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ORIGINAL ARTICLE

Pressure ulcers management: an economic evaluation

E. FOGLIA, U. RESTELLI, A.M. NAPOLETANO*, D. COCLITE*, E. PORAZZI, M. BONFANTI, D. CROCE
Centre for Research on Health Economics, Social and Health Care Management (CREMS), Carlo Cattaneo – LIUC University Castellanza (VA), Italy; * External Relations Office, Italian National Institute of Health (ISS), Rome, Italy

Key words

Cost effectiveness • Pressure ulcers • Advanced dressings

Summary

Introduction. *Pressure ulcer management represents a growing problem for medical and social health care systems all over the world, particularly in European Union countries where the incidence of pressure ulcers in older persons (> 60 years of age) is predicted to rise.*
Objectives. *The aim of this study was to provide evidence for the lower impact on economic resources of using advanced dressings for the treatment of pressure ulcers with respect to conventional simple dressings.*
Methods. *Two different models of analysis, derived from Activity Based Costing and Health Technology Assessment, were used to measure, over a 30-day period, the direct costs incurred by pressure ulcer treatment for community-residing patients receiving integrated home care.*
Results. *Although the mean cost per home care visit was higher in the advanced dressings patient group than in the simple dressings patient one (€ 22.31 versus € 16.03), analysis of the data revealed that the cost of using advanced dressings was lower due to fewer home care visits (22 versus 11).*
Conclusion. *The results underline the fact that decision-makers need to improve their understanding of the advantages of taking a long-term view with regards to the purchase and use of materials. This could produce considerable savings of resources in addition to improving treatment efficacy for the benefit of patients and the health care system.*

Introduction

Thanks to advances in modern medicine and better care delivered by health care services, persons with chronic and debilitating illnesses are living longer. Throughout Europe and the U.S., these factors are increasingly relevant in health care demographics. According to the WHO's annual World Health Statistic Report 2010 [1], Japan, Italy and Germany have the highest proportion (29%, 26% and 26%) of persons over 60 years of age in their populations, ranking slightly higher than Sweden, Bulgaria and Greece (all 24%) and far ahead of the U.S., China and India (18%, 12%, 7%, respectively).
In comparison with young persons, old persons more often suffer from disability or impairment, partial or complete, rendering them more prone to developing pressure ulcers, also called pressure sores or decubitus [2]. A general upward trend in the spread of pressure ulcers has been noted in developed countries [3] where its prevalence and incidence continue to rise [4]. The proportions of this global problem require the appropriate use of available means and methods.
The term 'pressure ulcer' refers to a tissue lesion that may evolve into necrosis, involving the skin and subcutaneous tissues, and in severe cases the muscle and bone. Pressure ulcers arise from pressure on skin areas overlying a bony prominence or from shear and friction forces that cause a circulatory defect [5, 6].
Pressure ulcers are often related to poor prevention or care and they significantly diminish the quality of life of persons affected [7, 8], prolong the need for care and, when hospitalized, prolong their duration of stay [9], incurring additional costs to the health care systems. Although based on expert opinion, these, lack actual basis in terms of data [10].

Theory/conceptual framework

A literature review based on medical databases was performed to retrieve articles on health economics which reported estimates of resource costs for the prevention or care of pressure ulcers. Main databanks (PubMed, BMJ, Joanna Brings, Cochrane Library, JAMA, Age & Aging, MedScape) were consulted to perform the review using the following keywords: pressure ulcer or cost-effectiveness or HTA or advanced dressing or simple dressing.
Sixteen articles were identified as being of interest and coherent with the topic of the study for further in depth analysis; five articles concerning budget impact or cost-effectiveness analysis of ulcer prevention [10-14]; three articles on the benchmarking concerning costs of different advanced dressing typologies [15-17], one article reporting on a cost of illness study [18], one article suggesting clinical and economic modelling in order to develop guideline for pressure ulcers [19] and two articles with a focus on clinical aspects [20, 21]. In addition, four articles [22-25] were identified for analysis of the economic evaluation, patient sample, and treatment administered.
Advanced wound dressings were found to be more effective than simple ones. Moreover, the economic im-

pact of treatment showed the advanced dressings to have a better cost-effectiveness value. In an earlier study [23], it was shown that advanced dressings are more cost-effective than conventional ones, and American national nursing wage data [22], showed a mean total cost of US $15.90 for advanced dressings versus US $25.31 for simple ones, per day.

Methods

Within the above mentioned context, in this multi-centric perspective observational health economics study, the two cognitive needs identified are related to the lack of empiric application within the field of integrated home care, taking into account the perspective of the public home care provider (region) and the necessity to conduct an analysis using a multidimensional methodology. Due to these needs, for the research (conducted jointly by the Centre for Research on Health Economics, Social and Health Care Management – CREMS of Carlo Cattaneo –LIUC University, and the Italian National Institute of Health - ISS) a cost-effectiveness approach was taken. The principal objective of the study was to determine whether there is an economic or organizational advantage for the provider [26] and to assess the equity impact, from the patient's point of view, of the use of advanced dressings rather than simple ones in the treatment of pressure ulcers in community-residing patients receiving integrated home care. This was to be done, using two different models of analysis derived from Activity Based Costing approach, considering only direct cost absorption and applying Health Technology Assessment methodology. In all, 23 health care centers in Italy accepted the invitation to participate in this study.

The output was the mean daily and monthly costs derived from three components of direct costs: gross cost (VAT inclusive) taken from provider supplier records of medications and devices, personnel costs, and transport costs. Personnel costs were calculated depending on the type of professional health care worker who visited the patient. Transport costs were measured in distance from the health care center to the patient's home, type of motor vehicle, and related fuel consumption. Economic data were collected in 2008 and discounted at 2010 value considering Italian inflation rates [27].

The analysis of the entire secondary care process for pressure ulcer management took only direct costs derived from spreading the cost over all the activities the operators performed [28, 29]. Although the indirect costs were not identical for the compared treatments, the analysis was performed only on the direct costs.

Based on the methodology of the Health Technology Assessment [30], the study developed a qualitative model for analyzing what the impact would be on the organization using new health technologies (advanced dressings), in comparison with the use of old technologies (simple and saline dressings).

A budget impact analysis was not performed due to the fact that, although the sample analyzed represents a real sample, it does not represent a complete and total population affected by this pathology and treated by healthcare providers within the Italian regions involved in the study. A multidimensional approach was used to collect additional information to that from the health economic evaluation.

The sample population was made up of patients meeting the inclusion criteria enrolled by each provider, after giving their written informed consent to participate to the study.

Each provider continued to use the type of dressing it normally employs in pressure ulcer care. As this was an observational study, the research team did not encourage or require any change in usual care practices. The analysis of the real utilization of advanced and simple dressings led to some differences in the two sample considered.

Observational data were collected on case report forms afterwhich a descriptive analysis and an inferential analysis of the data was performed using the SPSS 13 software program. The inferential analysis measured the statistical significance of the sample with regards to observed costs and lesion characteristics, and whether there was a relationship among the variables. Therefore, a data analysis per protocol was performed.

The differential organizational impact of the advanced dressing use over the 30-day period was then analysed, where the weight of the positive or negative organizational impact of each parameter was determined using Delphi methodology [31]: a questionnaire, starting with "open questions" was submitted to professionals, each of whom had several years of experience within the health sector, to determine which variables should be assessed. This questionnaire ended with "closed questions" through successive administrations with a final evaluation scale.

The parameters taken into consideration were: the number of visits, the time required for each visit, the possibility for the health workers involved in the process to perform other activities, the personnel required for each visit, and the personnel training required which included learning time.

Equity data were collected by semi structured interviews administered to caregivers, over the 30-day period. Three areas of analysis were taken into consideration: accessibility for the family and caregivers, pain, and severe adverse events. To analyze this specific dimension, a "closed questions" questionnaire with a five level evaluation scale was submitted to all families and caregivers.

In order to investigate the robustness of the results and to explore the impact of hypothetical variations on the costs taken into consideration within the study, three different analyses were performed: a sensitivity analysis, a bootstrapping analysis and a Monte Carlo simulation.

Simple and multivariate sensitivity analyses were performed varying the following parameters: personnel costs, medications and devices used for the advanced and simple dressings patients' costs and transport costs. A resampling bootstrapping analysis was performed to

create 100 different samples for both the advanced dressings group and the simple dressings one, in order to test the variance of the per visit and the 30-day period visits cost. In addition, a Monte Carlo simulation was run to simulate 100 different scenarios on a five year time period, with yearly variations for the costs of personnel, medications and devices used for the advanced dressings patients and for the simple dressings patients, transport costs. The variations were applied on each patient's cost category data in order to better reflect the differences of the categories impact on the total cost for each patient. The medications and devices costs for the two dressings groups were calculated separately to simulate different variances of the future costs for advanced dressings and of simple ones.

The study was conducted according to the International Conference on Harmonisation Good Clinical Practice guidelines, each enrolled patient completed an informed consent form and authorisation was obtained from the Local Health Authorities involved in the study.

Results

The study population consisted of 362 patients, 351 (97%) of which completed the observation period: 201 (57.26%) in the advanced dressings group and 150 (42.74%) in the simple dressings one. 11 subjects dropped out of the study, 73% of whom died and 27% were hospitalized.

There were no statistically significant differences between the two groups with regard to gender (P = 0.512), age (P = 0.142), comorbidities (P = 0.226), ulcer location (P = 0.744) and ulcer depth (P = 0.416) (Tab. I).

Overall, the two groups were similar and comparable for the purpose of this study. During the 30-day period, the number of visits by a professional health care worker to the patient's home dropped by half in the advanced dressings group. This reflects the fact that such dressings remain in contact with the skin longer than simple dressings which need to be changed more often.

As expected, the ex-post analysis proved a reduction in ulcer size, independently of the type of dressing used, demonstration of good nursing practice in terms of selection and dressing chosen for the particular kind of ulcer observed.

The mean cost per visit was higher in the advanced dressings group (€ 22.31 versus € 16.03). This difference derives from the higher incurrence of material and labor costs for ulcer cleaning and care (> 60% of the cost per visit in both treatment groups). Advanced dressings purchased from provider (which, in Italy, is the Hospital or Local Health Authority) cost more than simple dressings (€ 13.60 versus € 10.78).

However, within the 30-day period, the analysis of the monthly mean cost of care imputable to the providers favours advanced dressings. The use of advanced dressings requires fewer visits by the health care operators, resulting in lower staff costs imputable to the entire process which, in turn, offsets the higher purchase cost of such dressings (Tab. II).

When applied to ulcer stage, the results of the analysis are even clearer. The use of advanced dressings in the treatment of stage 2 ulcers (defined as: partial thickness loss of dermis presenting as a shallow open ulcer with a red pink wound bed, without slough; may also present as an intact or open/ruptured serum-filled blister [32]), which were more numerous in the simple dressings group, produced a saving of 40.17% (€ 199.21 versus € 332.94). The economic advantage of using advanced dressings, rather than simple ones, in case of stage 3 ulcers (defined as: full thickness tissue loss; subcutaneous fat may be visible but bone, tendon or muscle are not exposed; slough may be present but does not obscure the depth of tissue loss; may include undermining and tunnelling [32]) is equal to 20.99% (€ 298.83 versus € 378.24).

Sensitivity analysis to test the robustness of the results showed that, within the range of personnel costs, transport expenses, and materials costs, the minimum and maximum values led to savings of approximately 27% to 29% when advanced dressings were used, rather than

Tab. I. Descriptive analysis of sample data (Source: CREMS and ISS reprocessing of study data).

Variables	Advanced dressing	Simple dressing
Sex (P = 0.512)	M: 31.3% F: 68.7%	M: 34.7% F: 65.3%
Age groups (yrs) (P = 0.142)	20-40: 2.4% 41-60: 5.2% 61-80: 33.6% > 80: 58.8%	20-40: 1.3% 41-60: 6.6% 61-80: 44.4% > 80: 47.7%
Comorbidities (P = 0.226)	Nervous system 25.6% Psychiatric 24.2% Vascular 10.4% Musculoskeletal 10.0% Other 29.8%	Nervous system 33.8% Psychiatric 21.2% Musculoskeletal 15.2% Diabetes 6.6% Other 23.2%
Location (P = 0.744)	Sacral/spinal 57.8% Heel/ankle 27.5% Femor/trochanter 14.7%	Sacral/spinal 60.3% Heel/ankle 27.8% Femor/trochanter 11.9%
Depth (P = 0.416)	1.17 cm	1.08 cm

Tab. II. Mean monthly 30-day period cost of treatment (Source: CREMS and ISS reprocessing of study data).

Type of cost	Simple dressing	Advanced dressing	Advanced vs. simple dressing Δ	Advanced vs. simple dressing Δ
Mean monthly cost for health worker visits	233.85 €	153.52 €	- 80.33 €	- 34.35%
Mean monthly cost for dressing material	58.51 €	72.65 €	+ 14.14 €	+ 24.17%
Mean monthly transport costs	58.69 €	31.03 €	- 27.66 €	- 47.13%
Mean monthly total cost	351.05 €	257.20 €	- 93.85 €	- 26.73%
Estimated total monthly cost in hospital	292.36 €	226.17 €	- 66.19 €	- 22.64 %

simple ones. These results are similar to those available in the literature.

The organizational impact analysis results for advanced dressings, are reported in Figure 1 (where the larger the impact area referred to each parameter, the higher the positive impact on the organization). The use of advanced dressings has a positive organizational impact considering the number of visits within the 30-day period, the time required for each visit and the possibility for health workers to perform other activities. However, it has a negative impact when considering personnel learning time, personnel training required and the number of staff required for each visit.

The sensitivity analysis to test the robustness of the results within the range of staff costs, transport expenses, and materials costs, shows variations between +7.49% (increasing all the parameters) and -5.32% (decreasing medication and device costs, and transport costs) per visit for the advanced dressings group and between +7.61% and -5.12% per visit for the simple dressings one.

The same analysis, performed over the 30-day period, shows similar results: variations between +7.60% (increasing all the parameters) and -5.53% (decreasing medication and device costs, and transport costs) for the advanced dressings group and between +7.70% and -5.27% for the simple dressings one. The bootstrapping mean values are comparable to those found in the literature, with a minimum variance which reaches its highest rate of 0.63%. However, considering the maximum and minimum bootstrapping analysis results, a higher variance can be observed: +9.06% and -8.34% for the simple dressings group per visit costs, and +12.73% and -11.40% for the advanced dressings one over the 30-day period. The results of the Monte Carlo simulation show a mean cost increase within

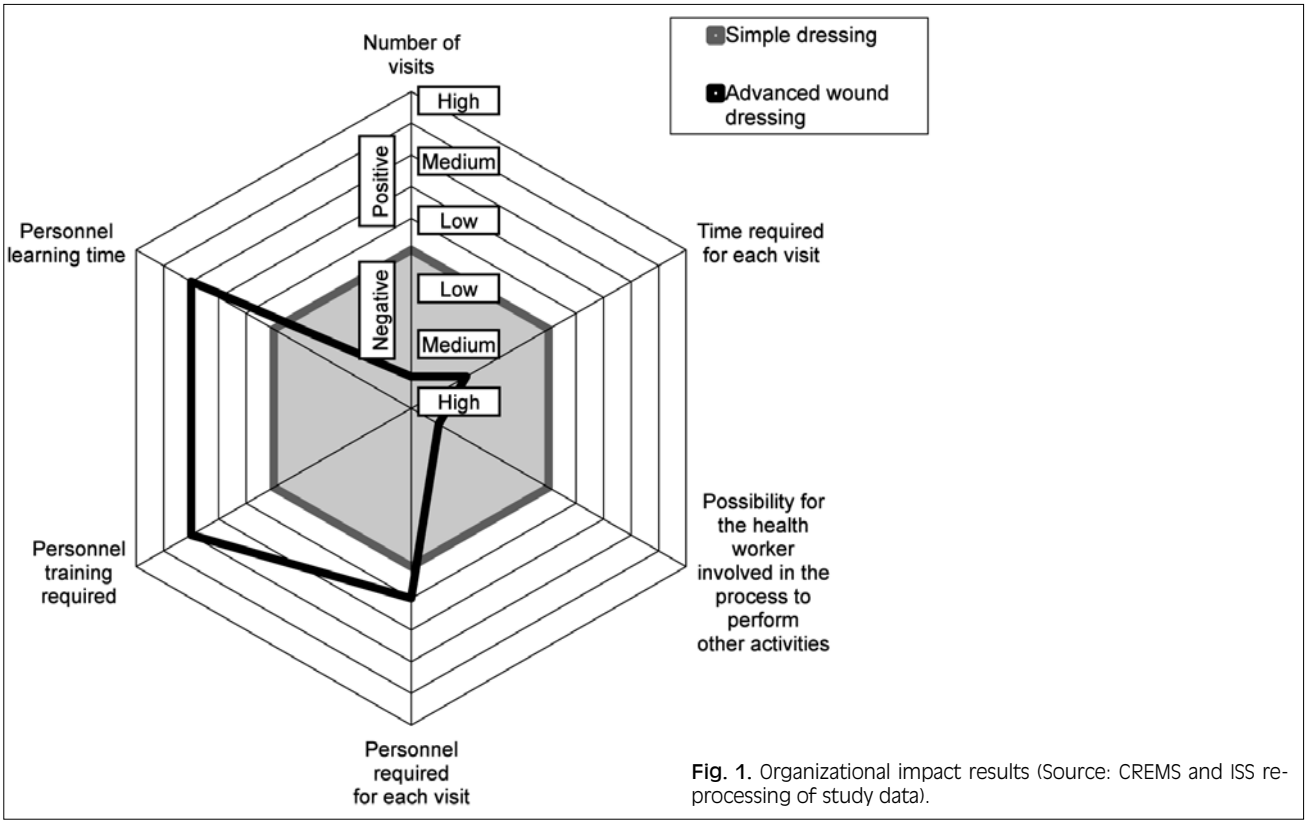

Fig. 1. Organizational impact results (Source: CREMS and ISS reprocessing of study data).

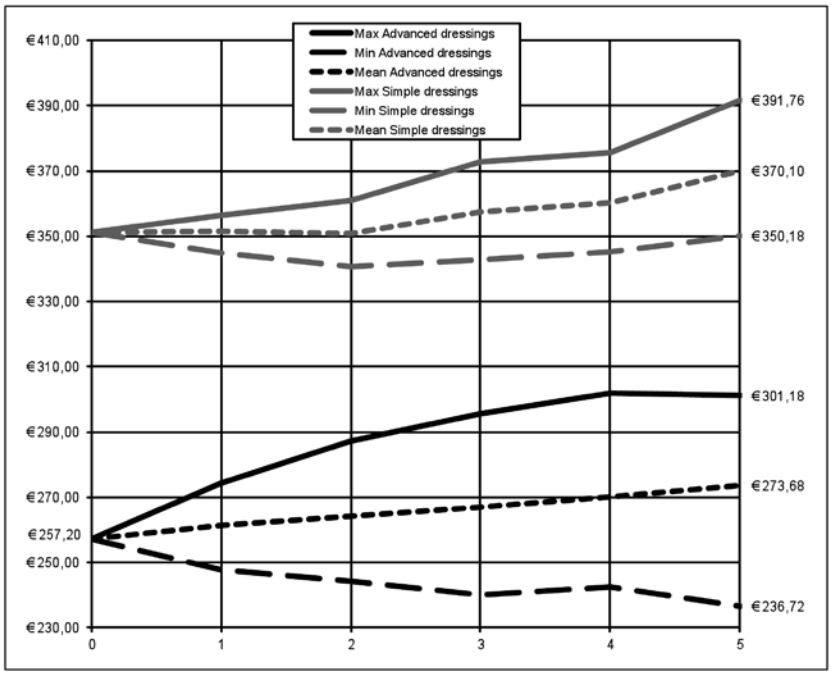

Fig. 2. Montecarlo analysis results of 30 days treatment's costs (Source: CREMS and ISS reprocessing of study data).

a 5 year time period, equal to +6.21% per visit and +6.02% considering the 30-day period for the advanced dressings group and equal to +5.49% per visit and +5.14% considering the 30-day period for the simple dressings one. The minimum, maximum and mean results of the analysis for both scenarios are reported in Figure 2. It is important to observe that the use of advanced dressings lead to savings, in terms of costs, in all the projections.

The data also showed a greater efficacy of advanced dressings. Although a general improvement, as measured by the reduction in ulcer size, was noted in both groups the ulcers in the advanced dressings group showed a wider reduction in terms of lesions' size (-40,34% versus -34,34%; P = 0.05).

Considering both cost and effectiveness data, a Cost-Effectiveness Value (CEV) equal to € 1,022.41 was calculated for simple dressings and equal to € 637.62 for advanced ones. The ICER result showed a saving of € 1,563.57 for each additional effectiveness unit. The use of advanced dressings is dominant if compared with the use of simple ones, with a lower costs absorption during the 30 day period and higher effectiveness (Fig. 3).

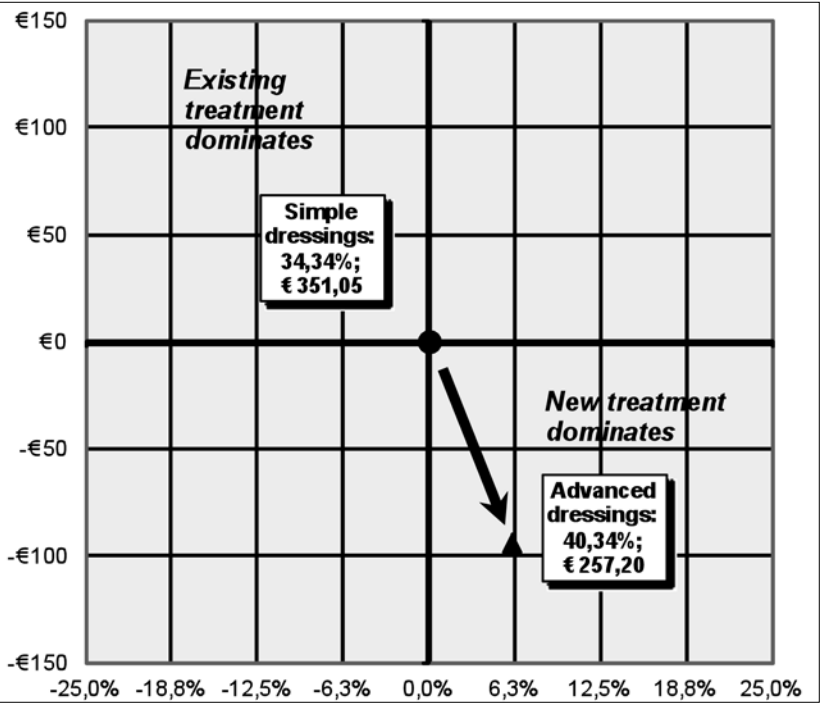

Fig. 3. Cost-effectiveness analysis of 30-day period (Source: CREMS and ISS reprocessing of study data).

Conclusions

The results of the study are highly replicable. It may be readily applied to community or hospital-based care, in addition to being useful for benchmarking between different facilities in Europe, the U.S. or elsewhere.
The decision to consider the sole direct costs, which are not related to any regulatory system, increases the generalizability of the results. Also, the study underlines the importance of evaluation, in accordance with the Health Technology Assessment methodology, with reference to organizational and equity impacts which clearly supports resource purchasing policies advocating the choice of advanced dressings rather than conventional ones, and the impact in terms of process efficiency.
Likewise, the methodology used in this study is easily replicable if used in national and international contexts, both in the private and public sectors, for hospitals, and home care.
For wider populations with different comorbidities and wounds stages, the results may vary. However, these variations should not be statistically significant, as evidenced by the sensitivity analysis performed. It is important to note this last aspect for the implications it has on the life of the patients and in the context of the treatment of wounds.
With the use of advanced dressings, home visits number may be reduced by up to 50%. In the 30-day period, visits by the professional health workers dropped by 50%, from 22 to 11. This decrease reduces the use of scarce resources (personnel) per case treated, thus increasing the potential number of home visits and improving the delivery of such services.
The data were also analyzed to estimate the cost of inpatient care. Even when the transport expenses were left out of the calculations, the cost for the advanced dressings remained advantageous compared with simple ones (cost reduction of 22.64%, see Tab. II).
Despite the negative advanced dressings impact on the organization, related to personnel training required, learning time, and personnel required for each visit, the other parameters have a higher positive organizational impact compared with simple dressings utilization. Moreover, the saving of resources required due to less requested access may compensate for the problems in the increase of learning time. In the long term, this knowledge will certainly have a tangible benefit within the organization. If it is true that pressure sores have continually presented a problem to the nursing profession for many years [33], and that many hospitals continue to evaluate themselves based on the prevalence of skin breakdown [34], the correct use of advanced dressings may become an organizational solution, thus giving a saving in time for skin care and prevention.
The study assessed a lower resources cost of advanced dressings for treatment of pressure ulcers in patients under integrated home care over a 30-day period. Many of the health care workers were observed to use an inordinate amount of low-cost materials (e.g., gauze for lesion cleaning) although such use was not really necessary. One possible explanation of this could be the operators limited perception of the economic impact of their activities which, from the institution's viewpoint, in the long run generate incremental expenditure. This discrepancy points to the growing need to train health workers in the appropriate use of ulcer care materials according to wound stage and depth, and the amount of disposables in order to give better results and hence, a saving in expenditure.
It is even more relevant in the use of advanced dressings where allocation of economic resources for the purchase of specialized technical support and devices should be seen by the institution as a short-term investment which will give long-term savings of up to 50%, widening the 30-day period used in this study.
For the equity results, assuming the viewpoint of the family and caregivers, there is an advantage in the use of advanced wound dressings. This is due to the fewer relative activities during the 30-day period. Accessibility is positive for advanced dressings. In addition, concerning the perception of the pain, the final results shows an advantage in using advanced wound dressings rather than simple ones. No severe adverse events were detected for both wound dressings' categories and no differences in terms of perception were found (Tab. III).
The study highlights the need for a global approach to pressure ulcer management as the use of antidecubitus devices, correct diet and repositioning cannot be replaced by only the usual treatment of the ulcer. Two fundamental elements necessary for appropriate and complete care are: an understanding of pressure ulcer causes and treatment, and a willingness of health workers to train the patient's family and caregiver in wound management. The caregiver's educational training in home care may significantly relieve the economic and social burden of this avoidable condition. Health workers should be ready to train caregivers and improve their skills. With this in mind, it is hoped that, in the future, resources will be freed for the training of caregivers.
The study also showed the importance of not restricting the analysis to institutional decision makers who need to operate choices considering economic variables when deciding on the type of dressing to be purchased from a central supplier and the product unit cost. The assessment of a technological choice impact should focus on the process, the analysis of organizational implications, and the costs related. A correct health care planning will envisage coherent use of economic resources and will apply principles of economy and efficiency in the selection of the best options for the patient and the institution.

Tab. III. Equity Impact of 30-day period (Source: CREMS and ISS reprocessing of study data).

Criteria	Advanced dressing	Simple dressing	P-value
Accessibility for the family and care giver	4.6	3.5	0.136
Pain	4.5	3.2	0.097
Severe Adverse Event	3.1	3.1	

At present, efforts to curb ever increasing health care expenditure may be guided by operating judicious cost saving care choices.
No ethical or equity problems have emerged from the study, in terms of the observational study carried out although concern might be expressed with regards to the capacity of the Italian Regional Health Care Services to cover the patient's need of advanced dressings: sometimes patients pay for their dressings, and this may be considered unethical. Regional Health Care Systems should guarantee the availability of these products.
Finally, one limitation of this study to be noted, with regards to the centers' recruitment method, is that as participation was voluntary, it might be assumed that the operators, and the institutions, gave their patients more attention, leading to inevitable improvement in institutional performance and reduction in costs recorded.

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■ Correspondence: Emanuela Foglia, Centre for Research on Health Economics, Social and Health Care Management (CREMS), Carlo Cattaneo, LIUC University, corso Matteotti 22, 21053 Castellanza (VA) Italy - Tel. +39 0331 572516 - Fax +39 0331 572513 - E-mail: efoglia@liuc.it