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Cost-Effectiveness Analysis of On-Line Hemodiafiltration in Japan

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Key Words

Socioeconomics-based value · Incremental cost-effectiveness ratio · Quality-adjusted life year · Reimbursement for medical fees · Cost-effectiveness

Abstract

Background/Aims: Evaluation of the socioeconomic value of medical intervention and establishment of the resources necessary for clinical practice are important for new developments in medical technology. The aim of this study was to determine the socioeconomic value of on-line hemodiafiltration (HDF). ***Methods:*** The subjects were 24 patients who underwent hemodialysis (HD) (9 HDF, 15 HD) for chronic renal failure. A total of 288 dialysis interventions were observed for 4 weeks in three clinics. Cost-effectiveness was evaluated based on quality-adjusted life years (Qaly) and a visual analogue scale. ***Results:*** EuroQOL-5D (0.776 ± 0.015) and visual analogue scale (67.9 ± 1.2) in the HDF group were higher than those in the HD group at baseline. The incremental cost utility ratio for HDF was 641.7 (JPY 10,000/Qaly) based on Qaly (0.776 ± 0.015) and reimbursement for medical fees (JPY 4,982,736 ± 7,852), and was lower than the incremental cost utility ratio for HD. ***Conclusion:*** These results suggest that on-line HDF could be cost-effective.

Introduction

Social resources are generally invested in items with value for humans and for which the level of reward is likely to increase. Medicine is a field involved in life and health and has irreversible features, therefore, more or less, investment of public capital and evaluation or administration by a third party is required. In a medical system with such features, it is important to evaluate the socioeconomic value of medical practice. For example, continuous development of treatment for renal failure requires clarification of the social meaning of the treatment and sharing of this information among the relevant people. On-line hemodiafiltration (HDF) improves quality of life (QOL) for patients with diseases including cutaneous dermal, peripheral neuropathy and anorexia, in comparison with conventional hemodialysis (HD), and is also likely to have economic effects such as inhibition of dialysis-related amyloidosis and arteriosclerosis.

The initial hypothesis in this study is that HDF has superior cost-effectiveness and high socioeconomic value. Evaluation of HDF-based medical economics was conducted to examine the maximum well-being to society, with recognition of complex issues in clinical research. The objective of this study was to evaluate the socioeconomic value of HDF in the medical system. The

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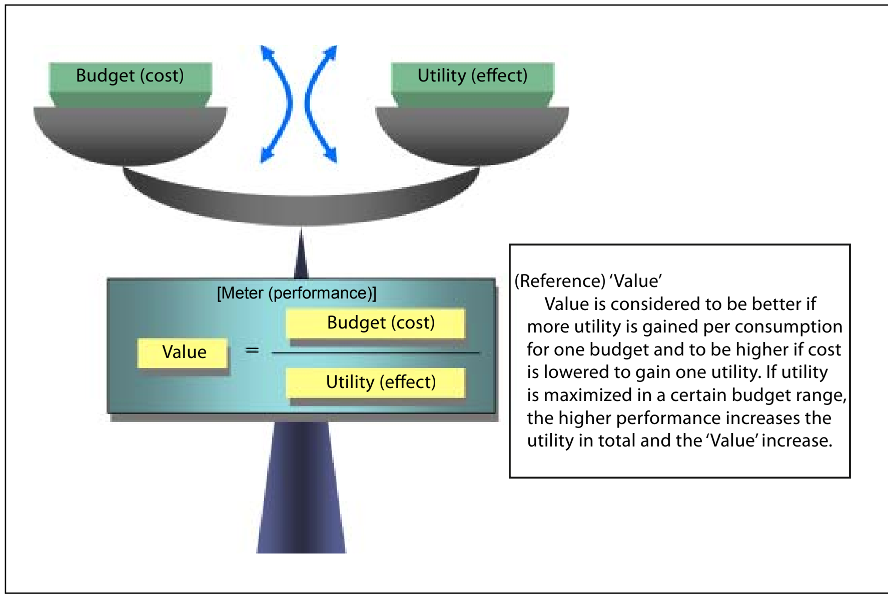

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Fig. 1. Evaluation of the clinical economics-based value of medical technology [see 14].

results obtained can be used as basic data to improve the clinical practice structure for chronic renal failure and to evaluate appropriate medical fees for HD in the healthcare system.

Methods

Clinical Economics-Based Value of Medical Technology

Value is generally considered to indicate the 'meaning and significance' of a 'tangible or intangible thing'. For example, economic and administrative values are identified by the ratio of investment to generation and are discussed using this ratio, i.e. the value of activities by a person with a certain function is presented as 'Function ÷ Cost = Performance → Value'. Since 'Function' is usually replaced by 'Outcome', the 'Value' can be arranged with the 'Utility' obtained by budgets (desire and satisfaction of a beneficiary). Therefore, values of clinical economics in medicine should be discussed based on the relationship between benefits and burdens and it is ideal to express values with performance (cost-effectiveness). Function is represented as recovery of health performance and cost as investment in clinical resources in the medical service.

Using this model, HD can be viewed as a function to maintain and recover health (renal function): e.g. 'Health recovery (Outcome) ÷ Consumption resource (Cost) = Clinical performance → Value' (fig. 1). Although values cannot always be discussed in this manner, happiness and burdens induced by medicine can be treated quantitatively and shared, leading to the best medical system for all medical professionals [1]. Inclusion of the relationship with the real economy is important to discuss actual socioeconomic values and complete the objectives of health technology assessment. In addition, the analysis of necessity is not only a relative evaluation but also a theoretical study of absolute evaluation, including methods for converting socioeconomic effects due to improved performance and health recovery into the value of money.

Clinical Economic Values of Medical Technology

The economic value of medical technology is best discussed in terms of cost and effectiveness, but recent studies have frequently selected outcome-oriented indicators that apply to 'Utility', as described above. One of the global standard indicators is the quality-adjusted life year (Qaly), which simultaneously evaluates the survival time (quantitative benefit) and QOL (qualitative benefit). Cost-effectiveness is calculated using the 'Cost/Qaly' as a unit, with a smaller value indicating higher performance. In a broad sense, this cost-effectiveness analysis attempts to evaluate the amount of healthcare cost per patient needed to maintain perfect health for 1 year.

The incremental cost utility ratio (ICUR) is an indicator for comparison of incremental cost and utility in evaluation of medical technology. The ICUR, the ratio of incremental cost/incremental utility, is based on the concept that Performance (cost-effectiveness) is improved if the utility increases more than the cost, even if the cost increases in comparison to medical technology. For example, ICUR is 'inferior' if the utility is less and the cost is higher than that for the comparator, whereas ICUR is 'superior' if the cost is less than the alternative technology. The 'effective' zone in which both cost and effectiveness increase is a controversial area of interpretation of the value of a new medical technology [2].

Subjects and Methods

The subjects were 24 patients (13 males aged 65.3 ± 12.4 years and 11 females aged 66.5 ± 8.4 years) who underwent HD for chronic renal failure (primary disease: chronic glomerulonephritis 33.3%, diabetic nephropathy 16.6%). A total of 288 dialysis

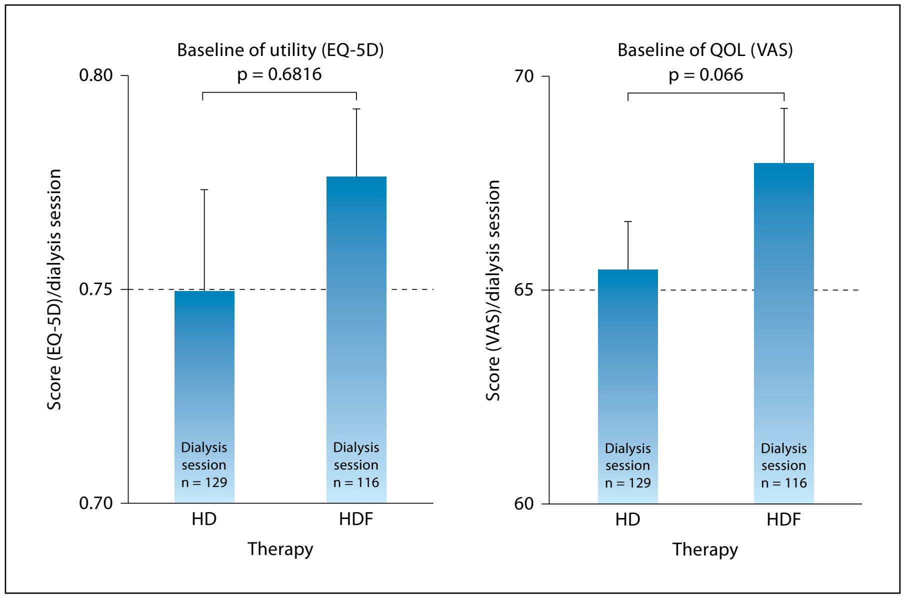

Fig. 2. EQ-5D and VAS scores showing improved health performance with HDF.

interventions were observed for 4 weeks in three clinics. Among these subjects, 9 were assigned to the HDF group (mean renal function: Cr 10.81 ± 1.53 mg/dl, BUN 55.42 ± 13.81 mg/dl) and 15 to the HD group (Cr 9.72 ± 1.84 mg/dl, BUN 56.98 ± 8.61 mg/dl) (table 1). All subjects provided informed consent to participation after receiving an explanation of the intent of the study.

The ICUR was used for analysis, with Qaly and visual analogue scale (VAS) used as indicators of effectiveness. Qaly was estimated using the EuroQOL-5D (EQ-5D), which has less restriction of disease features and application of medical technology among health-related QOL (HRQOL) instruments. A single expected utility value (EQ-5D score) was estimated from the results of 5 items of the EQ-5D using a conversion table of utility values developed by the time trade-off method for estimating values of survival in a completely healthy condition. The reimbursement for medical fees in the national health insurance system was used as an indicator of costs. The nationwide average of the Survey of Medical Care Activities in Public Health Insurance, which are designated statistics of the Ministry of Health, Labour and Welfare, and not reimbursement for medical fees of subjects, was used with correction of technical fees because these data clarify endpoints for medical fees related to dialysis [3].

The relation between the utility indicator (baseline score of EQ-5D) and the patient's condition (average of pre-BUN) was confirmed by Spearman's rank correlation coefficient. It referred as an indirect index that guessed the quality of the dialysis though BUN was different from the middle molecular weight substances that influenced the vital prognosis and QOL. The average of urea reduction rate is 74.0 ± 4.2 (%).

Using the Qaly calculated above (ΔQaly) and invested healthcare cost (ΔJPY), the ICUR (invested healthcare cost ÷ Qaly: JPY/Qaly) was estimated. The results were evaluated by reviewing the reported cost-effectiveness of conventional dialyses. The study was performed as a prospective observational study with a social basis. Analysis was conducted using Wilcoxon rank sum test and the significance level was 5%. All values are shown as mean ± SD. SPSS software was used for statistical analysis.

Table 1. Baseline characteristics of both groups: HDF and HD

	All subjects	HDF group	HD group
Cases	24 (100.0%)	9 (100.0%)	15 (100.0%)
Male	13 (54.2%)	3 (33.3%)	10 (66.7%)
Female	11 (45.8%)	6 (66.7%)	5 (33.3%)
Age, years	65.9±10.7	62.7±0.8	67.8±11.8
Male	65.3±12.4	60.6±5.3	66.8±13.5
Female	66.5±8.4	63.8±8.6	69.1±6.8
Etiology	24 (100.0%)	9 (100.0%)	15 (100.0%)
Glomerulonephritis	8 (33.3%)	4 (44.4%)	4 (26.7%)
Diabetic nephropathy	4 (16.7%)	0 (0.0%)	4 (26.7%)
Nephrosclerosis	4 (16.7%)	0 (0.0%)	4 (26.7%)
Others	8 (33.3%)	5 (55.6%)	3 (20.0%)
History of dialysis, years	11.8±10.7	13.6±9.9	10.7±11.6
Renal function			
Cr, mg/dl	10.15±1.80	10.81±1.53	9.72±1.84
BUN, pre, mg/dl	56.37±10.9	55.42±13.81	56.98±8.61

Results

EQ-5D and VAS at baseline were slightly higher in the HDF group compared to the HD group (EQ-5D: 0.776 ± 0.015 vs. 0.749 ± 0.023; VAS: 67.9 ± 1.2 vs. 65.4 ± 1.0;

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Table 2. Estimation of ICUR of HDF and HD (mean ± SD)

Index	HDF	HD
Utility, ΔQaly	0.776±0.016	0.749±0.024
Cost, ΔJPY/year	4,982,736±9,561	4,910,736±7,852
ICUR, JPY/Qaly	6,417,843	6,552,050

fig. 2). For changes in 1-week health performance, the EQ-5D scores were 0.010 ± 0.014 and 0.036 ± 0.029 and the VAS scores were 2.4 ± 5.1 and 4.6 ± 4.0 in the HDF and HD groups, respectively. There was significant correlation between the EQ-5D score and the pre-BUN (Rs = 0.533, p = 0.017). Qaly in the HDF group in the maintenance period was 0.776 ± 0.01, showing improved health performance from baseline. Analysis of cost-effectiveness using the estimated Qaly and the mean reimbursement of medical fees for HDF (JPY 4,982,736 ± 7,852) showed that the performance of HDF (JPY 641.7/Qaly) was higher than that of HD (JPY 655.2/Qaly) (table 2).

Discussion

Value is a fundamental factor determining human activities in society, and therefore, policies and systems should be established with consideration of value. Since medicine is a field with many contacts with society and diverse contents, a discussion based on value can contribute to decisions on various issues and problems in medicine.

The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom is an assessment organization that uses a value-based evaluation of medical technology for development of healthcare policies. NICE conducts cost-effectiveness analyses of new medical technology and provides data for medical economics-based assessment of public compensation by the National Health Service (NHS). Decision-making regarding public compensation by NICE is conducted using public surveys of total willingness to pay (WTP) data for medicine and also depends on social understanding of the medical environment (healthcare resources) and pathological mechanisms (rare diseases, age, etc.). A medical cost of about GBP 30,000 to 1 Qaly generally achieves social consensus, therefore a performance exceeding this cost is considered to be paid by public compensation [4].

Clinical research over many years including calculation of the ICUR of different diseases and comparative therapy and cost-effectiveness analyses of therapy related to chronic renal failure [5–11] have suggested that prevention of renal failure in patients with diabetes costs approximately USD 2,000–30,000/Qaly, which is better than the cost of normal HD (dialysis in regular facilities) of about USD 50,000/Qaly. These studies also showed that renal transplantation (including donors from fatalities and patients aged ≥65 years) cost USD 10,000–70,000/Qaly, generally indicating good value. All three treatments are likely to be lower than USD 40,000–60,000/Qaly, which is a threshold for public compensation in advanced countries that is suggested to have significance in social economics. The threshold itself should be evaluated based on exchange rates, economic trends and society/culture. The incremental cost-effectiveness ratio obtained in this study suggested that HDF was generally cost-effective.

In some countries, the results of cost-effectiveness analysis of daily HD, which greatly prolongs the survival of patients with chronic renal failure with almost complete health (i.e. corresponding to 1 Qaly/year), are used to decide the threshold of public compensation based on development of medical technology and established trial results [12, 13]. As described above, evaluation of dialysis outcomes based on clinical economics is an important issue in discussing the economic basis of the entire medical system.

EQ-5D has been shown to be a versatile measure of HRQOL, but its sensitivity to health performance is low, at about 0.7–0.8 [14]. For some diseases and procedures, it is difficult to detect small variations in health performance due to a ceiling effect (upper limit of score = 1.0) [15, 16]. The baseline value for gain of utility in dialysis is in a low score range with low sensitivity using the EQ-5D. Therefore, further studies using instruments with higher sensitivity to health performance are needed to evaluate the socioeconomic value of HDF more accurately.

Conclusion

Increased healthcare costs without socioeconomic effects and value may disrupt the medical system and prevent progress of medical technology. Development of therapy for renal failure requires the value of dialysis (value of medicine) to be examined not only on economic costs, but with matching of public funding (medical fees) to the value of the therapy. Advances in high-performance medical technology such as HDF coupled with discussion of the clinical and economic balance are needed to support developments in the dialysis field.

Conflicts of Interest

The authors declare that they have no competing interests.

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