Developing skills in leg ulcer nursing: the lessons learned

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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 use of compression bandage systems to treat leg ulcers. The two types studied were the original Charing Cross system and the Robinson's Ultra Four kit.

Type of intervention

Treatment.

Economic study type

Cost-effectiveness analysis.

Study population

The study population comprised patients with a leg ulcer. Patients aged over than 18 years, with venous leg ulcers, who lived in Leicestershire or Rutland were included, as were those with diabetes with venous disease. Patients who had an ankle brachial pressure index of less than 0.8 were excluded, as were those with arterial or mixed ulcers. Also excluded were patients who had used short-stretch bandages and those who did not adhere to treatment. In addition, patients treated with the Charing Cross system were excluded from the Robinson's Ultra Four group.

Setting

The setting was primary care. The economic study was conducted in Leicestershire, UK.

Dates to which data relate

The effectiveness and resource use data relating to the use of the Charing Cross system were collected between August 1996 and September 1997. Data for the Robinson's Ultra Four kit were collected between October 1997 and December 1998. The price year was 1996 for the use of the Charing Cross system and 1998 for the use of the Robinson's Ultra Four kit.

Source of effectiveness data

The effectiveness data were derived from a single study.

Link between effectiveness and cost data

The resource use and cost data were collected prospectively from the same patient sample as that used in the effectiveness study.

Study sample

All patients who were being treated by key leg ulcer nurses working for Leicestershire and Rutland NHS Trust between August 1996 and December 1998 were included in the study. Patients were included in the study as part of their

treatment, therefore there was no explicit sample selection process.

A total of 449 patients were included in the study. Of these, 225 were treated with the Charing Cross system (group 1) and 224 with the Robinson's Ultra Four kit (group 2). The individuals in group 1 had a median age of 76 years, a median ulcer duration of 35 days, and a median ulcer surface area of 7.4 cm2. The individuals in group 2 had a median age of 74 years, a median ulcer duration of 16 days, and a median ulcer surface area of 5.5 cm2.

No distinction was made between patients treated in the community and in leg ulcer clinics.

Study design

This was a prospective cohort study that was conducted in a single centre. Key leg ulcer nurses assessed all patients with leg ulceration using the Leicestershire leg ulcer assessment form. Assessment was made before the start of compression therapy and after each 12-week treatment period, when a new supply of bandages would be obtained. The patients were followed up until their ulcer healed, there was an adverse incident (death, unrelated amputation or altered vascular status), or for 60 weeks. Twelve patients were withdrawn from the Charing Cross group and 14 from the Robinson's Ultra Four group. Reasons for withdrawal included non-compliance with treatment and inability to tolerate treatment. The loss to follow-up was not reported. There was no blinding in this study.

Analysis of effectiveness

The paper did not report whether the analysis of effectiveness was conducted on an intention to treat basis or on treatment completers only. The primary health outcome measured was time to ulcer healing. The two treatment groups were shown to be comparable in age. However, the duration of ulcer and ulcer surface area were significantly higher in the group receiving the Charing Cross system. These patients were also more likely to have had an ulcer, deep vein thrombosis, bilateral ulcers and a fixed ankle, but the significance of these differences was not reported. The patients treated with the Robinson's Ultra Four kit were more likely to be unable to leave the house unaided, but the significance of this difference was not reported. No adjustments for these potentially confounding factors were made in the analysis.

Effectiveness results

Twelve weeks after starting treatment, 45% of ulcers treated with the Robinson's Ultra Four kit had healed compared with 33% of those treated using the Charing Cross system.

Patients treated with the Robinson's Ultra Four kit continued to show greater healing after 24, 36, 48 and 60 weeks.

After 60 weeks, 80% of ulcers treated with the Robinson's Ultra Four kit had healed compared with 76% of those treated with the Charing Cross system (not statistically significant).

A significant correlation was found between duration of the ulcer and surface area, and between healing time, age and surface area, ($p<0.002$, $p=0.002$, $p<0.001$, respectively). A multiple regression analysis showed that surface area and age could significantly predict healing time, ($p<0.061$ and $p=0.005$, respectively).

Clinical conclusions

The authors concluded that compression bandaging therapy was an effective method of achieving healing in patients with venous leg ulcers. However, they made no statements about the comparable effectiveness of the two treatments. The Robinson's Ultra Four kit resulted in faster healing than the Charing Cross system, although this difference was not statistically significant.

Measure of benefits used in the economic analysis

The clinical outcomes and costs were left disaggregated. Therefore, in effect, a cost-consequences analysis was conducted.

Direct costs
This study appears to have assessed the costs of treatment accruing to the hospital. The only cost calculated was the cost of bandages under the two treatment regimens. The quantity of bandages was based on their actual use amongst the two sample groups. However, neither these quantities, nor the unit costs were reported in the paper. The method of calculating the cost of the bandages was not reported, neither was the source of the costs. The costs of the Robinson's Ultra Four kit were calculated for 1998, while those of the Charing Cross system were calculated for 1996. The nursing time was also compared between the two groups, but the authors did not cost this element. The travelling time and the additional time spent with patients providing education and support were not considered. The costs were not discounted, which was appropriate since they were incurred during less than 2 years. The costs per patient per week (one week before compression and one week of four-layer bandages) were reported.

Statistical analysis of costs
The cost data were treated deterministically.

Indirect Costs
No indirect costs were included in the study.

Currency
UK pounds sterling ().

Sensitivity analysis
No sensitivity analysis was undertaken.

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

Cost results
The use of compression therapy led to a significant reduction in nursing time, ($p<0.001$). The compression dressing time was 20 minutes in the Charing Cross system group versus 60 minutes for the pre-compression dressing time. The compression dressing time was 25 minutes in the Robinson's Ultra Four kit group versus 50 minutes for the pre-compression dressing time.

The previous week dressing cost per patient was 10.85 with the Charing Cross system and 5.30 with the Robinson's Ultra Four kit.

The cost of bandages was 6.46 per patient per week for patients being treated with the Charing Cross system and 7.55 for those being treated with the Robinson's Ultra Four kit.

Savings of 4.39 per patient per week were observed in group 1 (Charing Cross system). An increase of 2.25 per patient per week was observed in group 2 (Robinson's Ultra Four kit).

There was a significant difference in overall cost between conventional and compression therapy, ($p<0.001$).

Synthesis of costs and benefits
The costs and benefits were not combined because, in effect, a cost-consequences approach was used in the study.

Authors' conclusions

The authors reported a general conclusion pertaining to compression therapy. They concluded that compression therapy was an effective method of achieving healing in patients with venous leg ulcers and significant costs-savings were made in dressing costs and nursing time. The authors did not draw any conclusions about the clinical effectiveness and cost implications of the two compression bandage systems studied.

CRD COMMENTARY - Selection of comparators

The selection of the comparator treatment in the effectiveness analysis (the original Charing Cross system) was based on the practice in the authors' setting between August 1996 and September 1997. You should consider how this relates to usual practice in your setting. The authors did not define the comparators used in the economic analysis (i.e. prior treatment regimens). These treatments represented the usual practices for leg ulcer treatment in the authors' setting before August 1996.

Validity of estimate of measure of effectiveness

The clinical effectiveness data were derived from a cohort study. The two patient groups were treated and studied consecutively, rather than simultaneously, and this may have introduced bias into the results. The two patient groups were also shown not to be comparable at baseline, and this could have introduced further bias into the outcomes reported. These potentially confounding factors were not accounted for in the analysis of the results. In addition, no power calculations were reported. Therefore, the sample size may have been insufficient to obtain robust results. A randomised controlled trial would have provided more robust results on which to undertake an economic analysis. The authors did not compare their sample with the patient population. However, they reported that their sample was representative of the patients presenting with venous leg ulcers in Leicestershire.

Validity of estimate of measure of benefit

The authors did not derive a summary measure of benefit from their clinical effectiveness data. The analysis was, in effect, a cost-consequences study.

Validity of estimate of costs

The authors did not state the economic perspective of the study, although the perspective of a health care provider appears to have been used. The only cost fully included in the study was the cost of compression bandages. The study assessed the nurse time taken to dress ulcers in the two treatment groups. However, they did not cost this element. If nurse time had been included in the analysis the results of the economic analysis would have been very different, although it is unlikely to have altered the conclusions. Since other costs were excluded from the analysis, the costs of the compression bandage systems may have been underestimated. Resource use and the unit costs were not reported separately, which will hamper any attempts to apply the results of this study to other settings. The price years were reported in the paper, thus assisting future reflation exercises. However, the fact that there was a 2-year difference in the price years used for the two treatments severely limits the conclusions that can be drawn from this study.

No statistical or sensitivity analyses of the resource use or cost data were undertaken. This means that the reliability of the results has not been assessed. The costs were not discounted, but this was appropriate since they were incurred during less than 2 years.

Other issues

The authors compared their clinical effectiveness results with other studies, but they did not consider how their economic results related to other studies. They also did not directly consider how their findings might be generalised to other settings. The results were not presented selectively, but a lack of clarity made it difficult to interpret the results. The authors did not draw any explicit conclusions about the compression bandage systems being compared. They acknowledged that the lack of comparability between the two patient groups may have influenced their clinical effectiveness results.

Implications of the study
The authors did not make any recommendations for changes in practice. They indicated a need for future monitoring to evaluate improvements in healing rates and the benefits of different treatment settings.

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