



# Comparison of EQ-5D-5L and SPVU-5D for measuring quality of life in patients with venous leg ulcers in an Australian setting

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## Abstract

**Purpose** Given the importance of measuring health-related quality of life (HRQoL) for cost–utility studies, this study aimed to determine the validity and responsiveness of two preference-based HRQoL instruments, the EuroQoL-five dimensions-five levels questionnaire (EQ-5D-5L) and the Sheffield Preference-based Venous Ulcer questionnaire (SPVU-5D) in patients with venous leg ulcers (VLUs) in an Australian setting.

**Methods** This study analysed de-identified data collected from 80 patients with VLUs recruited by a prospective study in Brisbane, Queensland, Australia. Patients were asked to complete EQ-5D-5L and SPVU-5D surveys at baseline, 1-month, 3-month and 6-month follow-up as part of the prospective study. Baseline data and follow-up data were pooled to test the construct validity and level of agreement of the two instruments. Follow-up data were used to test the responsiveness.

**Results** The ceiling effects were negligible for EQ-5D-5L and SPVU-5D utility scores. Both instruments were able to discriminate between healed VLU and unhealed VLU and showed great responsiveness when healing status changed over time. Weak to strong correlations were found between dimensions of EQ-5D-5L and SPVU-5D. The utility scores produced from EQ-5D-5L were generally lower.

**Conclusions** This study found that both EQ-5D-5L and SPVU-5D were valid and responsive in detecting change of VLU healing status among a small Australian population. Both instruments may be used in economic evaluation studies that involve patients with healed or unhealed VLUs. However, given the limitations presented in this study, further research is necessary to make sound recommendations on the preferred instrument in economic evaluation of VLU-related interventions.

**Keywords** Health-related quality of life (HRQoL) · EQ-5D-5L · SPVU-5D · Venous leg ulcer · Quality-adjusted life-year (QALY)

## Introduction

Venous leg ulcers (VLUs) are wounds that occur on the legs due to venous diseases [1]. The estimated prevalence of leg ulcers is between 0.11 and 1.1% of the general population [2–6] and 52–80% of leg ulcers are caused by venous

diseases [7–9]. Patients with VLUs usually suffer poorer health-related quality of life (HRQoL) [10]. The presence of pain is one of the most reported symptoms related to having VLUs, with 61–87% of patients experiencing pain [11–13]. Restricted mobility is another factor affecting the HRQoL of patients with VLUs [12, 14]. Moreover, the presence of VLUs has a negative impact on patient’s social function and mental health [13–15].

The extent to which patients’ HRQoL is affected by VLU can be assessed by patient-reported outcome measures (PROMs). The measure takes form of a survey and collects information on how patients perceive their health status. The value of including PROMs in clinical studies and regulatory uses has been acknowledged by international government bodies such as the UK National Health Service and the US Food and Drug Administration [16, 17]. Various PROMs instruments have been used by researchers

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to measure HRQoL among patients with VLUs [11, 18]. Instruments such as the 36-Item Short Form Health Survey (SF-36), 12-Item Short Form Health Survey (SF-12) and the 3-level version of EuroQol-five dimensions questionnaire (EQ-5D-3L) are standardized, well-validated instruments for measuring generic health status in different populations including Australia [19–21]. VLU-specific instruments include Hyland, Charing Cross Venous Ulcer Questionnaire, venous leg ulcer quality of life (VLU-QoL) and Sheffield Preference-based Venous Ulcer questionnaire (SPVU-5D). However, not all HRQoL instruments generate utility scores that are useful in economic evaluation studies. In cost–utility analysis, one type of economic evaluation, HRQoL utility scores are essential to calculate quality-adjusted life-years (QALYs) which is a summary measure of health outcomes. QALYs not only capture changes in quantity and quality of life but also allow comparison of health benefits across different health interventions or programs. The HRQoL utility score in most cases ranges from 0 to 1 where 0 denotes death and 1 denotes perfect health, and can only be derived from a preference-based HRQoL instrument.

So far, very few studies have investigated VLU patients' HRQoL for cost–utility studies. Iglesias et al. [22] compared three different HRQoL instruments for people with VLUs and presented utility scores for 'Healed VLU' and 'Unhealed VLU' states from the EQ-5D-3L survey. Brazier et al. [23] reported utility score from EQ-5D-3L survey for a VLU population irrespective of healing status. But there is evidence that the EQ-5D-3L instrument lacks responsiveness to changes over time [22, 24] and has large ceiling effects which limits its sensitivity [23]. When a generic preference-based measure is not appropriate, sensitive or responsive, condition-specific preference-based measures may be a useful alternative [25]. SPVU-5D has been identified as the only VLU-specific preference-based HRQoL instrument available [26–28]. However, its performance in terms of validity among populations other than UK and its responsiveness are unknown. Given the importance of measuring HRQoL within cost-utility studies, this study aims to evaluate and compare two preference-based HRQoL instruments, the 5-level version of EuroQol-five dimensions questionnaire (EQ-5D-5L) and SPVU-5D in patients with VLUs in an Australian setting.

## Methods

### Data source

This study analysed non-identifiable patient data previously collected by a prospective study that determined the costs and quality of life of patients affected by VLUs [29]. In the prospective study, patients were recruited from four

sites: two community wound clinics, one specialist wound clinic and one hospital outpatient wound clinic in Brisbane, Queensland, Australia between November 2016 and September 2017. Patients were eligible if they were adults over 18 years of age; had a principal diagnosis of VLU or mixed venous and arterial leg ulcer with predominantly venous origin (e.g.  $0.8 \leq$  ankle-brachial pressure index  $\leq 1.2$ ); and were able to give informed consent. A total of 80 patients were recruited by the end of the recruitment period. Participants were asked to provide information on their ulcer status and resource use to manage VLUs. They were also asked to complete two HRQoL surveys: EQ-5D-5L and SPVU-5D. Data were collected at baseline, 1-month, 3-month and 6-month follow-up. The prospective study received funding from the Wound Management Innovation Cooperative Research Centre and was approved by the Metro South Health Human Research Ethics Committee (HREC) and Queensland University of Technology HREC (Approval Numbers HREC/16/QPAH/370 and 1600000934, respectively). The use of non-identifiable patient data in this study was approved by the Queensland University of Technology University HREC (Approval Number 1700000874).

## Instruments

### EQ-5D-5L questionnaire

EQ-5D-5L is a generic and preference-based instrument that measures individual's quality of life from five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. For each dimension, respondents can choose from five levels to indicate whether they experience any problems on the day of the survey. Their answers are valued and transformed to utility scores. The Australian version of valuation algorithm for EQ-5D-5L is not available yet. One study tried to estimate an Australian algorithm for EQ-5D-5L using discrete choice experiment (DCE), but the regression results were not converted onto a 0–1 scale required for economic evaluation [30]. Thus, in this study, we adopted the scoring algorithm developed using the time trade-off (TTO) technique and DCE from a UK general population sample [31]. The utility values derived from this algorithm would range from  $-0.285$  (health state considered worse than death) to 1 (perfect health). The EQ-5D-5L questionnaire also contains a visual analog scale (EQ-VAS) that asks respondents to rate their overall health between 0 and 100.

### SPVU-5D questionnaire

SPVU-5D, the VLU-specific preference-based instrument, was recently developed using a bottom-up approach in UK [13, 26, 28]. The instrument has five dimensions

encompassing physical, psychological and social aspects (i.e. pain, mobility, mood, smell and social activities). Each dimension has between three and five levels. Respondents are asked to indicate which statements best describe how their VLU's have affected them in the last 7 days. The utility scores for worst health and perfect health are 0.084 and 0.955, respectively, in SPVU-5D and were obtained through a TTO valuation survey of a representative sample of the UK general population. In SPVU-5D, there is a possibility that even if a patient does not have perfect health, he/she can have a utility score above 0.955. This is because the regression coefficients showed that occasional limitations with social activities might result in a slight improvement in health.

### Data analysis

Descriptive analyses were conducted to summarize baseline patient characteristics. Continuous variables were presented as means, standard deviations (SD) and ranges, while categorical variables were presented as numbers and proportions. Due to the small sample size, baseline data and three sets of follow-up data were pooled to test the construct validity and level of agreement of two instruments. All analyses were conducted using the statistical software R [32].

### Floor/ceiling effects

Floor effects were calculated as the percentage of patients reporting the worst health condition. Ceiling effects were calculated as the percentage of patients reporting perfect health. A high floor/ceiling effect indicates that the instrument is unable to distinguish participants' scores at or near the lower/upper limit [33].

### Construct validity

The validity of EQ-5D-5L and SPVU-5D was first examined by testing the correlation with EQ-VAS scores. Since pooling baseline and follow-up data might compromise the independence of sample data, partial correlation was calculated between EQ-5D-5L/SPVU-5D and EQ-VAS scores given the different time points of data collection [34]. Spearman's rank correlation coefficient ( $\rho$ ) was computed, where a  $\rho$  value greater than 0.6 indicates strong correlation, 0.4 to 0.59 moderate correlation, and 0 to 0.39 weak correlation [35]. It was hypothesized that there was a moderate-to-strong positive correlation between the EQ-5D-5L/SPVU-5D utility scores and EQ-VAS score.

We also applied the "known-group" method [36] to test whether EQ-5D-5L and SPVU-5D can discriminate individuals between age, duration of ulcer, healing status and EQ-VAS score subgroups. For continuous variables (i.e. age and

duration of ulcer), the cut-off point to stratify patients into two groups was the sample mean or median if the variable was highly skewed. Cohen's  $d$  effect size was computed to show the size of the difference between two groups. For EQ-VAS score, we stratified patients into four groups: < 65 (bad), 65–79 (fair), 80–89 (good), 90–100 (excellent) [37]. Kruskal–Wallis  $H$  tests were used to identify any statistically significant effects of the polytomous variable on utility scores. Only patients with complete responses to both questionnaires were included in this univariate analysis.

### Level of agreement

The level of agreement between EQ-5D-5L and SPVU-5D was assessed by the intra-class correlation coefficient (ICC) and the Bland–Altman plot. ICC reflects both degree of correlation and agreement between measurements and an ICC value above 0.75 indicates good reliability [38]. In the Bland–Altman plot, the differences of two measurements were plotted on the  $y$  axis against the average of the two measurements plotted on the  $x$  axis. Three horizontal lines were drawn to show the mean difference and the limits of agreement which are commonly calculated as the mean difference plus and minus 1.96 standard deviation of the difference. However, given that the pooled data consisted of replicate measurements at different time points, the classic approach of deriving 95% confidence intervals could generate incorrect estimates [39]. Thus, a statistical model was applied to derive the limits of agreement [40]. Additional analysis on the correlation between EQ-5D-5L and SPVU-5D dimensions was conducted using Spearman's rank coefficient.

### Responsiveness

Responsiveness measures the degree of within-person change overtime. In this study, we assessed the responsiveness of two instruments using the standardized response mean (SRM) which was calculated by dividing the mean score change by the standard deviation of the change. Data from 6-month follow-up survey were compared with baseline data. A positive SRM would suggest an increase in HRQoL at follow-up. It was hypothesized that the change scores for those with healed VLU's at different follow-up time points should exceed the change scores for those who remained unhealed.

## Results

### Descriptive statistics for EQ-5D-5L and SPVU-5D

The four clinics from which patients were recruited shared similar patient profiles (Online Appendix Table A1). The

baseline characteristics of the 80 recruited patients are summarized in Table 1. The mean age of those who provided date of birth was 75 years. Over half of the patients were female (59%). Venous insufficiency and reduced mobility were observed in over 80% of the recruited patients. At baseline, seventy-seven patients completed EQ-5D-5L survey and 72 patients provided complete responses to the SPVU-5D survey (Table 2). The number of eligible patients decreased to 48 at 6-month survey due to loss to follow-up. Total number of observations obtained from baseline and follow-up surveys reached 237 and 230 for EQ-5D-5L and SPVU-5D, respectively. There was an increase in both EQ-5D-5L and SPVU-5D utility scores over time, while the mean SPVU-5D score was generally higher than the mean EQ-5D-5L score. HRQoL statistics by healing status are presented in Online Appendix Table A2.

### Floor/ceiling effects

At baseline when all patients were unhealed, the ceiling effects were negligible for EQ-5D-5L and SPVU-5D utility scores. Only two patients scored at the ceiling of EQ-5D-5L

and one of them also reported perfect health in SPVU-5D survey. Another patient reported that VLUs did not affect her in the last 7 days in SPVU-5D survey, but reported issues with mobility, self-care, usual activities and pain/discomfort in EQ-5D-5L survey. No floor effects were observed for EQ-5D-5L and SPVU-5D utility scores.

### Construct validity

When controlling the time points of data collection, EQ-5D-5L and SPVU-5D utility values demonstrated weak to moderate correlation with EQ-VAS scores. The partial correlation between SPVU-5D and EQ-VAS (0.44) was stronger than that between EQ-5D-5L and EQ-VAS (0.39). The discriminative ability of EQ-5D-5L and SPVU-5D instruments is presented in Table 3. No significant difference in utility score was found for age and duration of ulcer. The data showed utility scores were higher when ulcers had healed or with increasing EQ-VAS score, as we initially proposed.

**Table 1** Baseline patient characteristics

Baseline characteristics	Eligible patients ( <i>n</i> = 80)		
	<i>N</i> (number of patients)	Mean (SD)	Range
<b>Continuous variables</b>			
Age (years)	77	75.13 (13.88)	30–95
Height (m)	59	1.70 (0.12)	1.42–1.91
Weight (kg)	56	93.27 (33.03)	44–220
BMI (kg/m <sup>2</sup> )	51	33.10 (11.19)	18.29–69.44
<b>Categorical variables</b>			
	<i>N</i> (number of patients)	Percentage	
Male	33	41	
Venous insufficiency	65	81	
Reduced mobility	69	86	
Number of active ulcers			
1	45	56	
2	22	27	
3	6	7	
4	3	4	
5	1	1	
6	2	2	
> 20	1	1	
Duration of current ulcer (months)			
0–3	36		
4–12	49		
13–36	18		
37–72	13		
73–120	11		
121–240	2		
241–369	9		

**Table 2** HRQoL statistics of EQ-5D-5L and SPVU-5D at baseline and different points of follow-up irrespective of healing status

	Baseline		1-month		3-month		6-month		Combined	
	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Eligible patients	80		64		57		48		249	
EQ-5D-5L										
Complete response	77	0.67 (0.24)	61	0.74 (0.22)	54	0.80 (0.18)	45	0.85 (0.17)	237	0.75 (0.22)
Partial response	1		3		3		3			
Declined	2		0		0		0			
EQ-VAS										
Complete response	75	65.29 (17.38)	61	68.46 (15.56)	54	70.56 (13.62)	46	73.59 (11.72)	236	68.93(15.30)
Declined	5		3		3		2			
SPVU-5D										
Complete response	72	0.70 (0.17)	60	0.75 (0.18)	53	0.77 (0.17)	45	0.85 (0.15)	230	0.76 (0.18)
Partial response	5		3		4		3			
Declined	3		1		0		0			

**Level of agreement**

The ICC between EQ-5D-5L and SPVU-5D was moderate (0.55), which is supported by the Bland–Altman plot (Fig. 1) where most circles lie within the limits of agreement. SPVU-5D utility scores were generally higher than EQ-5D-5L scores, as the line representing mean difference is slightly below zero (−0.0016). EQ-5D-5L always generated lower utility scores compare with SPVU-5D at lower mean utility values (below 0.35).

The analysis on correlation between EQ-5D-5L and SPVU-5D dimensions is presented in Table 4. There is a strong and statistically significant correlation between mobility and mobility; usual activities and social activities;

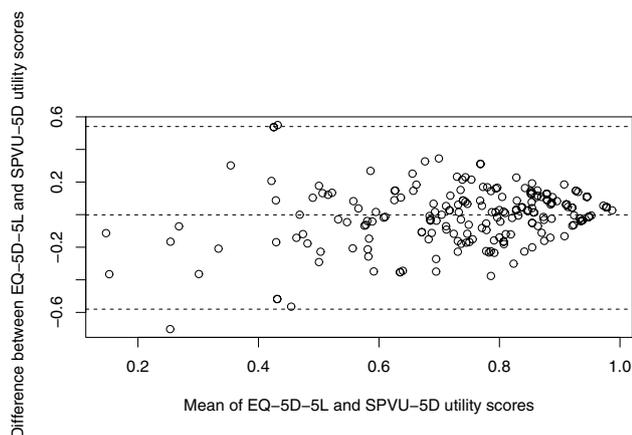
anxiety/depression and mood. Both EQ-5D-5L and SPVU-5D measure the impact of pain on HRQoL, but the correlation between pain/discomfort and pain is weak. Smell is a distinct dimension in SPVU-5D and displays weak correlation with EQ-5D-5L dimensions. The distribution of EQ-5D-5L and SPVU-5D responses in each dimension at baseline and follow-ups is presented in Online Appendix Table A3–A6.

**Responsiveness**

The responsiveness of EQ-5D-5L and SPVU-5D represented by SRM is shown in Table 5. In the analysis based on healing status, the SRM statistics were similar between the two

**Table 3** Univariate analysis of EQ-5D-5L and SPVU-5D utility scores for subgroups

	N	EQ-5D-5L		SPVU-5D	
		Mean	Effect size	Mean	Effect size
Age (years)			0.17 (negligible)		0.01 (negligible)
30–75	77	0.78		0.76	
76–95	145	0.74		0.76	
Duration of ulcer (months)			0.08 (negligible)		0.15 (negligible)
1–11	118	0.77		0.77	
12–369	111	0.75		0.75	
Healing status					
Healed	39	0.89	0.76 (medium)	0.91	1.09 (large)
Unhealed	191	0.73		0.73	
			<i>p</i> value		<i>p</i> value
EQ-VAS			<0.01		<0.01
< 65	70	0.67		0.67	
65–79	89	0.76		0.77	
80–89	38	0.81		0.81	
90–100	26	0.89		0.89	



**Fig. 1** Bland–Altman plot of level of agreement between EQ-5D-5L and SPVU-5D utility scores

**Table 4** Correlation between EQ-5D-5L and SPVU-5D dimensions (using Spearman’s rank coefficient)

EQ-5D-5L/ SPVU-5D	Pain	Mobility	Mood	Smell	Social activities
Mobility	0.17*	<b>0.84*</b>	0.25*	0.17*	0.51*
Self-care	0.12	0.36*	0.13*	0.06	0.21*
Usual activities	0.22*	0.62*	0.41*	0.23*	<b>0.60*</b>
Pain/discomfort	<b>0.32*</b>	0.20*	0.14*	0.19*	0.25*
Anxiety/depression	0.30*	0.32*	<b>0.91*</b>	0.19*	0.43*

\* $p < 0.05$ ; related dimensions between EQ-5D-5L and SPVU-5D are indicated in bold

instruments and indicated that EQ-5D-5L and SPVU-5D captured more changes in HRQoL when patients recovered from their wounds. However, even when patients remained

unhealed, the magnitude of change in utility scores was large at 6-month follow-up. The responsiveness was further investigated by focusing on the duration of ulcer which was used as a proxy for severity of ulceration. Rise in utility scores over time was found in all categories of ulceration regardless of the healing status. The magnitude of change was smallest among patients who have an active ulcer for more than 24 months.

### Discussion

This is the first study in Australia that compared the validity and responsiveness of two preference-based HRQoL instruments, EQ-5D-5L and SPVU-5D in patients with VLUs. We found that both instruments were able to discriminate between healed VLU and unhealed VLU and correspond well with patients’ general health measured by EQ-VAS. They also showed great responsiveness when healing status changed over time. Weak to strong correlations were found between dimensions of two instruments. The condition-specific instrument, SPVU-5D, usually generated higher mean utility scores than the generic instrument, EQ-5D-5L.

Our finding is consistent with other studies comparing generic and condition-specific preference-based measures, where lower mean utility scores produced from generic measures were reported [41, 42]. Several factors could contribute to this finding. The two instruments first differ in their descriptive system. SPVU-5D incorporates condition-specific traits such as “smell” into the survey. EQ-5D-5L measures patients’ health “today”, while SPVU-5D asked patients to recall if VLUs affected them in the past 7 days. There are also more levels in some dimensions of EQ-5D-5L. Second, although the value sets of health states in both instruments were derived from UK general population, the methods of

**Table 5** Responsiveness statistics comparing 6-month follow-up data with baseline data for EQ-5D-5L and SPVU-5D

	N	EQ-5D-5L difference (6-month vs. baseline) mean (SD)	SRM	N	SPVU-5D difference (6-month vs. baseline) mean (SD)	SRM
Healing status at 6-month						
Healed	21	0.14 (0.13)*	1.1249	21	0.16 (0.17)*	0.9493
Unhealed	24	0.15 (0.18)*	0.8405	23	0.15 (0.16)*	0.9340
Duration of ulcer at baseline (healed patients)						
1–4 months	10	0.10 (0.09)*	1.2177	10	0.09 (0.08)*	1.0888
5–18 months	11	0.08 (0.15)*	1.1852	11	0.23 (0.21)*	1.1026
Duration of ulcer at 6-month (unhealed patients)						
4–24 months	10	0.21 (0.23)*	0.9184	10	0.19 (0.13)*	1.4199
25–369 months	14	0.11 (0.13)*	0.8497	13	0.12 (0.17)*	0.6703

SRM standardized response mean

\* $p < 0.05$  (paired  $t$  test)

eliciting preferences differed slightly. Researchers applied both TTO and DCE to generate utility weights for EQ-5D-5L health states [31], while only TTO was used in the case of SPVU-5D. Although EQ-5D-5L and SPVU-5D utility weights are anchored at different values for full health and worst health, the correlation between similar dimensions has been found to be statistically significant. The distribution of responses in each dimension is also similar between the two instruments at each follow-up. Thus, the changes in EQ-5D-5L and SPVU-5D scores are comparable over time.

In terms of responsiveness, both EQ-5D-5L and SPVU-5D detected more changes in HRQoL in patients who were healed than those who remain unhealed at follow-up data collection. Based on 6-month follow-up data, EQ-5D-5L seems to be more responsive by generating a larger SRM. The differences in responsiveness of EQ-5D-5L and SPVU-5D may finally be reflected in the difference of cost-effectiveness results. As SPVU-5D generally produces higher utility scores, using SPVU-5D will accrue more QALYs than EQ-5D-5L. But in cost-effectiveness and cost-utility studies, it is incremental effectiveness (usually expressed as change in QALYs in cost-utility analysis) rather than effectiveness alone that determines the cost-effectiveness of an intervention or treatment. Using an instrument with higher responsiveness to VLU healing will produce a smaller incremental cost-effectiveness ratio and thus make the intervention or treatment appear more favourable. However, there is an upward trend in utility scores produced from both instruments over time. The responsiveness could have been confounded by other factors.

EQ-5D-5L was developed to improve the instrument's sensitivity and to reduce ceiling effects, as it has more levels in each dimension compared to the EQ-5D-3L. In this study, although we found a large proportion of responses reporting having no problem in individual dimensions, the ceiling effects of EQ-5D-5L were negligible. In terms of level of agreement between EQ-5D-5L and SPVU-5D dimensions, the correlation between pain/discomfort dimension in EQ-5D-5L and pain dimension in SPVU-5D was found to be weak. But this does not necessarily mean that the level of agreement is poor. The low correlation is probably caused by different number of levels within each dimension. In Table A3 in Online Appendix, if level 2 and level 3 in pain/discomfort dimension of EQ-5D-5L are combined, then it will produce a similar distribution of responses to that of the pain dimension of SPVU-5D.

The burden on patients to complete EQ-5D-5L or SPVU-5D is relatively low as there are only five questions in each of the surveys. In this study, full response rate was 96.0% and 94.3% for EQ-5D-5L and SPVU-5D surveys, respectively. We noticed that partial response was mainly caused by patients refusing to answer questions on anxiety/depression and mood. Even though most

respondents indicated that their physiological conditions were not affected by the presence of VLUs, the issue of anxiety and depression was found in around 40% of observations. For example, one patient did not provide answers on mood at baseline nor three follow-up data collections. Some patients were also not willing to answer question on smell in SPVU-5D surveys. Since both surveys were administered to participants via either face-to-face interviews or telephone follow-up in this study, it is possible that patients were concerned about their privacy. Using other survey modes on this population might improve the response rate.

One limitation presented in this study is the lack of clinical assessment for VLU patients. In other published studies that determined the validity of preference-based HRQoL instruments, condition-specific assessments were conducted alongside as benchmarks [43–45]. Other clinical indicators such as infection status could have been used to categorize the severity of venous ulceration. However, not all patients involved in this study had assessment on infection done. As a result, the only clinical indicators we could use to test validity and responsiveness were patients' healing status and ulcer duration. Another limitation of this study is the use of a scoring algorithm based on the UK population due to the lack of Australian value sets. Although previous studies found that the value sets for HRQoL instruments such as EQ-5D-3L between Australia and UK were comparable [20, 46], variation in utility scores for the same health state was still a concern. In cost-utility analysis, the differences in values set will translate to greater differences in final QALYs if a longer time horizon is adopted, which will, in turn, affect decision making. Thus, a country-specific valuation algorithm is needed to produce more accurate estimates for the Australian population. This study is also limited by the small sample size. We managed to increase power by pooling follow-up data with baseline data in validity tests, but this approach violated the assumption of independent observations. Therefore, in the "known-group" method, the statistical testing results could have been biased. The issue of small sample size also impacted on the responsiveness tests where follow-up data were compared with baseline data. Attrition further reduced the number of patients available for comparison. Although the characteristics of those lost to follow-up and those who completed all surveys were found to be similar (Online Appendix Table A7), the results on responsiveness should be interpreted with caution.

## Conclusion

In economic evaluation, especially cost-utility studies, utility weights play an important role. But with regard to VLU, there is a lack of consensus on the preferred measurement of HRQoL for cost-utility studies. Some previous studies applied EQ-5D-3L which is recommended for use in cost-effectiveness

studies in the USA by the Panel on Cost-Effectiveness in Health and Medicine, and in the UK by the National Institute for Health and Care Excellence (NICE). However, there is concern that EQ-5D-3L is not sensitive enough due to the limited number of levels within each dimension and the lack of disease-specific traits. Thus, in this study we compared the generic EQ-5D-5L and disease-specific SPVU-5D, and examined how the choice of instrument impacted on cost–utility studies. We found that both instruments were valid and responsive in detecting change of VLU healing status in a small sample of patients in an Australian setting. Both instruments may be used in economic evaluation studies that involve patients with healed or unhealed VLUs. Since the responsiveness of EQ-5D-5L is a bit higher than SPVU-5D when VLUs become healed, using EQ-5D-5L could make the intervention or treatment look more favourable in cost–utility analysis. However, due to the small sample size, attrition and lack of Australian value sets for EQ-5D-5L and SPVU-5D, further research using a larger sample size and Australian value sets is necessary to make sound recommendations on the preferred instrument in economic evaluation of VLU-related interventions.

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### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** The use of non-identifiable patient data in this study was approved by the Queensland University of Technology University HREC (Approval Number 1700000874).

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