Comparison of pressure ulcer treatments in long-term care facilities: clinical outcomes and impact on cost

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined the use of balsam Peru, hydrogenated castor oil and trypsin (BCT) ointment in the treatment of pressure ulcers. BCT ointment was compared with BCT plus other treatment (BCT+O) and with "Other" treatments. The other treatments were not uniform between BCT+O and Other, and included all other treatments found to have been used in a long-term care nursing facility setting. BCT ointment and the alternative wound-healing product were not necessarily used concurrently in the BCT+O group.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised residents in skilled long-term nursing facilities (SNFs) who had at least one Stage 1 or Stage 2 ulcer.

Setting
The setting was institutional care. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data, resource use and cost data related to the period from January 2001 to May 2004. The authors did not specify a price year.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The cost data were collected retrospectively from the same patient sample as that used in the effectiveness study.

Study sample
The authors did not report any power calculations. Eligible patients were identified retrospectively from a review of electronic records from 241 SNFs throughout the USA. Out of approximately 40,000 patients, 861 satisfied the inclusion criteria. The study was approved by the institutional review board, so refusals to participate were not relevant. Out of the 861 eligible patients, 527 had at least one minimum data set (MDS) of records; some evaluations were
performed only on these patients. There were 2,014 wound episodes among the 861 patients, but only 976 wound episodes had adequate treatment information for inclusion in the analysis. Of the 861 eligible patients, 473 were not prescribed a wound-healing product, 49 (5.7%) received BCT, 77 (8.9%) received BCT+O and 262 (30.4%) received Other. Of the 2,014 wound episodes included in the analysis, 649 had available MDS outcome data, 49 of which were treated with BCT, 124 with BCT+O and 476 with Other alone.

Study design
The study was a retrospective cohort study.

Analysis of effectiveness
It was difficult to determine the unit of analysis and number of patients or wound episodes included in each of the study analyses, as it seemed to vary between analyses. The authors conducted complete case analyses. It was also unclear as to whether analyses based on wound episodes were adjusted for clustering by patient. The primary health outcomes were healing rate, time to heal and duration of treatment. The authors did not describe how comparable the groups were at baseline, but they stated that any covariates that were statistically significant at baseline were included in adjusted analyses for certain key outcome measures.

Effectiveness results
The adjusted healing rate was significantly higher for patients receiving BCT (58.6%) than for those receiving Other (37.1%) or BCT+O (42.8%), (p<0.05), based on an analysis of covariance (ANCOVA). These findings were not statistically significant if Stage 1 and Stage 2 ulcers were analysed separately.

The adjusted mean time to heal was 31.3 days (95% CI: -7.7 to 70.4) for BCT, 74.9 days (95% CI: 42.6 to 107.2) for BCT+O and 62.3 days (95% CI: 45.5 to 79.2) for Other. The differences were not found to be statistically significant.

The mean duration of treatment was significantly shorter for patients receiving BCT than for those receiving BCT+O or Other, (p<0.001).

Clinical conclusions
The authors concluded that BCT and BCT+O produce better healing outcomes than Other treatments.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used in the economic analysis. In effect, the study was a cost-consequences analysis.

Direct costs
The resource use quantities were not reported separately from the costs. The study included the direct costs to SNFs. Nursing labour cost was the only cost included in the analysis. Labour time and wages were estimated from MDS records. The study reported the mean daily costs. The price year was not reported.

Statistical analysis of costs
The authors reported the mean costs with 95% CIs. The costs were compared using ANCOVA. ANCOVA relies on the assumption that the dependent variable, in this case costs, is normally distributed. This might have been appropriate for an analysis of the mean daily cost but the authors did not comment on the underlying distribution. The authors stated that they also employed post-hoc statistical techniques such as the Tukey method of multiple comparisons. The study is unlikely to have been sufficiently powered to detect a difference in the costs.
Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
Not relevant.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
For patients whose initial wound was Stage 1, the mean daily labour costs were $50.8 (95% CI: 47.1 to 54.4) for BCT, $54.5 (95% CI: 48.9 to 60.1) for BCT+O and $61.7 (95% CI: 58.7 to 64.7) for Other.

For patients whose initial wound was Stage 2, the mean daily labour costs were $58.1 (95% CI: 53.5 to 62.8) for BCT, $63.4 (95% CI: 60.0 to 66.8) for BCT+O and $62.3 (95% CI: 60.7 to 63.9) for Other.

The mean daily labour cost for patients treated with BCT was significantly lower than for those treated with BCT+O or Other for patients whose initial or highest ulcer stage was Stage 1, (p<0.05).

Synthesis of costs and benefits
Not relevant.

Authors' conclusions
Balsam Peru, hydrogenated castor oil and trypsin (BCT) ointment and BCT plus other treatment (BCT+O) compare favourably, in terms of positive healing outcomes and lower average daily nursing costs, with a large variety of alternative treatments in skilled long-term nursing facilities (SNFs) in the USA.

CRD COMMENTARY - Selection of comparators
The authors wished to examine the use of BCT ointment in the treatment of pressure ulcers, but they did not provide any justification for focusing on this treatment in particular. The comparators simply represented all other medications used in the study setting. The authors acknowledged that the failure to compare BCT with a specific product is a limitation of the study. You must decide whether these treatments are representative of treatment in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a retrospective cohort study. The study design, which compared all patients who received BCT with patients who received any other treatment, was not appropriate for establishing the cost-effectiveness of BCT. The study sample appears to have been representative of the study population. The patient groups were not shown to be comparable at analysis. The authors stated that some adjusted analyses were conducted, but it is unclear whether these could compensate for the selection bias in the study design as the appropriate information was not provided. The authors did not adequately report the size of the study samples, the unit of analysis, the impact of missing data, or the effect of clustering by patient for the analysis of wound episodes. This severely limits the validity of the study results. The use of BCT+O as a comparator, where BCT and Other were not necessarily concurrent, is particularly likely to bias the analyses. This is because ulcers that fail to respond to BCT may be treated with another medication and then counted in the BCT+O group, rather than counted as a failed case of BCT alone.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was in effect, a cost-consequences analysis.

Validity of estimate of costs
The authors did not specify the study perspective. The analysis included only the mean daily nursing labour costs. The interpretation of this direct cost item was unclear, and the omission of medication costs in particular is likely to have affected the authors’ conclusions. The costs and the quantities were not reported separately. The resource use data and price data were derived from a single study. The failure to report the unit costs and price year limits the generalisability of the study results. The authors acknowledged that the limited cost data included represents a limitation of their analysis. A statistical analysis of the costs was conducted.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively. However, the multiple comparisons and multiple variations of each analysis make it difficult to ascertain the validity of the study results. The authors’ conclusions, that BCT compares favourably with other treatments, was not justified as BCT was not compared with specific other treatments, only to a broad average of treatments used in the particular study setting.

Implications of the study
The authors stated that further research, including prospective studies, is required to validate their findings.

Source of funding
None stated.

Bibliographic details

Indexing Status
Subject indexing assigned by CRD

MeSH
Balsams; Castor Oil; Comparative Study; Costs and Cost Analysis; Health Care Costs; Long-Term Care; Nursing Assessment; Outcome Assessment (Health Care); Pressure Ulcer /economics /etiology /prevention & control; Sensitivity and Specificity; Treatment Outcome; Trypsin

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