Measuring Costs and Quality of Life for Venous Leg Ulcers

Introduction

There is a lack of nationally representative and recent data on the prevalence of venous leg ulcers (VLUs) in the Australian setting. In a 1991 study set in Perth, Western Australia, prevalence was estimated at 0.62 per 1000 in the general, metropolitan population (1). Prevalence of VLUs was highest in older age groups with a prevalence of 3.3 per 1000 in adults 60 years and older (1). As the ageing population in Australia is increasing (2), it follows that the prevalence and incidence of VLU has likely increased over time. Thus, prevalence estimates from the 1990's likely underestimate current prevalence.

Not only do VLUs represent a growing health burden, they also represent a condition which is expensive to treat for both patients and the health care system. Worldwide, studies have estimated annual costs of up to €2585, €1994 (cost of treating an initial ulcer, per patient, limited to health system perspective) and €9569 (direct and indirect costs, per patient, societal perspective) in Sweden, the UK and Germany respectively (3, 4). While these estimates illustrate the potential for high costs, due to differences in health care systems and services these costs may not reflect the situation in Australia. Out-of-pocket costs of consumables alone have been estimated at $27.5 million per year for Australians over 60 years with VLUs, although this figure may be underestimated due to underlying data limitations (5).

In Australia, the total, direct costs of treating VLUs (in public and private hospitals and residential care settings) was estimated to be US$802.55 million (±US$307.46 million) (6). This

estimate does not appear to include the costs in the non-residential care community setting, such as general practitioner visits, of treating VLU. This presents a significant gap in our knowledge of VLU costs.

In addition to the economic burden, VLUs also impact negatively on social functioning and reduce quality of life (QoL) (7, 8). There is limited local data about the effect of VLU on QoL, though it is expected to be significant. Elsewhere, a review described the impact of VLU on QoL as "profound" (7). Iglesias et al. describe an EQ-5D score, measured on a scale between 0 (death) and 1 (perfect health), of 0.62 associated with VLU (9). Greater understanding of the impact of VLUs on QoL would help to inform economic models.

Australian guidelines recommend compression therapy (CT) as the primary treatment for VLUs (10, 11); however, evidence suggests many people do not receive guideline-based care (1, 12). Coyer et al. (13) identify three main evidence-practice gaps, relating to knowledge, costs and systems, whereby care pathways are inconsistent. Yet, implementation of guideline-based, or optimal, care may represent improved health benefits and have important cost implications. For example, use of guidelines has been shown to reduce the costs of healing VLUs (14).

No study in the Australian setting compares the resources used or time-to-healing of optimal (guideline-based) care and usual (standard) care scenarios for VLUs. However, we do know that care pathways which increase access to specialist wound clinics and CT improve healing outcomes of leg and foot ulcers in the Australian setting (15) and evidence-based practice has demonstrated improved healing outcomes in other settings (14). Additionally, overall, we know little about the QoL benefits of optimal care as compared to usual care.

The present study is part of a larger project. The overall project will perform an economic evaluation to capture the costs and benefits of providing optimal care to VLU patients. The project will bridge knowledge gaps regarding the implementation of guideline-based/optimal care and contribute important knowledge of the costs, QoL and healing outcomes associated with optimal care in the Queensland, Australia setting. The present study describes costs of care for VLU patients and the impact on QoL associated with VLUs. Given the increasing population size

affected by VLUs and the substantial economic burden and reduced QoL associated with VLUs, this research has significant implications for patients, health professionals and healthcare policy makers.

Methods

Participants and setting

Recruitment occurred at four sites in Queensland, Australia: one private specialist wound clinic, one hospital outpatient clinic and two community care clinics.

Patients attending the private specialist clinic and the community clinics were charged standard fees with no subsidy and those attending the outpatient clinic were bulk-billed (no out-of-pocket costs to patients). Patients attending the community care clinics pay an out-of-pocket fee for each appointment, and are charged separately for dressings used. The clinics arrange delivery of dressings to patients and these dressings are then brought to and used at subsequent appointments. Patients attending the clinics are seen by registered nurses, podiatrists, dietitians and occupational therapists.

The public hospital outpatient clinic provides a bulk-billed service, with all dressings and consultancy fees covered with no out-of-pocket costs to the patient. Healthcare professionals in attendance include a vascular surgeon, registered nurses and occupational therapists.

Patients attending the specialist wound clinic are charged a fee for each appointment which covers the cost of consultancy and all dressings. Patients are seen by a multidisciplinary team comprised of a vascular specialist, a wound nurse practitioner candidate, a podiatrist and a registered nurse. Patients receive tailored wound dressing plans, designed to be managed by the patient or primary carer outside the clinic, through further clinic visits, or augmented through telehealth.

Patients with a VLU who met the inclusion criteria were invited to participate. Participants were eligible if they were over 18 years of age, the principal diagnosis was VLU (or mixed/arterial with predominantly venous origin), and if they could provide informed consent. Exclusion criteria included leg ulcers not of venous origin, inability to comply with the protocol of the study and cognitive impairment. Recruitment occurred between December 2016 and September 2017. Data were collected at study admission (baseline) and at one month, three month and six month follow-ups. Participation or non-participation in the study did not impact upon the care received by patients.

Data collection

Information on patient demographic, medical history, comorbidities and ulcer characteristics were collected upon recruitment at baseline. Ulcer characteristics – including time of first onset, duration, number of wounds, current ulcer history and clinical assessment (size, ankle brachial pressure index (ABPI) if available, whether new or recurrent, time-to-healing, time to recurrence and exudate description) – were recorded. Body mass index (BMI) was calculated and categorised as per the World Health Organisation classification (16). Medical history and risk factors were sourced from patients and clinicians and were confirmed and supplemented by medical record review subject to availability. Data on type of health services provided, investigations, types of dressings and bandages used, medication, travel, product and service patient out-of-pocket costs were recorded,. Data on QoL were collected using the EQ-5D-5L tool (17) at baseline and again at one, three and six months. Follow-up data were collected during clinic visits or through telephone interviews.

Definitions

For data analysis, patients were classified into two groups based on collected data: those receiving guideline-based prevention and treatment or "optimal care" and those receiving standard treatment or "usual care" at baseline. These classifications were made irrespective of the clinic of recruitment. Optimal care was defined as those patients who, during the study period and before healing, had at least one session of ankle brachial pressure index (ABPI) assessment to

confirm venous origin ($0.8 \leq$ ABPI ≤ 1.2), or toe pressure, or reason as to why ABPI was not performed and who received CT (compression bandages, compression hosiery or tubular compression bandage applied in three layers (18)). All other participants not meeting the criteria for optimal care were classified as receiving usual care. The treatment recorded at baseline was assumed to continue for the study duration or until healed. It was not possible to ascertain patient compliance with treatment unless noted in the medical records. Time-to-healing was defined as the number of months that each ulcer took to heal, from the time the patient was recruited into the study.

Costs

Data on costs of travel to receive wound care, consultancy with health professionals and products used allowed estimation of participants' average weekly costs. Patient out-of-pocket costs included costs to patients for travel and parking, private clinic consultation fees and wound care products. Health system costs included the Medicare costs of medical services (doctors, specialists, nurses and allied health professionals) and investigations as well as prescription costs for medications listed on the Pharmaceutical Benefits Scheme. Thus, this study takes a societal perspective. Costs are reported in Australian dollars unless otherwise indicated.

Travel and parking costs

Participant's travel and parking costs were estimated by capturing the mode of travel to the clinic, out-of-pocket costs and the frequency of attendance. Those who travelled by public transport, community transport or taxi provided exact travel costs. Car travel costs were calculated by multiplying the distance from clinic to participants' homes in kilometres by $0.66 (19). We assumed the same travel mode for each clinic visit.

Costs of medical services

The health services cost items included were all consultations with a community-based nurse, podiatrist and other allied health professional and medical specialists. Health services were valued in line with the Australian Federal Government reimbursements via Medicare or the Medical Benefits Schedule (MBS). Nurse practitioner, vascular surgeon, podiatrist and occupational therapist costs were based on MBS items 82215, 104, 10962 and 10958 respectively (20). Enrolled, registered and student nurse time costs were calculated based on hourly salary (21), assuming a 30 minute consultation in the absence of recorded appointment end time. The specialist wound clinic medical service was the patient out-of-pocket consultation fee which included the cost of consumables.

Additional to their regular attendance at a clinic or through a home nursing service, many patients also used other healthcare services (e.g. GP visits). These costs were calculated as a product of the cost of the visit to the service used and the frequency of service access.

Wound product costs

Product use data were collected through medical chart review, consultation with clinicians or observation during clinic visits by research staff. Consumable item costs were based on a review of market prices and are available in a spreadsheet format from the authors on request. Product use recorded included: primary/secondary dressings (e.g. absorbent dressings), compression systems (e.g. short-stretch bandages/hosiery), topical medications (e.g. antimicrobial ointments), skin care items (e.g. barrier creams), cleansers and other disposables (e.g. tape).

Quality of life

The EQ-5D-5L (17) tool was used to capture QoL data. EQ-5D-5L is a generic, preference-based tool which measures QoL according to five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression (17). For each dimension, respondents were asked to choose from five levels to indicate whether they experienced any problems from each dimension

of health. EQ-5D-5L survey answers were valued and transformed to a utility score using a scoring algorithm developed from a UK general population sample (22).

Statistical Analysis

Baseline characteristics and wound clinical outcomes at different time points for patients receiving optimal care and usual care were compared using a combination of t-tests, Mann-Whitney tests, z tests, Fisher's exact tests and median tests, as appropriate. Data were analysed using IBM SPSS Statistics 23 and z tests were performed using an online calculator (23). A significance level of 0.05 was used in the interpreting of the statistical test results. Median and mean time-to-healing was calculated in order to ensure comparability to previous studies.

Two patients had unknown costs related to travel and three patients had unknown costs related to product use. The multiple imputation procedure in SPSS was used to impute ten complete data sets to calculate the total cost estimate. Due to a small sample size, the Fisher's exact test was deemed most appropriate to test for differences in numbers of ulcers healed at one, two, three and six months.

Ethics

This study was approved by the Metro South Health Service District Human Research Ethics Committee (HREC) and Queensland University of Technology (QUT) Human Research Ethics Committees (approval numbers HREC/16/QPAH/370 and 1600000934, respectively). Written informed consent was obtained from all participants.

Results

Participants' baseline information is summarised in Tables 1-3. For all tables the available data were used, thus not all figures displayed included patients with missing data. Eighty-one participants were recruited; however, one patient had most baseline data missing and was also lost to follow-up by one month data collection, and thereby was excluded from analyses. Fifty-

four patients were classified into the usual care group and 26 patients into the optimal care group. At three months, 22.5% of participants were lost to follow-up.

The majority (68.6%) of participants were overweight or obese and were over 70 years of age (n=56, 70%) (Table 2). At baseline, the majority (81.3%) had venous insufficiency and reduced mobility (87.5%) recorded on their medical records (Table 2). Median ulcer duration at baseline was 10 months (IQR=42) for all patients (Table 3). By definition, all optimal care participants received CT. The majority (n=33, 61.1%) of usual care patients received CT as part of their care.

➔ Insert Table 1
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Average weekly costs of managing ulcers in the community are presented in Table 4. Average weekly cost was estimated at $214.61 for those in the usual care group and $294.72 in the optimal care group. This result was significant (p=0.04). Total patient out-of-pocket costs per week were significantly higher for patients receiving optimal care (p=0.016).

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The average ulcer healing time in the usual care group (3.9 months) was longer compared to the optimal care group (2.7 months) (p = 0.045). While the medians of the two care groups were identical (3), the median test results rejected the null hypothesis that the medians in both groups were identical as there was a larger proportion of patients in the usual care group with time-to-healing greater than the overall median compared with optimal care group (Table 6).

Service Provider

→ Insert Figure 1

Most patients (85%) received care from a registered nurse (tabulated data not shown). Similar proportions of optimal and usual care participants accessed registered nurses for care (Figure 1). A larger proportion (37%) of usual care participants received care from a vascular surgeon compared to optimal care participants (19.2%) while a larger proportion of optimal care participants received care from enrolled nurses (11.5%) and podiatrists (23.1%) than did usual care (3.7% and 14.8% respectively) patients. Most participants (61.5% of optimal care and 53.7% of usual care participants) accessed two or more service providers at baseline. A larger proportion of usual care participants accessed three service providers at baseline, 20.4% compared to 7.7% of optimal care participants.

Additional services use

→ Insert Figure 2

At baseline 52 participants (n=18, (69.2%) optimal care, and n=34, (63%) usual care) used services additional to their main clinic attendance for ulcer wound care (Figure 2).

Total wound management costs by clinic

→ Insert Figure 3

The total weekly cost of care provision by the specialist wound clinic was $445.13, of which $123.00 were health system costs and $322.13 were patient out-of-pocket costs (Figure 3). The costs associated with primary consultations appears to be the main contributor to high overall costs of care at the specialist wound clinic. Total weekly costs of care by the community wound clinics were $214.36, comprising $108.52 in health system costs and $105.84 in patient out-of-pocket costs. The cost of "other" medical services appear similar for all categories, perhaps

because the care is mostly from community services, and therefore invite fees of similar magnitude. Product costs fell almost exclusively onto patients attending the specialist wound clinic and the community clinics. Patients who attended the specialist wound clinic paid $105.34, while those attending community clinics paid $68.87. The hospital outpatient clinic incurred health system product costs of $58.00 with no out of pocket costs to patients (Figure 3).

Discussion

Costs

We present detailed findings of the cost of treating VLUs in the community setting in Australia. To our knowledge this is the first study to present such detailed costs for this setting. Understanding costs is the first step to assessing cost-effectiveness and to understanding more fully the burden this chronic health condition poses. These results have significant implications for VLU patients, policy makers and health professionals.

We estimated an average total weekly cost of $214.61 and $294.72 for those in usual and optimal care groups respectively. The optimal care group had higher costs overall, appearing to be driven by a higher cost of consultancy and product costs. Given the majority of patients in the optimal care group attended the specialist wound clinic, it is likely the out-of-pocket payment to the clinic influenced these results. However, the extra cost of attending the specialist wound clinic may be offset by factors such as faster time-to-healing.

A 2010 study estimated out-of-pocket costs to patients of managing VLU, finding a cost of $114 ($157.6, 2018 dollars) per month (24, 25), while the present study estimated out-of-pocket costs of between $104.25 and $178.99 per week, which seems to be substantially different. One point of difference for the study was that participants self-reported travel and consultation costs, and as the authors suggest may have underestimated them for use of private vehicles (24), while in the present study costs of using a car for travel was calculated by the research team and consultation costs were collected prospectively by the research team.

A report (5) assessed cost-effectiveness of VLU treatment in the Australian context. However, the report was unable to include out-of-pocket costs to patients for travel to wound clinics in economic models due to inadequate data (5). This demonstrates the importance of the present study in addressing this gap.

QoL

The baseline utility score, 0.67 (SD±0.24), for all patients at baseline (i.e. in the unhealed ulcer state) was similar to that found by Iglesias et al. (9), who reported a score of 0.62 (standard error 0.02) based on the EQ-5D tool. However, when comparing the type of care received, while usual care participants scores were similar to those reported by Iglesias et al. (9), optimal care patients had a 0.75 (SD±0.16) average utility score at baseline. As participants were not matched by characteristics, it is not necessarily surprising that the groups differed. After three months, the results of the present study were slightly higher than those reported by Iglesias et al. (9) for the same time point.

Healing outcomes

Previous work found a median time to ulcer healing of 12 weeks (3 months) (15) which compares similarly to our median findings of 3 months (IQR=3 for usual care; IQR=1.5 for optimal care) for both optimal and usual care groups. Time-to-healing was significantly different between usual care and optimal care groups. It is expected that decreased time-to-healing may reduce overall costs for treating VLU, despite the continued recommendation for CT which incurs additional costs. Apart from costs, considering the negative social functioning and QoL burden that ulcers can place on patients (7, 8), reduced time-to-healing may have implications for improved QoL and social function.

The finding that 61.5% of optimal care patients and 53.7% of usual care participants accessed two or more service providers is consistent with the literature which suggests that patients often have to seek multiple pathways/providers to receive care (15).

We described a 61.1% rate of CT in the usual care group received for VLU care. With CT being a significant factor in guideline based care, this low rate is concerning, particularly as these patients continue to pay out-of-pocket costs for care, however are not receiving guideline-based treatment. A comparison could also be drawn between the lower costs of usual care, and the lower rates of CT usage - compression bandaging systems and hosiery significantly contribute to upfront costs, particularly with the lack of reimbursement in place for this therapy (26).

Limitations

The type of wound care (e.g. compression/no compression) provided was recorded at baseline, and was assumed to continue throughout the study. Recall bias may have influenced estimation of the costs for health-professional visits outside of the main treatment visit as this relied on patient self-reported data. We assumed that patients used the same transport mode for all visits as travel costs were calculated from baseline data.

Participants were recruited into the study with an existing ulcer and may have been receiving treatment for this ulcer for several months prior to recruitment. Hence time-to-healing may have been underestimated.

Participants were classified according to the available data. As such, some patients may have been misclassified, for example, they were receiving CT but ABPI data were unavailable and so were classified into usual care. Some patient follow-ups were conducted via telephone and relied upon self-reported data, without inspection of the wound by a healthcare professional.
We did not compare the compression systems used or the level of compression used by participants. However, the Australian and New Zealand Clinical Practice Guideline for the Prevention and Management of Venous Leg Ulcers recommend that some compression is better than no compression, and further do not recommend use of a specific type of compression system but rather a range that is acceptable depending on a range of patient characteristics including patient tolerance (10). Data were not collected on patient compliance with recommended therapy. Other studies have found that patient compliance with CT may be limited and this could be the subject of further enquiry (27).

Conclusion

Patients receiving guideline-based optimal care incur higher costs initially, but these costs are expected to be outweighed by the long-term gains through fast healing times and improved quality of life. The higher costs of optimal care could be a contributing factor to the lower rates of patients receiving it, particularly as the majority of the costs are incurred by patients through product and service costs. If we are to begin closing the gap between the rates of optimal and usual care for patients, consideration should be given to providing reimbursement for wound-related costs such as dressings, CT and healthcare provision.

In addition, higher costs for optimal care could be outweighed by long-term savings through faster healing times, reduced recurrence and hospitalisation avoidance. This will be explored in an economic evaluation of optimal and usual care for VLU, using the data provided in this paper.

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