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Original article

Cost-effectiveness of nutritional intervention on healing of pressure ulcers

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SUMMARY

Background & aims: Pressure ulcers not only affect quality of life among the elderly, but also bring a large economic burden. There is limited evidence available for the effectiveness of nutritional interventions for treatment of pressure ulcers. In Japan, recently, a 60-patient randomized controlled trial of nutritional intervention on pressure ulcers demonstrated improvement in healing of pressure ulcers, compared with conventional management. To evaluate value for money of nutritional intervention on healing of pressure ulcers, cost-effective analysis was carried out using these trial results.

Methods: The analysis was carried out from a societal perspective. As effectiveness measures, pressure ulcer days (PUDs) and quality-adjusted life years (QALYs) were estimated. Prevalence of pressure ulcers was estimated by the Kaplan–Meier method. Utility score for pressure ulcers is derived from a cross-sectional survey among health professionals related to pressure ulcers. Costs (e.g., nutritional interventions and management of pressure ulcers) were estimated from trial data during observation and follow-up. Stochastic and qualitative sensitivity analyses were performed to examine the robustness of results.

Results: For observation (12 weeks) and follow-up (12-week observation plus 4-week follow-up), nutritional intervention reduced PUDs by 9.6 and 16.2 per person, and gained 0.226×10^{-2} QALYs and 0.382×10^{-2} QALYs per person, respectively. In addition, costs were reduced by $542 and $881 per person, respectively. This means nutritional intervention is dominant (cost savings and greater effectiveness). The sensitivity analyses showed the robustness of these results.

Conclusion: Economic evaluation of nutritional intervention on healing pressure ulcers from a small randomized controlled trial showed that this intervention is cost saving with health improvement. Further studies are required to determine whether this is a cost-effective intervention for widespread use.

1. Introduction

Pressure ulcers are a serious and costly problem within the hospital and aged care setting. The burden of having pressure ulcers is high, in clinical, emotional and economic terms. Prevalence rates of pressure ulcers in the UK, the US and Canada are reported to range from 4.7 to 32.1% in hospitals, 4.4–33% in community care and 4.6–20.7% in nursing homes.[1] In Japan, their prevalence rates are recently estimated to be from 2.2 to 3.3% in general hospitals, 2.5% in long-term care facilities, and 8.3% in home-visiting nursing care, respectively.[2] Prevalence rates vary in each country and between countries, since they are influenced by multiple factors, including definition, method of calculation and time. Therefore, it is difficult to directly compare them.

Pressure ulcers can reduce overall quality of life due to pain, treatments, and increased length of institutional stay, and may also contribute to premature mortality in some patients.[3] The economic burden of pressure ulcers is substantial. The annual costs for treatment of pressure ulcers are estimated to be £750 million in the UK, US$3 billion in the US, and A$285 million in Australia.[4,5] These costs are likely to be an underestimate, since they do not take into account additional costs for community-based nursing and long-term care, and loss of productivity for the patient and family.

With aging populations and structural changes in disease patterns, the prevalence and burden of pressure ulcers are continuously increasing. Therefore, any intervention that may help to prevent or treat pressure ulcers is important to reduce costs of pressure ulcer care and improve health and quality of life for affected individuals. Although limited evidence-based research is available,[6–9] general consensus and guidelines indicate that nutrition is an important aspect of a comprehensive care plan for

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prevention and treatment of pressure ulcers and it is essential to address nutrition in every individual with pressure ulcers.[3,10,11]

Recently, the first randomized controlled trial in Japan, which was also the first in Asia, has been conducted to evaluate the efficacy and safety of nutritional intervention on healing of pressure ulcers, and showed that nutritional intervention could directly enhance the healing process in pressure ulcers.[12] Since there has not been any economic evaluation of nutritional intervention for pressure ulcers, based on a randomized controlled trial, we conducted a study to confirm the cost-effectiveness of this intervention. This study would provide basic information on the cost-effectiveness of nutritional intervention on healing of pressure ulcers not only in Japan, but also in other countries.

2. Methods

2.1. Analytical overview

Economic analysis was conducted based on the nutritional intervention trial on healing of pressure ulcers.[12] In economic analysis, 4-week follow-up was added to 12-week trial observation to capture continuous benefits over the intervention period. Therefore, the two evaluation periods, i.e., the observation (12-week) and the follow-up (12-week observation plus 4-week follow-up), were set. Subjects were 60 tube-fed, bed-ridden patients with stage III–IV pressure ulcers classified by the NPUAP staging system[13] in the sacral, coccygeal, trochanteric or calcaneal region. They were hospitalized in long-term care facilities. They were randomly assigned to either nutritional intervention ($N = 30$) or conventional care ($N = 30$). The inclusion criteria were albumin (Alb) 2.5–3.5 g/dL, Ohura–Hotta (OH) scale[14] 8.5 or lower, and Braden scale[15] 9–17. The albumin range stipulated in the inclusion criteria represents the mean values in patients hospitalized in long-term care facilities. The OH scale, which is the Japanese patient intrinsic risk measurement, consists of the following four assessment items: deterioration of self sustainability, morbid bony prominence, edema, and joint contracture.

While the control group received the same nutrition management as that prior to participating in this trial, the intervention group was given a goal energy in the range calculated by Basal Energy Expenditure × active factor (1.1) × stress factor (1.3–1.5). Racol® was administered as a feeding formula to both groups. Racol® has been used for nutritional support in postoperative patients or extensively burned patients, especially for tube feeding in patients who for long periods of time either consume insufficient amounts of oral meals or are unable to do so at all. Racol contains 1.0 kcal/mL and it is characterized by its rich amount of protein and high ratio of omega-3 fatty acids compared to similar nutritional supplements. The formula contains protein 4.38 g, fat 2.23 g, and carbohydrate 15.62 g, all per 100 mL of product. The ratio of omega-3 to omega-6 essential fatty acids is 1:3 in this formula, which also includes Cu 125 μg and Zn 0.64 mg. Mean (SD) daily calories administered during the intervention period were 1,092.1 (161.8) kcal in the control group and 1,383.7 (165.6) kcal in the intervention group. The mean (SD) daily amount of protein administered during the intervention period was 46.4 (7.7) g in the control group, and 58.6 (5.8) g in the intervention group. During 4-week follow-up after intervention, both groups received the same level of calories as before the trial. Mean (SD) daily calories during this period were 1,142 ± 238 kcal/day in the intervention group and 1,094 ± 188 kcal/day in the control group, respectively.

In this trial, the management of pressure ulcers as regards nursing, care and treatment was consistently standardized among both groups.[12] Also, the patients were treated according to the guidelines for local treatment of pressure ulcers in Japan.[2]

Changes over time in the condition of pressure ulcers were evaluated according to DESIGN (Japanese evaluation tool of pressure ulcers: depth, exudates, size, inflammation/infection, granulation tissue, necrotic tissue and undermining).[16] The Braden scale and the OH scale were also used for observation. The healing and its process for pressure ulcers were determined by the investigators based on the NPUAP classification and DESIGN tool for evaluation. The total score of DESIGN for healing of pressure ulcers is zero. The number of subjects for a full analysis set, in the intervention and control groups, was 29 and 21, respectively.

As a type of economic analysis,[17] a cost-effective analysis was performed. Incremental costs and effectiveness of nutritional intervention to conventional management were evaluated. According to the effectiveness measure used (i.e., pressure ulcer days (PUDs) reduced and quality-adjusted life-years (QALYs) gained), incremental cost-effectiveness ratios (ICERs) were calculated.

The societal perspective was adopted as a perspective of economic analysis to evaluate value for money of the nutritional intervention.[17] As to cost items, direct medical care costs (e.g., costs of tests, nutrition, drugs, health care personnel, and so on) were examined. Indirect costs (e.g., time costs or production loss among patients and their families) were not examined, since both groups of patients were hospitalized due to debilitating diseases (e.g., stroke) during and after the intervention, and indirect costs were the same for both groups. Therefore, the societal perspective in this study is very similar to a perspective of health care providers. As a time horizon for evaluation, two levels of time periods, 1) observational period (i.e., 12 weeks), 2) follow-up period (i.e., 12-week observation plus 4-week follow-up = 16 weeks in total) were considered. As the base case analysis, follow-up period (16 weeks) was used, since this period covered relatively long-term consequences of intervention on health and costs.

2.2. Effectiveness

The results of the nutritional intervention trial[12] were used as evidence of effectiveness in the economic analysis. The clinical results have been presented in detail elsewhere.[12] As is shown in Table 1, between the intervention group and the control group, no statistical differences were observed in age, sex, and conditions for pressure ulcers and nutrition. The main underlying diseases for pressure ulcers and their proportion among the subjects were cerebrovascular diseases (50%), senile dementia (30%), and Parkinson's disease (6%). The main co-morbidities and their prevalence rates were hypertension (16%), sequel after stroke (16%), diabetes mellitus (16%), senile dementia (8%), and Parkinson's disease (6%). There was no statistical difference in the proportions and

Table 1
Characteristics of subjects and interventional outcomes.

Item	Nutritional intervention ($N = 21$)	Control ($N = 29$)	Test, p value
Sex (male)	28.6%	34.5%	χ^2, $p = 0.658$
Age	81.4 (8.1)	80.6 (8.9)	t, $p = 0.746$
BMI	18.6 (4.0)	17.1 (2.6)	Welch, $p = 0.147$
OH scale	*7.0 (4.5–8.5)*	*7.0 (3.0–8.5)*	Wilcoxon, $p = 0.747$
Braden scale	*11.0 (9.0–11.0)*	*11.0 (9.0–11.0)*	Wilcoxon, $p = 0.572$
Albumin (g/dL)	3.01 (0.24)	2.92 (0.27)	t, $p = 0.224$
Duration of PU days	248 (206)	207 (180)	t, $p = 0.462$
Intervention outcomes (12 weeks)			
Wound size (cm^2)	*0.7 (0–155.3)*	*11.6 (0–144.0)*	Wilcoxon, $p = 0.019$

Numerical value: mean (SD), Italic numerical value: median (range), PU: pressure ulcer, OH scale: Ohura–Hotta scale.