INTRODUCTION

As shown by Kissick's iron triangle of healthcare, all countries confront the same challenges with regard to balancing access to health services, quality of healthcare, and cost containment [1]. When cost and quality have achieved a certain level of balance, the next step is to ensure that these health technologies are allocated in the most efficient and appropriate manner possible, and made equally available to every patient in need [2]. However, the diffusion of these technologies under market influence does not tend to occur in the most equitable or appropriate ways.

The dilemma of cost containment versus equitable availability of high-cost medical devices is not a new one, and continues to grow in importance [3, 4]. In terms of resource allocation, the most common dilemma is the accurate determination of the number of high-cost medical devices needed within a region to adequately meet its healthcare demands, as opposed to the maximization of convenience to patients or the economic interests of physicians and hospitals [5, 6]. Many countries have tried to examine how best to ensure sustainable healthcare investments by regulating the diffusion of high-cost medical devices [7, 8].

In Japan, however, this dilemma has not been regarded as an issue of concern [9]. The Japanese government has adopted a hands-off approach, and encouraged the enhanced accessibility of high-cost medical devices through market behavior under a low fee-for-service reimbursement schedule. However, results from a multiple regression analysis of OECD countries have shown that allowing flexible payment methods to hospitals appeared to be an influential factor in the diffusion of high-cost medical technologies [10]. The market system has caused a so-called medical arms race [11] and has contributed to the rapid diffusion of medical devices. In particular, the dramatic diffusion of magnetic resonance imaging scanners (MRI) was supported by other driving forces: for example, domestic medical equipment companies have developed high-quality products and market prices have thus declined [12]. Japan has recently become one of the world's leading countries in terms of the number of high-cost medical devices installed per population [13, 14].

On the other hand, the consequent ubiquity of these medical devices has resulted in the associated procedures performed being taken for granted and many physicians, if pressed, tend to provide an intervention even if they did not think it was warranted or cost-effective [15]. It has been reported that many of the available high-cost medical devices had low utilization rates [16]. Thus, it has become necessary to treat the issue of allocative efficiency in Japan as seriously as in any other country.

The issue of allocative efficiency in high-cost medical devices could be regarded as consisting of the distributions of both these device units and the corresponding human resource. Due to the reasons outlined above, the issue of whether the distribution of devices is well-balanced with regional demands in Japan is in doubt. A number of previous studies have evaluated the geographic distribution of high-cost medical devices based on the number of device units per population [14, 17-19]. There is a possibly that these previous indicators mislead decisions making regarding the control of technology diffusion because the relationship between the number of residents and the actual eligible population for a technology may not always correspond within a geographical area. Thus, an indicator that measures how the number of supplied device units differs from the number of device units in demand is required. As such, a more precise assessment of resource distribution can be attained by taking into account regional disease distributions.

The purpose of this study was to develop an indicator for the evaluation of the supply-demand balance of high-cost medical devices based on regional disease distribution and utilization, to apply this indicator to analyses of MRI and extracorporeal shockwave lithotripters (ESWL) within all 47 prefectures in Japan, and to investigate the relationship between device distribution statuses, human resource distribution statuses and operating statuses.

METHODS

Diffusion patterns of MRI and ESWL

We investigated the recent diffusion patterns of MRI and ESWL in Japan using data received from a National Survey of Medical Care Institutions conducted by the Ministry of Health, Labour and Welfare (MHLW).

Data Collection

Data were obtained from 3 sources: (1) the number of medical device units in each prefecture were obtained from a National Survey of Medical Care Institutions conducted in 2002 by the government [20], (2) estimated patient volume was obtained from a National Patient Survey in 2002 also conducted by the government [21], and (3) claims data for patients discharged between April 2001 and December 2005 from 16 sampled hospitals.

All of the 16 private hospitals were members of the Quality Indicator/Improvement Project (QIP), a program administrated by our department in which participating hospitals widely distributed throughout Japan voluntarily provide discharge summary data for analysis. All hospitals had at least one MRI installed, and only one out of 16 hospitals did not have an ESWL on-site. The QIP database includes information on demographics, disease classification, surgical procedures, other medical procedures, and claims information.

For correlation analyses, the number of radiologists, radiological technologists and urologists were obtained from Hospital Report [20] and National Survey of Physicians, Dentists and Pharmacists [22]. To calculate the operating rate of selected medical devices, the utilization volume (number of examinations/procedures) during one month was used.

Calculation procedure for the OE Ratio

In this study, we developed an indicator based on the ratio of the observed number of device units (O) to the expected number of device units (E) (henceforth the OE ratio). The observed number of device units reflects the actual number of supplied device units. The expected number reflects the number of device units in demand, and was estimated based on patient volumes and utilization proportions categorized according to primary diagnosis classifications. When the OE ratio is greater than 1 in a particular area, it implies that the area is in a state of relative excess supply. This approach is based on the concept of demand estimation, in which resources demanded are proportionally distributed in accordance with the expected frequency of use in each area. The expected frequency of use is obtained by multiplying the levels of resource utilization by the number of patients in each primary diagnosis classification.

The OE ratio can be obtained as follows: first, the crude expected frequency of use (CEF) in area r is represented by:

$$CEF_r = \sum_c \left(n_{c,r} \cdot \sum_h f_{h,c} / \sum_h s_{h,c}\right) \quad (1)$$

where $n_{c,r}$ is the number of patients in a disease classification c in area r, $f_{h,c}$ is the frequency of use among patients in disease classification c in sampled hospital h, and $s_{h,c}$ is the number of patients in disease classification c in sampled hospital h. This formula assumes that the proportions of medical device utilization according to disease classifications are the same in all hospitals. Next, the expected number of device units EU_r is given by the following formula:

$$EU_r = \sum_r OU_r \cdot \left(CEF_r / \sum_r CEF_r\right) \quad (2)$$

where OU_r is the observed number of device units. Finally, the OE ratio is derived from the observed number of device units divided by the expected number of device units. It should be noted that the OE ratio is not based on absolute demand estimates but instead represents relative assessments of demand.

The OE ratio was applied to evaluate the supply-demand balance of MRI and ESWL units at prefectural level in Japan. We selected these capital-intensive devices primarily due to availability of data and because the installed numbers of these particular device units per population in Japan are extremely large when compared to other developed countries [23].

Evaluation of the OE ratio

To evaluate its usability as an indicator, the OE ratio was compared to the adjusted relative number of device units per population. However, there is no benchmark for the ideal number of device units per population that could be used for validation of our indicator. Previous studies have used the number of device units per population as a conventional indicator to evaluate the relative appropriateness of the installed number. We have thus used this indicator for comparative purposes with the OE ratio. In order to ensure that this conventional indicator is capable of judging relative appropriateness, we have adjusted the number of device units per population in each prefecture by the national mean of the number of device units per population.

Correlation analyses

We conducted correlation analyses to investigate the relationship between OE ratio as the supply-demand balance of device units, the number of staff who operate MRI or ESWL to indicate human resource replacement status and the number of utilization per selected device units indicating the operating rate. In addition to these cross-section variables, the increasing rate of the number of these device units during the period between 2002 to 2005 was included. *P*-values were taken to be significant at $p<0.05$ (two-tailed). Statistical analyses were conducted using SPSS ver.12.0. Choropleth maps were produced using ArcGIS 9.2.

RESULTS

Table 1 shows the diffusion of MRI and ESWL in hospitals and clinics from 1996 to 2005. The numbers of units of both devices were observed to rise consistently throughout the study period. Furthermore, all prefectures had at least one MRI and ESWL by 2002. **(Table 1 should be included here)**

Table 2 shows the summarized data of utilization proportions for MRI and ESWL by 16 major diagnosis categories derived from 465 primary diagnosis classifications. Data from a total of 387 644 patients from 16 hospitals utilizing MRI and 383 362 patients from 15 hospitals utilizing ESWL were used. Within our study population, the major diagnosis categories with the highest mean utilization proportions for MRI and ESWL were the nervous system (8.8%) and kidney, urinary tract, and male reproductive system (3.4%), respectively. The primary diagnoses within the major diagnosis categories with the highest utilization proportions were stroke (37.5%) and upper ureteral calculous (30.2%) for the MRI and ESWL, respectively. **(Table 2 should be included here)**

Figures 1 and 2 illustrate the relationship between the OE ratio and the adjusted relative number of device units per population. To evaluate the assessment of demand based on utilization proportion for each primary diagnosis classification, we compared the OE ratio with the adjusted relative number of device units per population. The OE ratios of some prefectures were plotted within the second quadrant of the Cartesian coordinate system, in which the point of origin exists at the intersection where the abscissa unit and the ordinate value equal 1. Based on the conventional indicator, the second quadrant represents prefectures with a supply shortage of devices. However, the same quadrant represents prefectures with supply excess based on the new OE ratio indicator. There were 7 prefectures plotted in the second quadrant with respect to MRI, and 14 prefectures with respect to ESWL. On the other hand, the fourth quadrant represents prefectures with an excess in supply based on the conventional indicator, while representing prefectures with a supply shortage based on our developed indicator. There were 3 prefectures plotted in the fourth quadrant with respect to MRI, and 1 prefecture with respect to ESWL. **(Figures 1 and 2 should be included here)**

The OE ratio according to prefectural distributions of MRI was calculated to be 1.05 ± 0.19 (mean $\pm$ SD), while the OE ratio for ESWL was found to be 1.18 ± 0.41. There were wide geographic variations in the supply-demand balance for these devices (0.69-1.52 for MRI and 0.43-2.18 for ESWL estimations). The OE ratios according to prefectural distributions of MRI and ESWL in 2002 are shown in Figures 3 and 4, respectively. Regions with high OE ratios, implying a state of excess supply, show some clustering for both MRI and ESWL. **(Figures 3 and 4 should be included here)**

Table 3 shows summary statistics for each selected variable. The largest number of specialist personnel per MRI or ESWL in a prefecture was more than twice or fourfold that of the smallest one, respectively. Likewise, the largest operating rate of

MRI or ESWL was more than thrice or fourfold that of the smallest one. In addition, there was no prefecture where the number of MRI had decreased from 2002 to 2005. On the other hand, as seen in table 3, the negative value observed in the minimum increasing rate of number of ESWL implies that there was a least one prefecture where the number of ESWL had been decreasing. **(Table 3 should be included here)**

The results of correlation analyses are shown in Table 4. With regard to MRI, there was a statistically significant, negative correlation between the OE ratio with the number of radiological technologists per MRI ($r = -.701$) and the increasing rate of the number of MRI ($r = -.303$). On the other hand, there was no significant correlation between the OE ratio with the number of radiologists per MRI. In the case of ESWL, the OE ratio, the number of urologists per ESWL ($r = -.417$) and the number of utilization per ESWL ($r = -.377$) show a statistically significant, negative correlation. **(Table 4 should be included here)**

DISCUSSION

In this study, we developed an indicator for evaluating the supply-demand balance of high-cost medical devices that takes into account differences in regional patient volume and utilization patterns, and applied this indicator to evaluating MRI and ESWL. The conventional population-based indicator is based on the assumption that the proportion of devices in demand to population size is constant in all prefectures. While both the volume of stroke (which accounted for the highest utilization proportion of MRI) and upper ureteral calculous (which accounted for the highest utilization proportion of ESWL) were positively correlated to population size in all prefectures, sub-analysis revealed that for both devices, the largest patient number per million population ratio in a prefecture was three times that of the smaller one (data not shown). The existence of such a large variation implied that a disease-specific patient-based indicator would have the advantage of taking into account differences in prefectural distribution of diseases when compared to the conventional indicator.

By comparisons between our developed indicator and the conventional population-based indicator, the OE ratio can be expected to decrease the possibility of misreading as to whether a situation represents one of excess or shortage in supply. Applying this concept to the dataset in this study, 21% (10/47) and 32% (15/47) of prefectures were at risk of misleading the supply-demand balance of MRI and ESWL, respectively. In addition, more than half of the prefectures at risk (MRI: 7/10, ESWL: 14/15) were likely to be judged as being undersupplied when they were in actuality facing a situation of excess supply for high-cost medical devices. Furthermore, the numbers of these device units continue to increase in hospitals and even in clinics (Table 1).

Choropleth maps displaying the distribution of OE ratios (Figures 3 and 4) showed that there were some oversupplied areas for both MRI and ESWL that tended to cluster, such as the Shikoku and Hokuriku districts. Additionally, some prefectures which showed an oversupply of MRI also tended to be oversupplied with ESWL. Furthermore, some prefectures in the north tended to be in a situation of supply shortage. This might be indicative of the chronic workforce shortage from which many hospitals suffer, particularly in the northern districts [22].

A possible priority issue of resource planning of MRI could be that the adoption of MRI and the placement of human resource should be treated in parallel. With regard to manpower involved with MRI operation, we analyzed both radiologists and radiological technologists. Japan has only one-third the OECD average of the number of radiologists per population [24]. Thus, the assessment of the regional distribution of radiologists should be treated as seriously as that of radiological technologists in order to ensure sufficient manpower for this particular resource. Our results showed that there was no statistically significant correlation between the OE ratio of MRI and the number of radiologists per MRI, although there was a statistically significant negative correlation between the OE ratio and the number of radiological technologists per MRI (Table 4). This could be caused by the diffusion of telemedicine and the working pattern of radiologists who work for more than one medical institution, sometimes covering more than one regional area. According to a report on the regional distribution of telemedicine in Japan, telemedicine projects are developing in the rural areas of the Tohoku district and Hokkaido prefecture [25]. The small OE ratios of MRI were shown in many prefectures in the Tohoku district. These findings would indicate that hospitals have tried to meet increasing workload requirements by sharing a finite radiological manpower resource.

As previously mentioned, it has often been argued that a market-oriented diffusion of high-cost medical devices would have a risk of excess placement. The results from correlation analysis, however, show that areas with excess supply tended to have lower increasing rates of the number of MRI and a lower number of radiological technologists. This could imply that the supply-demand imbalances of MRI units are in the process of improvement due to constraints on human resources, rather than pressures arising from competitions for patients.

Due to the fact that there are still waiting lists for MRI utilization [26] and that there was no prefecture where the number of MRI has declined (Table 3), it is assumed that MRI would continue to increase in numbers. On the other hand, the human resource shortage for operating MRI has been found to hinder the establishment of emergency delivery systems [27]. Thus, a policy that is based on selection of healthcare delivery functions and in particular, focusing on the control of healthcare resource should be implemented at the regional level. In order for this policy to work, there needs to be a continuous assessment of the relationship between healthcare demands, distributions of MRI and human resource placement.

As the MRI is a diagnostic device, and not a treatment device like the ESWL, it is possible that excessive utilization may occur in areas of excess supply due to inappropriate utilization by patients who may not fit the application criteria for MRI [28]. However, it is difficult to claim that excessive use of MRI is being aggressively driven because a negative correlation was observed between the OE ratio of MRI and the operating rate, though this correlation was statistically insignificant. Furthermore, the Japanese hospital payment system has partly changed to a case-mix payment system in place of a fee-for-service payment system since 2003 [29]. Inpatient care in hospitals that fall under the case-mix payment system would therefore have less economic incentives for changing the application criteria for MRI utilization.

A priority issue of resource planning in the case of ESWL could be that, in addition to facing the same issues as MRI, the decision-making concerning the adoption of ESWL by hospitals should take into greater account the regional demand of these devices. This is because the correlation between the OE ratio in ESWL and the increasing rate of the number of ESWL was positive, unlike the trend observed in MRI. From an operational standpoint, it is highly unlikely that excessive use of ESWL frequently occurred as it is only used in limited diseases, there are strict clinical guidelines for treatment with ESWL, and also because the reimbursement charge is constant regardless of how many times a single patient utilizes an ESWL per month. This assumption would be supported by the result that the OE ratio in ESWL was negatively and significantly correlated with the operating rate.

With regard to data availability, OE ratios were estimated under the following assumptions: Firstly, since outpatient claims data are not structured, we assumed that outpatient utilization numbers are proportional to inpatient utilization numbers. Secondly, given that data involving multiple utilizations by a single patient of medical devices in one month could not be obtained, we assumed that there was a proportional relationship between initial utilization and subsequent utilization of each device within a given month. Furthermore, our dataset was limited to private hospitals.

However, we do not consider that these factors would significantly introduce bias into our indicator. Approximately 80% of hospitals in Japan are, like the hospitals used in this study, privately owned and not-for-profit, according to a National Survey of Medical Care Institutions [20]; and this therefore minimizes selection bias. Furthermore, regardless of whether they are privately or publicly owned, Japanese healthcare providers are paid according to the nationally uniform reimbursement schedule. This implies that there may be few, if any, significant differences between private and public hospitals with regard to medical device utilization, and may thus reduce the impact on our indicator's validity. The hospitals used in our sample are relatively large, and may therefore be thought to have a higher proportion of severe cases in need of greater resource utilization. However, as our indicator was based not on an absolute value of utilization, but rather a relative scale between diagnoses, any bias that may arise due to the aforementioned conditions should be minimized.

Public Health Policy Implications

In order to obtain a greater allocative efficiency of high-cost medical devices within the healthcare system, active regulation of the distribution of these devices by the government may be a useful intervention. We believe the OE ratio may assist such regulation, and may even be applicable to monitor changes in the supply-demand balance post-intervention.

As an alternative, in place of government regulations, committees consisting of representatives from hospitals, physicians' associations, local governments and other stakeholders may be able to redefine hospital roles and cooperative utilization of high-cost medical devices within a given area [30]. Even in such cases, the OE ratio would still be applicable as an indicator of allocative efficiency.

Conclusions

As international comparisons of the diffusion of high-cost medical devices continue, the need for a thorough evaluation of the supply-demand balance of these devices grows. Previous attempts at such evaluation have relied on indicators that do not take into account variations in patient volume or utilization. Therefore, we derived the OE ratio as a more realistic estimate by combining the level of resource utilization with the number of patients in primary diagnosis classifications. When compared to population-based assessments, the OE ratio would be less inclined to misread the supply-demand balance of high-cost medical devices.

When considering the rational reformation of a healthcare delivery system, it is necessary that resources with a complementary relationship to each other should be treated in parallel during resource allocation planning. Our studies revealed that there were mismatches between the distribution of device units and human resources. Furthermore, we found that areas of excess MRI and ESWL supply were not always related to excessive device utilization. However, the characteristics of the Japanese healthcare delivery system, in which a fee-for service payment system with no governmental regulations regarding the purchase of such devices, may have driven the diffusion of high-cost medical devices and thus influenced a state of excess supply. The methodology in this study will contribute to assisting decision makers review gaps between health policy and health management under other reimbursement systems and regulation, and help motivate further research geared towards efficient healthcare resource planning at hospital, regional and governmental levels.

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Tables

Table 1. Total number of MRI and ESWL by facilities for each fiscal year

Table 2. Utilization proportion of MRI and ESWL by classification of primary diagnosis

Table 3. Summary statistics of OE ratio and supply indicators of MRI and ESWL at prefectural level (N = 47)

Table 4. Correlations between OE ratio and supply indicators of MRI and ESWL at prefectural level (N = 47)

Figures

Figure 1. Relationship between OE ratio and relative number of MRI per population

Figure 2. Relationship between OE ratio and relative number of ESWL per population

Figure 3. OE ratio by prefecture – MRI

Figure 4. OE ratio by prefecture – ESWL