoidectomies, maxillary antrostomies, and sphenoidotomies, performed over the 3-year time period (Table IV).

**DISCUSSION**

Physician–industry collaboration is essential for the development and integration of new technology into patient care. Although these collaborations have undeniable value, the concept of undue influence affecting clinical decision making in the use of new technologies requires close scrutinization. This study showed a positive association between increasing payments from BD companies to otolaryngologists and increasing numbers of BD procedures performed by these individuals. In addition, it found that both the type and size of payment made to physician influenced their clinical decision making. Because a large percentage of payments received by the participants were only from companies that manufacture BD devices, the study suggests surgeons may select industrial contacts based on emerging technologies that support their clinical practice.

Although concern regarding industry influence is not novel, the relationship of procedurally based specialties with industry influences has not been well documented. Initial studies of industry influence in Laryngoscope 128: July 2018

**TABLE III.** Linear Regression Comparing Payment Amounts Stratified by Payment Categories on Number of Procedures Performed (2014).

<table>
<thead>
<tr>
<th>Payment Type</th>
<th>Regression Coefficient</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food/beverage</td>
<td>-0.0008</td>
<td>[-0.0057, 0.0042]</td>
<td>0.761</td>
</tr>
<tr>
<td>Consulting fees</td>
<td>0.0004</td>
<td>[0.0001, 0.0007]</td>
<td>0.006</td>
</tr>
<tr>
<td>Travel/lodging</td>
<td>0.0010</td>
<td>[-0.0049, 0.0068]</td>
<td>0.158</td>
</tr>
<tr>
<td>Education fees</td>
<td>-0.1168</td>
<td>[-0.4207, 0.1872]</td>
<td>0.450</td>
</tr>
<tr>
<td>Speaking fees</td>
<td>0.0447</td>
<td>[-0.0175, 0.1069]</td>
<td>0.158</td>
</tr>
<tr>
<td>Honoraria</td>
<td>-0.1421</td>
<td>[-0.5220, 0.2377]</td>
<td>0.462</td>
</tr>
</tbody>
</table>

Consulting fees were the only payment type having significant impact on the number of procedures performed.

Fig. 2. Reimbursements versus number of procedures performed. Reimbursement from balloon dilation manufacturers by number of procedures performed. For every $1,000 USD increase in reimbursements, four extra procedures were performed. USD = U.S. dollar.

Fig. 3. Balloon dilations payments and procedures performed over time. (3A) BD payments stratified by payment quartile. Quartile assignments were based on 2014 BD payment status with the fourth quartile corresponding to the highest BD payment recipients. Fourth quartile BD payment recipients in 2014 remained the highest BD payment recipients in 2015 and 2016. (3B) BD procedures performed over time for each quartile. Quartile assignments were based on 2013 payment status with the fourth quartile corresponding to highest BD payment recipients. Fourth quartile BD payment recipients in 2013 remained the highest BD performers in 2014 but not in 2015. BD = balloon dilation.
healthcare focused on the prescribing of drugs because both the indication and relative benefit could be easily assessed. Recently, the role of industry in surgical specialties and new surgical technologies has been a rapidly growing topic of investigation, particularly with increasing focus on procedural costs.\textsuperscript{19,20} As individual procedures, BD and FESS alone have similar procedure costs and reimbursement rates. However, as an adjuvant tool to FESS, costs can be markedly higher for FESS/BD procedures when compared to FESS alone, particularly in bundled payment systems. The estimated incremental cost of balloon sinuplasty as an adjuvant to FESS varies significantly, with approximations of around $3,000.\textsuperscript{21} This study supports the concept that the industry influence does indeed extend to procedurally based specialties such as otolaryngology.

A recent study of industry payments stratified by subspecialties showed that otolaryngologists tended to have slightly less but overall still significant payments from industry compared to other surgical subspecialties.\textsuperscript{20} In addition, there was a heavy skew toward the top 10% of otolaryngologists receiving industry payments, as defined by total payment amount received.\textsuperscript{20} In the current study, there was a similar skew, with the top 10% percent of otolaryngologists who most frequently perform BD procedures receiving 95% of the payments from BD companies. Similar results were found by Eloy et al in their analysis of BD industry payments to otolaryngologists who perform BD procedures.\textsuperscript{15} In the setting of the debated utility of BD, the positive association between industry payments and procedures performed and the skewed payment distribution become particularly relevant when considering industry influence on clinical practice.

Following BD payments over time provided an interesting dynamic aspect for evaluation of industry influence. Balloon dilation payments fluctuated for individual providers across years; however, a general trend showed that those receiving the highest amount of BD payments continued to receive the highest amount of BD payments despite the number of BD procedures performed. This finding held particularly true for the highest quartile of BD payment recipients. Because the largest component of the amount received was consulting fees, these results suggest that individuals consulting for BD companies have relatively stable longitudinal relationships with these companies. The decline in number of procedures performed over time by highest performers at the beginning of the study period is an interesting finding that further supports the highest performers of BD as a unique population. The drop in the numbers of BD procedures between 2014 and 2015 could be attributed to a number of factors, including reduced enthusiasm following the initial introduction of a new technology into the marketplace and economic pressures from hospitals to curb usage of the relatively high-cost BD equipment. Additional market forces that could not be readily tracked, such as modifications in the contractual relationship between the BD industry and their consultants over time, could also play a role in explaining these findings.

Although it is expected that industry would initially recruit consultants from the most experienced users, the results of this study imply that increased payments are associated with increased usage among other nonconsultant users. However, one would expect that BD usage would remain consistently higher among the consultant population than usage in the standard population. The results of this study support the behavior of the highest BD users as a unique population not influenced by payments in an expected way.

In order to evaluate whether the performance of BD procedures themselves impacted frequency of nonballoon sinus procedures, individual provider procedure rates were compared across years for BD compared to frontal sinusotomies, ethmoidectomies, maxillary antrostomies, and sphenoidotomies. Because these procedures may have similar indications as balloon sinuplasty, we hypothesized that an increase in BD procedures may result in a decrease of these nonballoon procedures. However, such an inverse correlation in procedure frequency was not found for any of the surgeries evaluated. This finding could imply that BD procedures are being used for unique cases that would not otherwise be treated with other procedure types, or that standard fluctuations in case volume are masking any effect that BD procedures are having on surgical planning. Notably, because CPT codes were used to track BD procedures, determining whether these procedures occurred in the context of larger endoscopic sinus procedures was not possible.

Quantifying the positive role of industry influence in advancing technology is an abstract and difficult task. Industry provides access to innovative technological solutions as well as education and research support for

### TABLE IV.
Number of BD Procedures and Non-Balloon Procedures Performed, Stratified by Year

<table>
<thead>
<tr>
<th>Year</th>
<th>BD Procedures (Mean (SD))</th>
<th>Frontal sinusotomies (Mean (SD))</th>
<th>Ethmoidectomy (Mean (SD))</th>
<th>Maxillary Antrostomy (Mean (SD))</th>
<th>Sphenoidotomy (Mean (SD))</th>
<th>All Non-Balloon Procedures (Mean (SD))</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>27.8 (23.4)</td>
<td>16.9 (5.1)</td>
<td>20.3 (10.0)</td>
<td>20.3 (7.3)</td>
<td>21.5 (1.9)</td>
<td>35.6 (24.8)</td>
<td>0.359</td>
</tr>
<tr>
<td>2014</td>
<td>34.2 (31.6)</td>
<td>23.4 (8.2)</td>
<td>21.7 (9.3)</td>
<td>22.1 (8.2)</td>
<td>18.3 (9.2)</td>
<td>36.9 (27.0)</td>
<td>0.4</td>
</tr>
<tr>
<td>2015</td>
<td>30.9 (29.8)</td>
<td>19.7 (9.5)</td>
<td>20.0 (10.0)</td>
<td>24.6 (10.1)</td>
<td>24.4 (8.9)</td>
<td>36.0 (31.5)</td>
<td>0.233</td>
</tr>
</tbody>
</table>

P value represents regression analysis comparing BD procedures versus all non-balloon procedures (frontal sinusotomies, ethmoidectomies, maxillary antrostomies, and sphenoidotomies).

BD = balloon dilation; SD = standard deviation.
physicians; however, measurement of this impact can be challenging. Increased physician–industry interaction can also lead to enhanced training and familiarity with new technologies that may not otherwise be accessible. A confounding factor, however, is that those same individuals receiving high consulting fees are likely the ones with the most industry contact, knowledge of BD procedures, and may have been introduced to BD technology earlier than those without consulting fees. Physicians consulting for industry companies would not only be familiar with BD companies but would already have self-selected themselves as physicians who were available and willing to interact with BD industries. Medical device companies have attempted to combat the negative stereotypes surrounding industry interaction by instituting guidelines, including those imposing restrictions of payments and other items of value to healthcare professionals.

Although this study provides valuable insight into an association between industry payments and BD procedures, it has several limitations. As a retrospective study, there is inherently an inability to fully assess the cause-and-effect relationship between industry payments and BD procedures performed.

Furthermore, although this study implies that more frequent industry contact may lead to an increased number of procedures performed, the reason for this association is complex and may include increased familiarity with a new technology. Additionally, this study relied on Medicare patients in the PUP database and did not capture all patients receiving these procedures. Finally, CPT codes were used to track BD procedures but could not be used to determine whether these procedures occurred in conjunction with other endoscopic sinus procedures. Determining whether surgeons are using these procedures as stand-alone procedures or adjuvant procedures could provide additional information on the use of BD procedures. Despite these limitations, this study provides valuable insight into the complex association between industry payments and surgeon utilization of industry technology over time.

**CONCLUSION**

Increasing payments to otolaryngologists from companies that market devices for the performance of sinus BD procedures is directly associated with an increased number of these procedures performed. Consulting fees represent the largest dollar value of industry payments, whereas food and beverage payments are the most frequent type of payments. Physicians receiving the highest amount of BD payments did so independently of fluctuations in the number of BD procedures performed over time. Physicians should consider the role of industry influence on clinical decision making when evaluating patients for BD procedures.

**BIBLIOGRAPHY**