***This is the accepted version of the following article: Barnsbee, Louise, Cheng, Qinglu, Tulleners, Ruth, Lee, Xing Ju, Brain, David, & Pacella, Rosana (2019) Measuring costs and quality of life for venous leg ulcers. International Wound Journal, 16(1), pp. 112-121., which has been published in final form at 10.1111/iwj.13000. This article may be used for non-commercial purposes in accordance with the Wiley Self-Archiving Policy [ ].http://www.wileyauthors.com/self-archiving.***

Table 1: Participant baseline characteristics (continuous variables)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All patients*Mean (SD)*n=80 | Usual care *Mean (SD)*n=54 | Optimal care*Mean (SD)*n=26 | p-value |
| Age, *years* | 75.1 (13.9) | 73.3 (14.7) | 79 (11.3) |  0.053  |
| Height, *cm*  | 170.2 (11.6) | 171.7 (11.1) | 166 (12.3) | 0.094 |
| Weight, *kg*  | 93.3 (33.0) | 97.9 ( 34.3) | 80.6 (26.2) | **0.037**  |
| BMI, *kg/m2* | 33.1 (11.2) | 34.1 (11.8) | 30.0 (8.7) |  0.260 |
| Ankle circumference, *per leg, cm* | 23.9 (2.5) | 24.2 (2.6) | 23.6 (2.5) | 0.450 |
| Calf circumference*, per leg, cm* | 36.8 (4.9) | 37.6 (5.2) | 36.0 (4.5) | 0.289 |
| Left ABPI\* ratio | 1.01 (0.21) | 1.2 (0) | 0.98 (0.22) | - |
| Right ABPI ratio | 0.99 (0.25) | 1.09 (0.16) | 0.97 (0.27) | - |
| Toe pressure index | 0.69 (0.16) | 0.84 (0.3) | 0.64 (0.06) | - |

\*ABPI – ankle brachial pressure index

“–” designates samples with too few data collected, or too few data for statistical testing

Table 2: Participant baseline characteristics (categorical variables)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Characteristic | All patients*n*, (%)+++n=80 | Usual care patients*n*, (%)+++n=54 | Optimal care patients*n*, (%)+++n=26 | p-value |
| BMI Category |  |  |  |  |
|  Underweight  | 2 (3.9) | 2 (5.3) | 0 (0) | 0.31 |
|  Normal | 14 (27.5) | 8 (21.1) | 6 (46.2) |  |
|  Overweight  | 8 (15.7) | 6 (15.8) | 2 (15.4 ) |  |
|  Obese  | 27 (52.9) | 22 (57.9)  | 5 (38.5) |   |
| Gender, male  | 32 (40) | 25 (46.3) | 7 (26.9) | 0.1 |
| Venous insufficiency | 65 (81.3) |  46 (85.2) |  19 (73.1) | 0.19 |
| Reduced Mobility | 70 (87.5) | 47 (87) | 23(88.5) | 0.86 |
| Age >70 | 56 (70) | 38 (70.4) | 18 (69.2) | 0.91 |
| Clinical signs of infection (at admission) | 18 (22.5) | 11 (20.4) | 7 (26.9) | 0.52 |
| Hypercholesterolemia | 10 (12.5) | 5 (9.3) | 5 (19.2) | 0.21 |
| Lymphedema/Oedema (history) | 40 (49.4) | 27 (50)  | 13 (50) | 1 |
| Oedema (at admission) | 51 (63.8) | 33 (61.1) | 18 (69.2) | 0.48 |
| Eczema ( at admission) | 15 (18.8) | 10 (18.5) | 5 (19.2) | 0.94 |
| Hypertension | 31 ( 38.8) | 17 (31.5) | 14 (53.8) | **0.055** |
| Peripheral arterial disease | 4 (5) | 3 (5.6) | 1 (3.85) | 0.73 |
| Smoker | 5 (6.25) | 3 (5.6) | 2 (7.7) | 0.72 |
| Deep vein thrombosis | 2 ( 2.5) | 1 (1.9) | 1 (3.85) | 0.60 |

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+++Please note variables may not add to 100 in percentages, as each variable had different numbers of available data.

^BMI category was tested using Chi-Square analysis and all other tests were completed using z test

Table 3: Wound characteristics at baseline

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Wound measurement, cm (per wound)** | **All patients****n=80** | **Usual care patients****n=54** | **Optimal care patients****n=26** | **p-value** |
| Wound length,*Mean (SD)*  | 2.9 (2.3) | 3.4 (2.6) | 2.6 (2.2) | 0.426 |
| Wound width,*Mean (SD)*  | 2.2 (1.5) | 2.3 (1.6) | 2.1 (1.4) | 0.983 |
| Wound depth,*Mean (SD)*  | 0.6 (0.5) | - | 0.4 (0.3) | - |
| Ulcer duration, *Mean (SD), in months* | 46.9 (91.3) | 46.1 (86.8) | 48.5 (100.7) | 0.885 |
| Ulcer duration, *Median (IQR)+, in months* | 10 (42) | 12 (45) | 6 (29.75) | 0.309 |

+IQR - interquartile range

+for analysis <1 was assumed to be 1 and >360 months was assumed to be 360 months

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Table 4: Average weekly costs per patient at baseline (AUD$)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Usual care** **Mean**  | **Optimal care** **Mean** | **p-value** |
| Transport cost  | $13.95 | $17.69 |  |
| Consultancy cost (out-of-pocket)  | $16.37 | $67.10 |  |
| Consultancy cost (health care system) | $71.41 | $78.13 |  |
| Costs of using other medical services (out-of-pocket)  | $9.94 | $8.27 |  |
| Costs of using other medical services (health care system) | $38.95 | $37.60 |  |
| Product cost  | $62.87 | $85.93 |  |
| Total weekly costs (health system) | $110.36 | $115.73 | 0.736 |
| Total weekly costs (out-of-pocket) | $104.25 | $178.99 | **0.016** |
| Total weekly costs  | $214.61 | $294.72 | **0.04** |

The “Totals” rows display the pooled results from the use of multiple imputation to handle missing data. Only the total weekly costs (by payer perspective and overall) were statistically tested.

Table 5: Baseline and three-month EQ-5D-5L scores

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Time point** | **All patients****Mean, (SD)** | **Usual care group****Mean, (SD)** | **Optimal care group** **Mean, (SD)** | **Difference between optimal and usual care groups****p-value, (95% CI\*)** |
| Baseline | 0.67 (±0.24) | 0.64 (±0.26) | 0.75 (±0.16) | **0.025**(0.014 - 0.206)  |
| 3 month  | 0.80 (±0.18) | 0.78 (±0.19) | 0.83 (± 0.15) |  0.414(-0.061 to 0.146) |

\*CI – Confidence interval

At baseline, the mean utility score of optimal and usual care patients were 0.75 (±0.16) and 0.64 (±0.26) respectively. The difference in these scores reached statistical significance (p=0.025).

Table 6: Time-to-healing

|  |  |  |  |
| --- | --- | --- | --- |
| **Number of ulcers healed after 1, 2, 3 and 6 months** | **Usual care (n=27)** | **Optimal care (n=19)** | **p-value** |
| 1 month healing *n,(%)* | 5 (18.5) | 5 (26.3) | **0.045** |
| 2 month healing*n,(%)* | 1 (3.7 ) | 2 (10.5) |  |
| 3 month healing*n,(%)* | 8 (29.6) | 10 (52.6) |  |
| 6 month healing*n,(%)* | 13 (48.1) |  2 (10.5)  |  |
| **Time-to-healing** | **Usual care (n=54)** | **Optimal care (n=26)** | **p-value** |
| Time-to-healing(months)*Mean, per ulcer* | 3.9  | 2.7  | - |
| Time-to-healing (months)*Median (IQR+), per ulcer* | 3 (3) | 3 (1.5) | **0.012** |
| Total number of ulcers during the first 3 months | 94 | 75 |  |
| Ulcers healed at 3 month data collection *(n, %)*  | 15 (16%) | 17 (22.7%) | **0.27** |
| Patients healed at 3 month data collection*(n, %)* | 12/42 (28.6%) | 6/20 (30%) | 0.912 |

+ IQR – Interquartile range

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Figure 1: Proportions of participants receiving care from different service providers

Figure 2: Use of additional services at baseline

Figure 3: Weekly cost of VLU management by clinic