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Original article

Cost-effectiveness of a disease-specific oral nutritional support for pressure ulcer healing

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SUMMARY

Background & aims: The Oligo Element Sore Trial has shown that supplementation with a disease-specific nutritional formula enriched with arginine, zinc, and antioxidants improves pressure ulcer (PU) healing in malnourished patients compared to an isocaloric–isonitrogenous support. However, the use of such a nutritional formula needs to be supported also by a cost-effectiveness evaluation.

Methods: This economic evaluation – from a local healthcare system perspective – was conducted alongside a multicenter, randomized, controlled trial following a piggy-back approach. The primary efficacy endpoint was the percentage of change in PU area at 8 weeks. The cost analysis focused on: the difference in direct medical costs of local PU care between groups and incremental cost-effectiveness ratio (ICER) of nutritional therapy related to significant study endpoints (percentage of change in PU area and $\geq 40\%$ reduction in PU area at 8 weeks).

Results: Although the experimental formula was more expensive (mean difference: 39.4 Euros; $P < 0.001$), its use resulted in money saving with respect to both non-nutritional PU care activities (difference, –113.7 Euros; $P = 0.001$) and costs of local PU care (difference, –74.3 Euros; $P = 0.013$). Therefore, given its efficacy it proved to be a cost-effective intervention. The robustness of these results was confirmed by the sensitivity analyses.

Conclusion: The use of a disease-specific oral nutritional formula not only results in better healing of PUs, but also reduces the costs of local PU care from a local healthcare system perspective.

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1. Introduction

Pressure ulcers (PUs) are an important healthcare issue associated with a substantial economic burden as, depending on the setting of care and the population, they affect approximately

10–20% of patients [1]. Previous estimations have reported that the annual direct costs for treatment of PUs are US\$3 billion in the US, £750 million in the UK, and A\$285 million in Australia [2,3]. Particularly, in Australia it has been estimated that one third of these costs are attributable to malnutrition [4], which is closely related to PUs [5,6]. However, overall costs are likely to be higher, as these analyses date back about ten years ago and they do not take additional cost sources (e.g. costs of loss of productivity to the patient and family, community-based nursing and long-term care) into account. Along with this, ageing and related comorbidities and disabilities are significantly associated with PUs [7]. The “old-age epidemic” and related changes in disease patterns are likely to have

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an even greater negative impact. Therefore, interventions that can reduce costs by improving prevention and treatment are very much required. Although up to 2014 the benefit associated with nutritional interventions for the treatment of PU was found to be hampered by methodological limitations and heterogeneity in the study designs [8], in recent years, different studies have provided supporting evidence of a role of nutritional interventions in PU healing [6,9–14]. Particularly, in line with previous findings on a similar oral nutritional intervention [11,12], a large high-quality RCT [14] has recently shown that the use of an oral high-calorie, high-protein nutritional support enriched with arginine, zinc and antioxidants – nutrients that likely influence protein accretion (e.g. collagen synthesis), immune function and tissue blood flow [15,16] – in malnourished patients results in accelerated PU healing as compared to an isocaloric–isonitrogenous formula. On the other hand, new treatment strategies are generally more expensive and the overall impact on resource use and related costs is also an important issue.

Economic evaluations of nutritional interventions in PU patients are limited. After a preliminary estimation of cost saving [17], a first attempt to address this issue with a pertinent methodological approach has been provided only recently in Japan [18]. Using the data of a small RCT [13], the Japanese authors showed that a high-calorie, high-protein nutritional support results in reduction in overall costs as compared to usual care [18]. Our objective was to investigate whether the use of a nutritional supplement enriched with nutrients (arginine, zinc and antioxidants) promoting wound healing is also a cost-effective intervention for patients with PUs. To this purpose, we analyzed the data of the OEST study [14], a high-quality trial during which also health economics data were prospectively recorded per-protocol (ClinicalTrials.gov: NCT01107197) according to a piggy-back approach.

2. Methods

Data reporting on the present economic evaluation was performed in agreement with the CHEERS statement [19]. The study protocol was approved by the local Ethics Committees of all respective sites.

2.1. The OEST study

The OEST study was a multi-centre (7 sites), 2-arm, randomized, controlled clinical trial [14]. Adult long-term care residents or patients receiving home-care services presenting with a stage II, III or IV PU [6], suffering from malnutrition (according to body mass index and albumin age-specific thresholds, unintentional weight loss and energy intake) according to literature-based criteria [14] and able to drink oral nutritional supplements were randomized to receive two different high-calorie, high-protein oral formulas in addition to free oral diet (tailored to chewing and swallowing abilities) for 8 weeks (or until complete healing, whichever occurred first). The interventions were isocaloric and isonitrogenous (500 kilocalories and 40 g of protein per day) in order to ensure that protein and calorie requirements were met [20]. The experimental formula (Cubitan[®]; Nutricia) differed from the control formula (Fortimel[®] plus Fantomalt[®]; Nutricia) mainly in the source of nitrogen (15% as arginine) and in the content of zinc and antioxidants (Supplementary Table 1). The oral formula was supplied in unlabelled bottles to the patient's residence. Patients and outcome assessors (nurses and doctors responsible for wound care, and dieticians) were blind to treatment allocation.

In addition to nutritional support, all patients received the best wound care according to existing evidence-based guidelines on prevention and treatment strategies [6]. Before the trial started, in

order to obtain operating methodology standardization, the personnel appointed by each study site attended a training day, which was repeated twice during the study. Particularly, topical treatments were always applied by the same registered nurse (one for each centre) specialized in wound care; the type of dressing and the frequency of its change depended on lesion depth and position, amount of exudates, type of tissue in the wound bed and presence of infection. Additional details on the study protocol are provided elsewhere [14].

As already reported, nutritional support was well tolerated and compliance to both intervention was comparable and high, thus resulting satisfactory in covering protein-calorie requirements [14].

2.2. Economic analysis

We conducted a cost-effectiveness analysis of incremental costs of local PU care against significant efficacy endpoints which were [14]: the percentage of change in PU area at 8 weeks (primary efficacy measure) and the proportion of patients achieving reduction in area $\geq 40\%$ (key secondary outcome measure), a marker of effectiveness of nutritional support in PU patients [21]. Since observations on several patients ($N = 62$; 31%) were censored in our trial, related costs were unknown. However, the evaluation of missing outcomes allowed us to assume that they were missing at random [22]. On the other hand, patients' characteristics and costs associated with wound management are significantly heterogeneous in PU patients. Accordingly, base case analysis was conducted on patients who had undergone the final efficacy evaluation ($N = 138$). Then, scenario analyses for the two setting populations were considered: long-term care institutions ($N = 102$) and home-care services ($N = 36$). The time horizon over which costs and effects of nutritional intervention (for both groups, two bottles daily [400 mL/day] of ONS) were evaluated were the 8 weeks of the trial.

Direct medical costs closely related to the local treatment of PUs were assessed, while indirect costs (e.g., time costs or production loss among patients and their families) were not addressed, since caregiving depends mainly on external resources according to the main underlying disease. Besides, the level of dependence is likely to be constant during the intervention and is not primarily due to the presence of PU. Resource utilization during the trial was recorded daily by means of a diary record method. The quantities of the following items were tracked: oral nutritional supplements (number of bottles), dressing materials, antibiotics, tests (PU swabs and culture and blood tests), debridement procedures, negative-pressure wound therapy (NPWT), expenses for health professional services (nursing care and medical visits) and pressure redistribution mattresses. With respect to antibiotics, we took into account only those prescribed for the treatment of wound infections. Likewise, the costs associated with mechanical or surgical debridement performed before study entry (before baseline measurement of PU area and randomization) were not considered. Mean acquisition prices (as unit or per-day costs) for the local healthcare facilities involved in the study were primarily used, unless otherwise specified. Particularly, drug costs were established consulting the official price list of the Italian National Healthcare System, while regional tariffs per hour (nurse) or per visit (physician) were considered for the estimation of expenses for health professional services. Therefore, the economic analysis was conducted adopting the perspective of the local healthcare system which is responsible for the management of patients cared at home and of those living in long-term care institutions. Furthermore, the OEST study was mainly conducted in a single Italian region, a key feature in a regionalized healthcare system. Prices are reported in Euros and refer to 2013 in order to be updated as much as possible. Although the study was approximately 2-year long, discounting for

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