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Non-research payments to board-certified cardiologists from pharmaceutical industry in Japan from 2016 to 2019: a retrospective analysis

Anju Murayama ,[1] Kenichi Higuchi,[1] Yuki Senoo[2]

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[1]School of Medicine, Tohoku University, Sendai, Miyagi, Japan
[2]Higashi Totsuka Kinen Byoin, Yokohama, Kanagawa, Japan

Correspondence to
Anju Murayama;
anju.murayama.s8@dc.tohoku.ac.jp

ABSTRACT

Objectives To evaluate the extent and trends of personal payments from pharmaceutical companies to cardiologists board-certified by the Japanese Circulation Society.

Design A retrospective analysis study using data from a publicly available database.

Setting The study focused on payments to cardiologists in Japan.

Participants All 15 048 cardiologists who were board-certified by the Japanese Circulation Society as of 2021.

Primary and secondary outcome measures The primary outcome was the extent of personal payments to cardiologists in 2016–19. Secondary outcomes included the analysis of trends in these payments over the same period.

Results Of all 15 048 board-certified cardiologists, 9858 (65.5%) received personal payments totaling $112 934 503 entailing 165 013 transactions in 2016–19. The median payment per cardiologist was $2947 (IQR, $1022–$8787), with a mean of $11 456 (SD, $35 876). The Gini Index was 0.840, indicating a high concentration of payments to a small number of cardiologists. The top 1%, 5% and 10% of cardiologists received 31.6%, 59.4% and 73.5% of all payments, respectively. There were no significant trends in the number of cardiologists receiving payments or number of payments per cardiologist during the study period.

Conclusions More than 65% of Japanese cardiologists received personal payments from pharmaceutical companies over the 4-year study period. Although the payment amount was relatively small for the majority of cardiologists, a small number of cardiologists received the vast majority of the payments.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ All pharmaceutical companies affiliated with the Japan Pharmaceutical Manufacturers Association (JPMA) are required to disclose their payments made for lecturing, consulting and manuscript drafting to individual physicians with the physicians' names.
⇒ These payment data were collected by an independent research organisation, which developed a publicly accessible and searchable payment database.
⇒ This study used data from a comprehensive payment database containing personal payments to physicians from all pharmaceutical companies in 2016–19.
⇒ One study limitation was that it did not include financial relationships between the cardiologists and non-JPMA-affiliated companies.
⇒ Another study limitation is that it did not detail other types of personal and research payments made to the cardiologists.

INTRODUCTION

Collaborations between physicians and pharmaceutical companies play a crucial role in advancing healthcare innovation and improving patient care through joint research efforts. However, such collaborations can also create financial conflicts of interest (COIs) for physicians. Furthermore, physicians may engage in companies' promotional or marketing activities,[1 2] potentially biasing their decision-making efforts including prescribing patterns and guideline recommendations.[3 4] These COIs could bias physicians' decision-making including prescribing patterns and guideline recommendations.[3 5–17]

To improve the transparency of these financial relationships, the Japan Pharmaceutical Manufacturers Association (JPMA), the largest pharmaceutical trade organisation in Japan, implemented a policy in 2013 requiring its member companies to disclose payments made to physicians on their websites.[18] These data are then collected by an independent research organisation and journalists and have been voluntarily available on a comprehensive searchable database since 2016. Previous research using this database revealed prevalent financial relationships between physicians and pharmaceutical companies in Japan.[19–30]

Cardiologists are among the most heavily targeted specialists by pharmaceutical companies. A previous study reported that society executive board members of the Japanese Circulation Society (JCS), the most influential

cardiology society in Japan, received the second highest mean payment totaling $311 653, with the fourth highest median payment of $207 888 for lecturing, consulting and writing among 15 internal medicine subspecialty societies in Japan.[20] Another study found that authors of the Japanese Society of Hypertension clinical guidelines received a mean $21 447 in personal payments in 2016.[31] The JCS itself received a total of $10.2 million in donations and sponsorship payments from pharmaceutical companies in 2016–20, the second highest total amount among 34 major professional medical societies in Japan.[32 33] Tringale *et al* reported that cardiologists received the highest median payment ($862) among 26 specialties in the USA.[2] Similarly, another study reported that cardiologists received a median $725 in personal payments in the USA in 2019.[1] Despite the likely presence of prevalent and substantial financial relationships between cardiologists and pharmaceutical companies in Japan, no studies have evaluated the size and extent of financial relationships between cardiologists and pharmaceutical companies. Using a publicly accessible database, this study investigated the extent and trends of personal payments made by pharmaceutical companies to all board-certified cardiologists in Japan in 2016–19.

METHODS

Study setting & participants

Using the publicly available payment database (https://yenfordocs.jp/), this retrospective analysis examined all personal payments made to all cardiologists from JPMA-affiliated pharmaceutical companies in 2016–19. We included all cardiologists board-certified by the JCS as of September 2021. The JCS, established in 1935, has been the sole professional body to board-certify cardiologists since 1989. As of the specified date, we identified 15 048 board-certified cardiologists on the JCS webpage.

Payment disclosure & payment source

In Japan, all JPMA-associated pharmaceutical companies are required to disclose their payments made to healthcare providers and healthcare organisations on their company webpages after 2013. As of January 2020, 73 (70.2%) of the 104 pharmaceutical companies manufacturing prescription drugs in Japan were affiliated with the JPMA. Prescription drugs manufactured by these JPMA-affiliated companies accounted for 94.0% ($101.0/$107.4 billion) of all drug costs in Japan in 2020.[34] However, most of these companies regularly update their payment data each year and delete the data for previous years from their webpages.[35] The publicly accessible and searchable payment database, which was developed by an independent research organisation and journalists, contains payments to individual physicians from all JPMA-affiliated pharmaceutical companies and several subsidiary companies disclosing payment data for lecturing, consulting and writing fees after 2016. At the time of the data collection for this study, payment data in 2019 were the latest available. The JPMA requires its member companies to disclose personal payments to individual physicians for lecturing, consulting and writing services at individual physician level only. More common payment categories such as meals, travel, accommodations and other gifts are reported in aggregate[2 35–37]: thus, an individual-level analysis was not possible. Therefore, we searched for the names of cardiologists and collected from the payment database only those payments made to them for lecturing, consulting and writing services.

Identifying payments to cardiologists

After extracting payments to physicians whose names matched those of board-certified cardiologists, we excluded those payments made to individuals who were not actually cardiologists by cross-referencing affiliation and practice location data from the JCS with the recipients' affiliation and specialty data from the payment database. When identifying a cardiologist was challenging using only the payment database and the information from the JCS, we conducted additional searches for the physicians' names and affiliations and reviewed relevant webpages (eg, hospitals, universities, clinics) of the physicians' affiliations to verify that they were the eligible cardiologists as previously explained.[22 29 38 39] Payments made to physicians who were not confirmed board-certified cardiologists through these steps were excluded from the study.

Statistical analyses

We conducted descriptive analyses including mean and median payments per cardiologist and the proportion of cardiologists receiving payments. The concentration of payments among cardiologists was assessed using the Gini Index as in previous studies.[36 40 41]

Next, we examined trends in the number of cardiologists receiving payments and their amounts in 2016–19 using generalised estimating equation (GEE) models. To adjust for the highly skewed distribution of payments, we used a log-linked GEE model with a Poisson distribution for the number of cardiologists receiving payments and a negative binomial GEE model for payments per cardiologist as in previous studies.[19 21 23 42 43] Linear regression models were used to examine the yearly trends in the total payment amounts and numbers. For the trend analysis, inflation was adjusted by converting all payment values to 2019 Japanese yen.[44] Subsequently, the Japanese yen values were converted to US dollars using the 2019 average monthly exchange rate of ¥109.0 per $1.

Furthermore, we analysed the characteristics of the top 100 cardiologists who received the largest total amounts of payments over the 4-year period. For the top 100 cardiologists who received the largest total amounts, we collected information regarding their involvement in the creation of clinical practice guidelines issued by the JCS in 2015–22, their status as executive board members of the JCS and their position at their affiliation as of September

2021 when we extracted the cardiologists' names from the JCS as previously noted.[20 42 45]

Ethical clearance

Given that all data used in this study were publicly available and met the definition of non-human-subject research in Japan, institutional review board approval was not required. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology guideline.

Patient and public involvement

No patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this study.

RESULTS

Summary statistics of personal payments to board-certified cardiologists

Of the 15 048 eligible cardiologists board-certified by the JCS, 9858 (65.5%) received at least one personal payment from a pharmaceutical company in 2016–19 (table 1). The total amount of these payments was $112 934 503, entailing 165 013 payment transactions. For cardiologists who received at least one payment, the median amount was $2947 (IQR, $1022–$8787), with a mean of $11 456 (SD: $35 876) over the 4-year period. The Gini Index was 0.840 for personal payments per cardiologist, indicating that only a small proportion of cardiologists received the vast majority of the payments. Specifically, the top 1% (150 cardiologists), 5% (752 cardiologists) and 10% (1505 cardiologists) received 31.6%, 59.4% and 73.5% of all personal payments, respectively. Over the 4-year period, only 0.5% (67 cardiologists) received payments exceeding $200 000, while one cardiologist received 565 payments totaling $782 015.

Lecturing payments accounted for 88.6% of the total payments ($100 067 695) in value and 89.7% in the number of payments over the 4-year period, with 64.5% (9710) of cardiologists receiving at least one lecturing payment. Consulting and writing payments accounted for 8.0% ($9.1 million) and 3.3% ($3.8 million) of the overall value. The mean value per payment was $769 (SD, $1296) for consulting payments, $733 (SD, $340) for writing payments and $676 (SD, $341) for speaking payments.

Payments made by pharmaceutical companies

Of 83 pharmaceutical companies making payments to the cardiologists, Daichi Sankyo made the largest payments ($26.4 million [23.4% of all payments]), followed by Bayer ($11.8 million [10.4% of all payments]), Boehringer Ingelheim Japan ($8.8 million [7.8% of all payments]), Otsuka Pharmaceutical ($8.3 million [7.5% of all payments]), Bristol Myers Squibb ($5.7 million [5.0% of all payments]) and Takeda Pharmaceutical ($5.2 million [4.6%% of all payments]). The top 5 and 10 companies with the largest payment amounts were responsible for 54.2% ($61.2 million) and 71.3% ($80.5 million) of all payments over the 4-year period, respectively.

Personal payment trends to cardiologists, 2016–2019

The total annual payments made to cardiologists ranged from $27.4 million in 2016 to $28.8 million in 2017 (table 2). Overall, 46.4%–47.4% of all cardiologists received at least one personal payment each year. The median annual payment per cardiologist increased slightly from $1226 (IQR, $511–$3247) in 2016 to $1354 (IQR, $613–$3335) in 2019. The GEE models showed no significant trends in the number of cardiologists receiving personal payments (relative annual average percentage change (RAAPC), 0.3% [95% CI, −0.2% to 0.8%], p=0.23) and payments per cardiologist (RAAPC: 0.6% [95% CI: −0.7% to 1.8%]; p=0.39) in 2016–19. The linear regression models also showed no significant trends in the annual total payment amounts and number of payments over the 4-year period.

Characteristics of top 100 cardiologists receiving largest total payments

The top 100 cardiologists received a total of $29.3 million, representing 25.9% of the total personal payment amounts over the 4-year period. Of the top 100 cardiologists, 68 (68.0%) were authors of at least one cardiology clinical guideline developed by the JCS, while 18 (18.0%) were executive board members of the JCS (table 3). 68 (68.0%) and 6 (6.0%) were full professors and associate or assistant professors at their affiliated medical schools and universities, respectively, while 12 (12.0%) were directors at their hospitals or clinics.

DISCUSSION

Our study revealed that 65.5% of all board-certified cardiologists in Japan received personal payments from pharmaceutical companies for activities such as lecturing, consulting and writing in 2016–19. The total amount of these payments exceeded $112.9 million, equivalent to approximately 12.3 billion Japanese yen over the 4-year period. Although the amounts of these payments remained stable throughout the study period, a disproportionately small group of cardiologists received the majority of the payments. Furthermore, these top-paid cardiologists were professors at their affiliated medical schools and universities, participated in the creation of clinical practice guidelines for cardiovascular diseases and played leading roles at the JCS. To the best of our knowledge, this is the first study to explore the comprehensive financial interactions between pharmaceutical companies and cardiologists in a country other than the USA.[1 2 46]

Contrary to findings in the USA, where approximately three-quarters of cardiologists reportedly received various personal payments, including compensation, honoraria, travel fees, royalties, and food and beverage payments from pharmaceutical and medical device corporations,[1 2]

Table 1 Summary of personal payments to board-certified cardiologists

Variables	Value
Total amounts of payments	
Payment values, $	112 934 503
Number of payments, no.	165 013
Payments per cardiologist	
Mean (SD)*	
Payment values, $	12 649 (35 012)
Number of payments, no.	16.7 (33.9)
Median (IQR)*	
Payment values, $	2947 (1022–8787)
Number of payments, no.	7.0 (2.0–17.0)
Maximum*	
Payment values, $	782 015
Number of payments, no.	576.0
Gini Index	0.840
Cardiologists with specific amounts of payments (n=15 048), n (%)	
No payment	5190 (34.5)
Any payments	9858 (65.5)
$1–$1000	2318 (15.4)
$1001–$10 000	5314 (35.3)
$10 001–$50 000	1825 (12.1)
$50 001–$100 000	225 (1.5)
$100 001–$200 000	109 (0.7)
$200 001 or more	67 (0.5)
Payment categories	
Lecturing payments	
Monetary value (%), $	100 067 695 (88.6)
Number of payments (%), no.	148 036 (89.7)
Mean value per payment (SD), $	676 (341)
Number of cardiologists receiving payments (%), n	9710 (64.5)
Consulting payments	
Monetary value (%), $	9 084 765 (89.7)
Number of payments (%), no.	11 815 (7.2)
Mean value per payment (SD), $	769 (1296)
Number of cardiologists receiving payments (%), n	3561 (23.7)
Writing payments	
Monetary value (%), $	3 782 044 (3.3)
Number of payments (%), no.	5162 (3.1)
Mean value per payment (SD), $	733 (340)
Number of cardiologists receiving payments (%), n	2300 (15.3)

*Payments per cardiologist were calculated among cardiologists who received one or more payments, as 34.5% of cardiologists did not receive any payments over the 4 years.

our research in Japan indicates that approximately half of all board-certified cardiologists annually received payments in the form of reimbursements for lecturing and consulting from pharmaceutical companies. Although the study findings were consistent with those of previous studies in Japan,[19 21–23 29 30 42] this lower percentage of cardiologists receiving such payments in Japan vs the USA would substantially under-represent

Table 2 Trend in personal payments from pharmaceutical companies to board-certified cardiologists between 2016 and 2019

Variables	2016	2017	2018	2019	Average relative yearly change between 2016 and 2019 (95% CI), %
Total payments					
Monetary value, $	27 358 539	28 757 456	28 090 504	28 728 005	1.2 (–0.6 to 3.1)
Number of payments, no.	40 535	41 834	40 581	42 063	0.8 (–1.0 to 2.6)
Payments per cardiologist					
Monetary value, $					
Mean (SD)	3917 (10 883)	4068 (11 314)	3938 (10 416)	4082 (10 764)	0.6 (–0.7 to 1.8)
Median (IQR)	1226 (511–3247)	1328 (511–3372)	1320 (511–3270)	1354 (613–3335)	
Maximum	248 198	221 104	173 339	211 955	
Gini Index	0.865	0.862	0.858	0.858	
Number of payments, no.					
Mean (SD)	5.8 (10.1)	5.9 (10.4)	5.7 (9.7)	6.0 (10.0)	0.4 (–0.1 to 1.7)
Median (IQR)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	3.0 (1.0–6.0)	
Maximum	189.0	160.0	155.0	162.0	
Gini Index	0.810	0.808	0.802	0.805	
Physicians with payments (%) (n=15 048), n	6984 (46.4)	7070 (47.0)	7133 (47.4)	7038 (46.8)	0.3 (–0.2 to 0.8)

the actual degree of their financial engagements with the healthcare companies. Our study data were limited to compensation payments to individual cardiologists and did not encompass other prevalent payment categories or payments from medical device companies despite the fact that cardiologists frequently used medical equipment and devices such as implantable cardioverter-defibrillators, cardiac catheters and stents.

Table 3 Characteristics of the top 100 cardiologists who received the largest total amounts of payments from 2016 to 2019

Variables	Number of cardiologists
Participation in creation of cardiology clinical practice guidelines, n (%)	
Clinical practice guideline authors	66 (66.0)
Non-guideline author cardiologists	34 (34.0)
Board membership	
Executive board members	18 (18.0)
Non-board members	82 (82.0)
Positions at cardiologists' affiliations	
Full professor	68 (68.0)
Department director at a hospital	12 (12.0)
Hospital/clinic director	11 (11.0)
Associate or assistant professor	6 (6.0)
Other positions (eg, chief advisor, consultant and vice hospital director)	3 (3.0)

Although the majority of cardiologists received only modest payments relative to their overall income, the impact of these payments should not be underestimated. Previous studies in the USA demonstrated that even small payments to cardiologists from medical device and pharmaceutical companies are significantly associated with increased usage of percutaneous coronary interventions, stent placements[4] and prescriptions for oral anticoagulants and antiplatelet drugs.[4] Nonetheless, given the absence of studies exploring the associations between payments to cardiologists and their clinical practices, future research is warranted to investigate the impact of industry payments on the clinical practices of cardiologists in Japan.

Interestingly, our trend analysis found no significant annual trends in personal payments to the cardiologists in 2016–19, while previous studies in the USA reported contrary findings.[1 47] This finding may be related to fewer novel drugs being approved in Japan during the study period prior to the introduction of sacubitril/valsartan (brand name: Entresto), the first angiotensin receptor–neprilysin inhibitor manufactured by Novartis and marketed/promoted by Otsuka Pharmaceutical in Japan in August 2020. In contrast, in the USA, sacubitril/valsartan was first approved for heart failure in 2015, leading to extensive marketing activities. These

activities for sacubitril/valsartan resulted in payments to physicians exceeding $50 million, representing the 11th largest payment amount made to physicians in the USA.[48] In addition, despite a lack of detailed information for product names for which companies made payments to the cardiologists, the companies making largest payments to cardiologists in Japan were related to marketing for several direct oral anticoagulants (DOACs). Of the top 5 companies, four manufactured DOACs in Japan, including edoxaban (Daiichi Sankyo), rivaroxaban (Bayer), dabigatran etexilate (Boehringer Ingelheim) and apixaban (Bristol Myers Squibb). These DOACs were approved in the early 2010s, and the patents will expire within a few years. Thus, the companies would have less motivation to increase their marketing payments to cardiologists during the study period.

We found that only a small number of cardiologists received the vast majority of the personal payments. As we elucidated above, the average payments to JCS executive board members[20] and cardiology guideline authors[31 45] were substantially larger than those received by the board-certified cardiologists. Additionally, the top-paid cardiologists were positioned in leading roles such as university professors, hospital directors, clinical practice guideline authors and society executive board members. These physicians, often referred to as key opinion leaders, are frequently targeted by pharmaceutical and medical device companies[27 49] due to their authoritative and influential positions. Given their significant influence on other cardiologists, it is crucial that COIs among these influential cardiologists are properly managed. However, previous studies indicated significant undeclared and under-reported COIs between physicians and pharmaceutical companies in Japan.[20 25–27 31 45 49–52] Our previous study elucidated that more than 94% of authors of clinical practice guidelines for cardiovascular diseases received personal payments from pharmaceutical companies in Japan.[45] Additionally, the policies used to manage COIs in Japan are less rigorous and transparent than those in other high-income countries.[27 45 49] These study findings further underscore the critical need for the effective management of financial COIs among influential cardiologists in Japan.

This study had several limitations. Potential inaccuracies in the payment data reported by companies and in the database may exist. Moreover, the omission of certain types of payments, including meals, travel expenses and gifts, which are not readily available in Japan, likely leads to a substantial underestimation of the magnitude and proportion of financial relationships between cardiologists and pharmaceutical companies in Japan. Furthermore, as the study encompassed only payments from JPMA-affiliated companies, it may not fully represent the entire range of financial interactions between cardiologists and JPMA-unaffiliated pharmaceutical companies or medical device companies.

In conclusion, our study demonstrated that more than 65% of cardiologists certified by the Japanese Circulation Society received personal payments from pharmaceutical companies related to lecturing, consulting and writing services in 2016–19. These payments were concentrated among a small group of cardiologists. Future studies should explore the influence of these payments on the clinical practice of cardiologists in Japan.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval As this study was a retrospective analysis of publicly available data and met the definition of non-human subjects research, no institutional board review and approval were required. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guideline.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. All data used in this study is available from Yen For Docs database run by Medical Governance Research Institute (https://yenfordocs.jp/) and each pharmaceutical companies belonging to the Japan Pharmaceutical Manufacturers Association. The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

ORCID iD

Anju Murayama http://orcid.org/0000-0002-4279-4748

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