

## Report

# Current Disparities in the Prices of Medical Materials Between Japan and the United States: Further Investigation of Cardiovascular Medical Devices

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### Abstract

**Objectives.** Prices of medical devices in Japan were previously reported to be 2 to 4 times higher than those in the United States in 1996 and 1997. However, such data are out of date. We previously compared the market prices in early 2005 between Japan and the US for 16 items in 10 categories of medical materials, and showed that price differences still existed for all these items. However, the number of items investigated was small for each category, and generalization of the results might have been limited. The present study conducted a further investigation into price information for multiple items for each category, focusing on 5 cardiovascular devices.

**Methods.** The US market price information was obtained from interviews of a healthcare provider network and 2 different group-purchasing organizations. We could obtain price information on 19 items in 5 categories. We substituted the Japanese reimbursement prices for the Japanese market prices.

**Results.** The price ratio (Japanese reimbursement price / US market price) was 2.0 - 3.5 for coronary stents, 5.9 - 6.8 for percutaneous transluminal coronary angioplasty catheters, 2.2 - 3.5 for pacemakers, 1.6 - 2.5 for mechanical valves, and 3.4 - 4.7 for oxygenators.

**Conclusions.** The price disparities for cardiovascular devices between Japan and the US were reconfirmed. Japan's healthcare system should establish group-purchasing organizations, promote centers of clinical excellence, and abolish regulation of parallel imports and protectionism under the Japanese Pharmaceutical Affairs Law.

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### Key Words

■Cardiology, management (price differences, medical devices, market price, reimbursement price) ■Cost-effectiveness

### INTRODUCTION

Differences between domestic and foreign prices of medical devices still remain a controversial issue.<sup>1-4)</sup> Several investigations have showed that

Japanese prices of medical devices were estimated to be 2 to 4 times higher than those in the United States or Europe. In 1996, the Japan External Trade Organization (JETRO) reported that Japanese reimbursement prices were about 2.5 times higher than

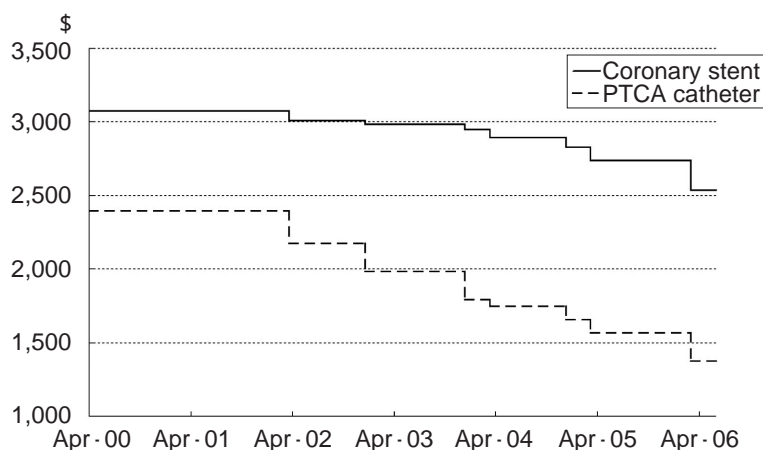
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MA = master of arts



**Fig. 1** Decreases in Japanese reimbursement prices of PTCA catheters and coronary stents

PTCA = percutaneous transluminal coronary angioplasty.

the US market prices for pacemakers, about 4 times higher for percutaneous transluminal coronary angioplasty (PTCA) catheters, and about 1.8 times higher for coronary stents.<sup>1)</sup> In 1997, the Institute for Health Economics and Policy (IHEP) reported that the Japanese market price was 1.6 - 1.8 times higher than the US market price for pacemakers, about 3.6 times higher for PTCA catheters, and about 1.5 times higher for oxygenators.<sup>2)</sup> However, these data are already out of date because both domestic and foreign prices have continuously changed due to fluctuations in the market.

The Japanese government has been trying to solve this problem. In 2002, the Ministry of Health, Labour, and Welfare (MHLW) introduced a policy, the so-called foreign average price adjustment (FPA) rule,<sup>5)</sup> to simply cut reimbursement prices. With that policy, reimbursement prices are reduced biennially by a maximum of 25% if the average market price in Japan is higher than twice the mean price in the US, UK, Germany, and France. **Fig. 1** shows step-by-step decreases in reimbursement prices of PTCA catheters and coronary stents in Japan. According to this rule, the reimbursement price of PTCA catheters was reduced by 25% in 2002, and by 12.5% in 2004.

We previously reported recent price differences between Japan and the US with regard to several medical devices including 16 items in 10 categories: 2 types of autosutures, 3 types of PTCA catheters, 2 types of percutaneous transluminal angioplasty (PTA) catheters, 1 type of Swan-Ganz catheter, 3 types of coronary stents, 1 type of pacemaker, 1 type of implantable cardioverter defibrillator, 1 type of mechanical valve, 1 type of oxygenator, and 1 type of vascular graft.<sup>6)</sup> In the previous

study, price differences still existed for all these items. However, the number of items investigated was small for each category, and generalization of the results might have been limited.

In the present study, we conducted further investigations to follow price information on multiple items for each category, focusing on PTCA catheters, coronary stents, pacemakers, mechanical valves, and oxygenators, to reconfirm the latest status of price differences between the US and Japan, evaluate the efficacy of Japanese policies for reducing such price differences, and discuss what is really important to mitigate this problem.

## METHODS

For the present study, we used the same information source as our previous study.<sup>6)</sup> We asked a physician in the US to give us further information on the US market prices of cardiovascular medical devices including coronary stents, PTCA catheters, pacemakers, mechanical valves, and oxygenators. In May 2005, he interviewed 3 separate, independent organizations: a large healthcare provider network that purchases its own products; and 2 different group purchasing organizations (GPOs) that negotiate and contract on behalf of many hundreds of hospitals throughout the US.

Information on market prices of medical devices is usually commercially confidential; but we were able to obtain all information by agreeing to protect the confidentiality of information sources. Therefore, we cannot disclose the identities of the physician or the 3 organizations.

From all the items that were actually purchased by the 3 organizations, we selected items that had been approved in Japan. We compared the US mar-

**Table 1 US and Japanese prices of cardiovascular medical devices**

Category	Item description	Company	US market price	Japanese reimbursement price	Price ratio
Coronary stent					
	Express 2	Boston Scientific	\$940 - 900	\$2,736	2.9 - 3.0
	Radius	Boston Scientific	\$1,380 - 1,050	\$2,736	2.0 - 2.6
	Driver	Medtronic	\$1,000 - 900	\$2,736	2.7 - 3.0
	S660D	Medtronic	\$900 - 780	\$2,736	3.0 - 3.5
PTCA catheter					
	Quantum Maverick	Boston Scientific	\$280 - 230	\$1,564	5.9 - 6.8
	Sprinter	Medtronic	\$250 - 230	\$1,564	6.3 - 6.8
Pacemaker					
	Actros DR	BIOTRONIK	\$5,800 - 5,400	\$13,455	2.3 - 2.5
	Kappa 700 DR	Medtronic	\$5,200 - 4,320	\$13,455	2.6 - 3.1
	Diamond III	Vitatron	\$5,450 - 4,590	\$13,455	2.5 - 2.9
	Kappa 700 VDD	Medtronic	\$5,195 - 4,406	\$13,091	2.5 - 3.0
	Ruby III	Vitatron	\$5,295 - 4,316	\$13,091	2.5 - 3.0
	Clarity DDDR	Vitatron	\$5,450 - 4,590	\$12,091	2.2 - 2.6
	Jade III	Vitatron	\$3,995 - 3,056	\$10,545	2.6 - 3.5
Mechanical heart valve					
	SJM	St. Jude Medical	\$5,600 - 3,600	\$8,918	1.6 - 2.5
	ATS	ATS Medical	\$5,600 - 3,600	\$8,918	1.6 - 2.5
	CarboMedicus	CarboMedicus	\$5,600 - 3,600	\$8,918	1.6 - 2.5
	Edwards TEKNA	Baxter	\$5,600 - 3,600	\$8,918	1.6 - 2.5
Oxygenator					
	Liliput 2	Dideco	\$550 - 500	\$1,891	3.4 - 3.8
	Carmeda Maxima	Medtronic	\$470 - 400	\$1,891	4.0 - 4.7

The exchange rate was assumed to be 110 yen per US dollar.

Price ratio = Japanese reimbursement price / US market price. Other abbreviation as in Fig. 1.

ket prices and Japanese reimbursement prices for each of these selected items. Japanese prices were converted to US dollar prices at the exchange rate of 110 yen per dollar.

We compared the results from our investigation with those from the JETRO study,<sup>1)</sup> where the US market prices were compared with Japanese reimbursement prices.

## RESULTS

We could obtain information on the following 19 items in 5 categories: 4 coronary stents, 2 PTCA catheters, 7 pacemakers, 4 mechanical heart valves, and 2 oxygenators. **Table 1** shows all the items and manufacturers, US market prices, Japanese reimbursement prices, and price ratios (Japanese reimbursement price / US market price).

All reimbursement prices in Japan were higher than market prices in the US. The price ratio of

PTCA catheters was relatively large: 5.9 ( \$1,564 / \$280 ) to 6.8 ( \$1,564 / \$230 ). Price ratios of coronary stents, pacemakers, and oxygenators were 2.0 ( \$2,736 / \$1,380 ) to 3.5 ( \$2,736 / \$780 ), 2.2 ( \$12,091 / \$5,450 ) to 3.5 ( \$10,545 / \$3,056 ), and 3.4 ( \$1,891 / \$550 ) to 4.7 ( \$1,891 / \$400 ), respectively. The price ratio of mechanical valves was relatively small: 1.6 ( \$8,918 / \$5,600 ) to 2.5 ( \$8,918 / \$3,600 ).

According to the JETRO investigation,<sup>1)</sup> price ratios ( Japanese reimbursement price / US market price ) of PTCA catheters and coronary stents were 3.7 - 4.3 ( \$2,400 / \$560 - 650 ) and 1.8 ( \$2,800 / \$1,600 ), respectively. Our study indicated that price ratios of these 2 categories have increased. In the JETRO investigation, the market price of pacemakers was \$12,900 - 13,700 in Japan and \$4,800 - 5,600 in the US, with a price ratio of about 2.5 - 2.7, almost equal to the current price ratio of pace-

makers (2.2 - 3.5) in our study.

## DISCUSSION

### Limitations of investigations on price differences

Properly speaking, US market prices should be compared with Japanese market prices. However, in Japan, it is extremely difficult to obtain information on market prices of medical devices, which are highly confidential for each medical institution. The MHLW obliges wholesale dealers to give information on selling prices of medical devices biennially, but this information is kept confidential. New reimbursement prices are set for each functional category of medical devices by adding 4% (so-called R-zone) to the actual average market prices. When medical institutions use expensive medical devices, the public health insurance reimburses their expenses at reimbursement prices. Sellers offer products to medical institutions at prices less than reimbursement prices. According to the Central Social Insurance Medical Council (Chuikyo) in Japan, the average difference between reimbursement prices and market prices of expensive medical devices was 11.4% in 2004.<sup>7)</sup> In the present study, we substituted the Japanese reimbursement prices for the Japanese market prices. Since reimbursement prices are higher than market prices, the estimated price ratios in this present study were also higher than actual price ratios.

Another unavoidable limitation in our investigation was based on the long delays in approval of novel medical devices in Japan. In this study, we selected items that were approved in both the US and Japan. However, some items used in the US have not yet been approved in Japan. Some products used in Japan are no longer marketed, or prices have heavily decreased on the US market. Such situations made it difficult to accurately evaluate the price disparity.

### What is important to solve price differences?

Over a period of 10 years, prices have decreased in both countries, but more markedly in the US than in Japan. In fact, the FPA rule has allowed reduction of Japanese reimbursement prices to a certain degree, but it has not effectively improved price differences.

Cardiovascular medical devices are often traded at different prices worldwide.<sup>8)</sup> Particularly, high prices in Japan seem to be extraordinary.<sup>9)</sup> Some Japanese authors have suggested possible reasons

for such price differences.<sup>1-4)</sup> The first reason is that subsidiary companies of US manufacturers monopolize the right of importing a particular item, and set a higher price than the original US price when the item is just imported in Japan. Parallel imports are impossible because the Japanese government issues the approval number only to a single importer. No product can be reimbursed without an approval number. Such a regulation is based on the Japanese Pharmaceutical Affairs Law.

The second reason relates to the fact that medical institutions in Japan lack bargaining powers. In Japan, business approaches like group purchasing are rare; each medical institution individually purchases medicines or medical devices. Furthermore, physicians determine items to be purchased, and can not negotiate with the providers about purchasing prices.

The third reason is that Japanese high prices of medical devices include costs for Japanese-style customary services. Providers offer additional services such as consignment of inventory management for cardiac catheters. In addition, Japan has many small hospitals that perform procedures so infrequently that they do not develop or maintain the necessary expertise. This requires expensive ongoing technical support from manufacturers independent of the size of the hospital. Furthermore, a complex multi-layered distribution system leads to a high profit margin for dealers and considerable distribution costs.

The Japanese government does not account for these fundamental reasons, but simply cuts reimbursement prices. The FPA rule has caused a great deal of criticism from the foreign industry. The US Trade Representative (USTR) asserted that the FPA rule acts as a barrier against participation in the Japanese market, which would be an obstacle to technological innovations, and restricts access to the best technology.<sup>10)</sup> The European Confederation of Medical Devices Association (EUCOMED) claimed that the FPA rule would result in a compounded loss of funds available to manufacturers for research and development of future generation medical devices.<sup>11)</sup>

In conclusion, our study indicates that the FPA rule has not sufficiently improved the price differences. Japan's health policy is so palliative that it cannot improve any of the structural problems in the Japanese market. What is important to solve these problems? We propose the following radical

improvements: i) Establish group-purchasing organizations in Japan, ii) Promote centers of clinical excellence and centralize coronary interventions

and cardiac surgeries, and iii) Abolish regulations of parallel imports and protectionism by the Japanese Pharmaceutical Affairs Law.

## 要 約

### 医療材料の内外価格差の現状: 循環器医療材料の日米価格調査

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目的: 1996年と1997年に実施された2報告によって, 日本の医療材料の価格は海外価格の2-4倍であることが明らかとなった. しかしながら, これら2報告のデータはすでに古くなっている. 我々は最近の報告で, 2005年における10種類16品目の医療材料について日本と米国の市場価格を調査し, すべての品目について内外価格差がまだ存在することを報告した. ただし, 前回調査は調査項目数が少なく, 1品目しか調べられなかった医療材料もあったため, 結果の解釈に一定の限界があった. 今回我々は, 5種類の循環器医療機器に焦点をしばって, 複数の品目の価格情報を得るための追加調査を実施した.

方法: 米国の市場価格情報は, 1つの病院チェーンと, 2つの共同購入組織からのインタビューによって得た. 今回, 5種類の循環器医療機器について19品目の価格情報が得られた. それぞれの品目について日本の市場価格は入手困難であったため, 償還価格で代用した.

結果: 価格比(日本の償還価格/米国の市場価格)は, 冠動脈ステントが2.0-3.5倍, 経皮的冠動脈血管形成術カテーテルが5.9-6.8倍, ペースメーカーが2.2-3.5倍, 機械弁が1.6-2.5倍, 人工肺が3.4-4.7倍となった.

結論: 日米の内外価格差が顕然として存在することが再び明らかとなった. 共同購入の組織化, 医療機関の集中化, 薬事法による並行輸入の断絶や保護主義を廃止することが, この問題の解決に重要であると考えられる.

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