

Venous Leg Ulcer Recurrences – the Relationship to Self-Efficacy, Social Support and Quality of Life – a Mixed Method Study.

ABSTRACT

Aim: The aim of this study was to explore the occurrence of venous leg ulcer recurrence and the relationship with self-efficacy, social support and quality of life. Further, we investigated the lived experiences of those patients and their understanding of why they developed a recurrence.

Design: We used a convergent parallel mixed method design consisting of a cohort and an interpretative phenomenological study arm.

Methods: Consecutive patients (n=145) were recruited into the study. Between 2014 and 2018, three primary care centres took part in the study. Data collection methods included chart review, administered questionnaires and semi-structured interviews.

Results: The incidence of the venous leg ulcer recurrence was 33.1% within the study period. The scores for self-efficacy, social support and venous leg ulcer health related quality of life show little variation between all measurement points and within subgroups. The qualitative findings identified two main themes: Accidentally damaging the skin, and Avoiding venous leg ulcer recurrences.

Venous leg ulcer recurrences frequently arose from accidents. Therefore, participants developed strategies to avoid additional ulcers.

Conclusion: To optimise recurrence prevention improvements in knowledge in people with VLUs should be considered.

Impact:

- A mixed method, convergent, parallel design was used to explore the occurrence of venous leg ulcer recurrence and the relation of a venous leg ulcer recurrence with self-efficacy, social

support and health related quality of life. As well as the lived experiences of venous leg ulcer patients and why they developed a recurrence.

- The incidence of venous leg ulcer recurrences within the study period was 33.1%.
- Damaging the skin and avoiding a recurrence were the main identified themes.

Key words: venous leg ulcer, recurrence, self-efficacy, social support, quality of life, nursing

Main paper

INTRODUCTION

A venous leg ulcer (VLU) is a poorly healing wound, caused by chronic venous insufficiency (CVI). VLUs are located on the lower extremities and show an occurrence between 0.8 and 2.2 per 1000 people/year (Berenguer Perez, Lopez-Casanova, Sarabia Lavin, Gonzalez de la Torre, & Verdu-Soriano, 2019). VLUs are a healthcare issue, in terms of treatment, cost, recurrence and chronicity. Of all the poorly healing wounds, 60% are attributable to VLUs (Graham, Harrison, Nelson, Lorimer, & Fisher, 2003). Healing times are long with 93% of VLU requiring up to 12 months to heal and seven percent remaining unhealed after five years (Franks et al., 2016). Evidence shows that frequent VLU-signs and symptoms include pain, wound odour and/or heavy exudate, which have an impact on the health related quality of life (HRQoL) (Finlayson, Edwards, & Courtney, 2011; Kapp, Miller, & Santamaria, 2018; Persoon et al., 2004; Vandenkerkhof, Hopman, Carley, Kuhnke, & Harrison, 2013).

Background

Factors contributing to a VLU occurrence are multifaceted. Important factors include the severity of the underlying venous disease (McDaniel et al., 2002), deep vein insufficiency (Gohel et al., 2005), hypertension, malnutrition, smoking and/or depression (Finlayson, Edwards, & Courtney, 2009; Heinen, van Achterberg, op Reimer, van de Kerkhof, & de Laat, 2004; Persoon et al., 2004; Vandenkerkhof et al.,

2013). Current therapeutic approaches focus firstly on the management of risk factors and secondly on the prevention of recurrences. These include compression therapy, elevation of legs, ankle-exercises and a high-protein diet (Tan, Luo, Onida, Maccatrozzo, & Davies, 2019). Although the therapeutic regimens are broadly used in clinical practice, evidence demonstrates that patient-adherence to treatment varies widely (Van Hecke, Grypdonck, & Defloor, 2009). The consequences of non-adherence are impaired wound healing and an increased recurrence rate (Finlayson, Wu, & Edwards, 2015; Moffatt, Murray, Keeley, & Aubeeluck, 2017). Factors associated with non-adherence are self-efficacy and social support (Martos-Méndez, 2015). Evidence demonstrates that patients with lower self-efficacy and social support have a bigger risk to develop a VLU-recurrence (Finlayson et al., 2011). Such wounds are costly not only for the health care system but also for the affected.

Budget results from Ireland show annual expenditure for the treatment of acute and chronic wounds of €629,064,198. This is equivalent to 5% of Irish health care expenditure (Gillespie, Carter, McIntosh, & Gethin, 2019). In the United Kingdom (UK) the annual costs of care for those conditions is estimated to be £6 billion for 2.2 million wound patients (Guest et al., 2015). According to our knowledge, there is no study investigating the occurrence of recurrences in relation to self-efficacy, social support and the quality of life or patients' understanding of why they develop a VLU.

THE STUDY

Aims:

The aim of this mixed method study is to explore:

- (1) the occurrence of a VLU recurrence.
- (2) the relation of a VLU recurrence and self-efficacy, social support and health related quality of life and
- (3) the lived experiences of VLU patients and why they developed a recurrence.

Design

A convergent parallel mixed methods study is proposed consisting of a cohort study for the quantitative arm and an interpretative phenomenological study for the qualitative arm. Both arms of the study are exploratory in nature and will be conducted simultaneously and independently with equal priority and weighting. The results will be merged following analysis of each arm (Creswell & Plano Clark, 2017) (see figure 1).

Setting and Participants

The study was conducted in three Swiss outpatient wound clinics. Consecutive patients were recruited into the study with the following eligibility criteria: having a healed VLU and being proficient in German or French. Wound care specialists at the respective outpatient clinics recruited participants.

Data collection

Data were collected between March 2014 and November 2018 whereby each participant has been followed for 12 months.

Quantitative data collection

Data were collected using standardized questionnaires at five measurement points (time 0, 3 months, 6 months, 9 months and 12 months). Sociodemographic characteristics were only assessed at time 0 whereas recurrences, self-efficacy, social support and quality of life data was collected at all time-points.

The main outcome variable VLU recurrence was assessed as a binary categorical variable. The secondary outcomes (self-efficacy, social support and HRQoL) were measured using validated standardized administered questionnaires.

Validity and Reliability of the used instruments

The self-efficacy was measured using the questionnaire by Schwarzer and Jerusalem (1995). The scale contains 10 items measuring taps beliefs in one's capability to handle new and difficult tasks with a total score of 40 (range: 10-40) (Luszczynska, Scholz, & Schwarzer, 2005). The Cronbach's alpha is 0.80 (Luszczynska et al., 2005).

The seven item ENRICHHD Social Support Scale (ESSI) was used to measure the participant's range of social support in their life (emotional, instrumental, informational, and appraisal) (Enriched Investigators., 2001). The scale has a total score of 34 (range 8-34) and a Cronbach alpha of 0.88 (J. Vaglio, Jr. et al., 2004). Higher scores indicate greater social support.

HRQoL was measured with the 34-item Venous Leg Ulcer – Quality of Life (VLU-HRQoL) questionnaire by Hareendran et al. (2007) is using a three-domain structure (activities, psychological and symptom distress). The scale has a total score of 3400 (range 0-3400). The scale has a Cronbach alpha >0.80 (Hareendran et al., 2007). Lower scores indicate a higher QoL.

Qualitative data collection

In the qualitative arm of the study, we recruited seventeen patients with a newly developed VLU for a semi-structured face-to-face interview. The mean sample size for the phenomenological studies in health sciences is 25 with a minimum of 8 and maximum of 52 (Guetterman, 2015).

Participants chose the location where the interview took place (home or wound clinic). The mean interview duration was 55 min (range 40 and 75 min).

Validity and reliability

The first and third author audio-recorded all interviews digitally and transcribed them verbatim. We then transcribed the entire interview verbatim in the respective language (French or German). Only key themes

were translated into English. To preserve anonymity and confidentiality, we used fictional participant names.

Ethical considerations

Ethical approval for the study was granted (KEK-ZH-Nr_2014-0688). All participants provided written consent prior to participating in this study.

Data analysis

Quantitative analysis

Standard statistical procedures were used to determine absolute and relative frequencies, measures of central tendency and measures of dispersion as appropriate. Exact 95% confidence intervals (CI) were calculated for the differences between persons with recurrences and without recurrences in regards to self-efficacy, social support and HRQoL. SPSS V.25 (IBM Corp., 2017) and STATA 16 software (StataCorp., 2019) was used for data entry and analysis.

The sample size for the cohort study (n= 145) was based on a type 1 error of 0.05, a power of 0.8, and a difference of 4 points on the self-efficacy scale and a loss of follow-up of 20%.

Qualitative analysis

We analysed the interviews using the interpretative phenomenological analysis (Smith, Flowers, & Larkin, 2009). We firstly transcribed the interviews verbatim. We then closely read each transcript a number of times. This helped to immerse ourselves in the data, recall the atmosphere of the interviews, and the setting in which it was conducted. Each reading and listening to the recording provided us with new insights. The aim of the qualitative part guided this process. We transformed our notes into emerging themes, formulated a concise phrase at a higher level of abstraction and referred to a more psychological conceptualisation. Additionally, we searched for connections between the emerging themes, grouping

them together according to conceptual similarities, and providing each cluster with a descriptive label. A final list comprised three superordinate themes with its subthemes. Through this process, we identified and discovered the essential qualities of the narrated experiences and how the VLU occurred. Filed notes helped to reflect on the context of the data. We used MAXQDA (VERBI Software, 2019) to analyse the data.

RESULTS/FINDINGS

We included 145 participants in this mixed method study. Out of these 145 participants, 17 were interviewed when they developed a VLU recurrence. The characteristics study population of the quantitative arm demonstrated that 59.3% (86/145) were female. The mean age was 68 years (range of 41 to 95 years). 63,4% (92/145) were married. For the qualitative arm, 53% (9/17) were women with a mean age of 71 years. 82% (14/17) were married. Detailed information is tabulated in table 1.

Quantitative results

Occurrences of VLUs

During the first three months, 13.1% (19/145), 95%CI 8.1 to 19.7 of the study population developed a recurrence. A follow up between three and six months still showed no recurrences. Between nine and twelve months 33.1% (48/145), 95%CI 25.5 to 41.4 of the study population developed a recurrence.

Self-efficacy

The mean of the self-efficacy score at all time points was between 27 and 29 (SD between 1.9 and 2.2) with a range of 20 and 40 (details see table 2). There is no difference in self-efficacy scores between participants with and without a recurrence (27.64 vs 27.63). The difference in the self-efficacy score between females and males was 0.4 points at baseline and 0.6 at the end of the study.

Social support

The range of the social support scale score was between 8 and 34 points. During the entire observation phase, the mean for all 145 participants was between 25.8 and 26.7 (details see table 2). There is no difference in social support scores between participants with and without a recurrence (29.16 vs 29.52). The difference of the social support scores of female and male participants was 0.4 points at baseline and remained the same throughout the study.

Health related quality of life of VLU patients

The mean score of the VLU-quality of life (VLU-QoL) score between all measurement points was between 1276.38 (SD 216.56) and 1273.10 (SD 211.10). The minimum was 700 points and the maximum 1850 points (details see table 2). There is no difference between HRQoL scores in participants with and without a recurrence (1281 vs 1256). The difference of the HRQoL scores of female and male participants was 9.5 points at baseline and 8.2 at the end of the study.

VLU-pain, burning and stinging of a VLU recurrence

VLU associated pain or burning / stinging of the new recurrence was reported by 67.6% (98/145) of participants. Nearly half of the study population (48.3%, 70/145) indicated experiencing VLU related pain when a recurrence occurred. Wound burning / stinging occurred in more than 60 % of the 145 participants. 43,4% (63/145) suffered from wound burning / stinging as well as from wound pain (details see table 3).

The relation between the occurrence of a recurrence, self-efficacy, social support and quality of life

The scores for self-efficacy, social support and VLU-HRQoL did not differ between all measurement points. There was no difference between the groups with and without a recurrence. There was no association between the variables self-efficacy, social support and quality of life when developing a VLU recurrence. The absolute difference between the occurrence of a recurrence and self-efficacy was 0.014 [CI -0.75; 0.78], the one with social support was 0.356 [-1.23; 0.52] and the one with HRQoL was 25.19 [-48.67; 99.06]. These (see table 4).

Qualitative findings

We identified two main themes related to VLU occurrence or recurrence:

«Accidentally damaging the skin» and «Avoiding VLU recurrences».

Most of the participants (n=13) indicated their VLU recurrence arose from an accident. They took the necessary steps to cope with their activities of daily living although the wound was hurting. Participants cared for their wound according to their previous experiences with ulcer care. They used therapeutic measures such as wearing compression stockings at least some of the time. Additionally they were careful not to accidentally damage the skin.

In the following, the themes of «Accidentally damaging the skin» and «Avoiding VLU recurrences» are summarised:

«Accidentally damaging the skin»

Not concentrating and subsequently hurting the leg causing a wound was illustrated by thirteen participants. They narrated they were doing a quick incautious move and hurt their leg badly. All thirteen participants narrated their story like Nicole:

«My husband was in the attic and called me because he needed some help. I was ironing and then I quickly climbed up the stairs. I went too fast. I fell and it bleed. I had to get something to stop the bleeding... yes it hurt a lot. It (wound) was hurting for a long time.....yes this is the reason of the occurrence of it, a bad accident».

Other participants said they were tripping over a cord or hitting the leg on furniture. Others illustrated that they accidentally damaged their skin while doing some handicraft. Henri was repairing a chair and when he was drilling, the armrest fell on his lower right leg. He developed an oedema and that evening he discovered a wound. Georg had a similar experience while building up his electric trainset. He said:

«I was in the basement building up my electric trainset. I wanted quickly to get my ruler. In doing so, I fell over the cord of my drill and I hurt my lower left leg. Thankfully it (wound) did not bleed. It hurt a lot and my leg was swollen. One morning I discovered two wounds. They have not healed and have hurt since then».

In summary, the occurrence of their VLU led back to accidental damage of their skin. Pain was associated with the wound.

«Avoiding VLU recurrences»

Strategies for avoiding a recurrence were mentioned by all participants. They tried to use recommended therapeutic measures such as putting on their compression stockings and/or hydrating their skin.

However, putting on their stockings was often challenging, painful and unsuccessful, as many did not have enough strength. All participants reported that they did not want to accept professional help to apply the compression stockings because they did not want to lose their autonomy. Martha expressed her worries:

«I am really worried that this leg will open up again. I try to wear my stockings but I do not have the strength to put them on. My doctor suggested that a community nurse visits each morning. I have heard that you have to stay in bed until they (health care professionals) are visiting to put the stockings on. No, this is nothing for me. I am too independent. I do not want to wait for them ».

Other participants (Magdalena, Bill and Anne) developed prevention strategies (wearing stockings and/or moisturising their skin) only if clinical signs like oedema or dry skin were present. Frank developed his own prevention intervention by taking hot and cold showers. Pain caused by stockings was another problem participants were facing. Yvonne illustrated:

«Wearing stockings was sometimes very painful. Especially during summer, when my legs were swollen. I put them on only when the weather was cooler. However, I moisturized my legs daily and protected them from the sun. But even though I was trying to avoid a new wound; I have it (the wound) again ».

In summary, all patients developed strategies to avoid a recurrence without losing their autonomy.

Mixed method results

The merged results provide additional understanding about the occurrence of a VLU recurrence in relation to self-efficacy, social support and HRQoL. The observed consistency of the self-efficacy, social support and HRQoL scores in participants with recurrences over the entire study period can be covered and expanded by the findings of the qualitative arm, which showed that a VLU occurrence can be attributed to an acute trauma mostly in the domestic setting. The performance of the activities of daily living were not limited by the VLU. Patients find a way how to dress the wound. The quantitative results demonstrate that participants developing a VLU commonly observe pain as well as burning/stinging. These results are mirrored in the qualitative findings where participants mentioned how painful such a recurrence can be and how they develop strategies to avoid accidental damage of their skin.

DISCUSSION

This is the first mixed method study exploring the occurrence of a VLU recurrence, the relation of a VLU recurrence and self-efficacy, social support and HRQoL and the lived experiences of VLU patients why they developed a recurrence. The observed incidence of recurrence within the study period was 33.1% (95% CI=25.5; 41.4) which is much lower than that reported in the literature which is 60 to 70% (Abbade, Lastoria, de Almeida Rollo, & Stolf, 2005; Finlayson et al., 2015; McDaniel et al., 2002). However, our observed incidence of 13.1% (95%CI=8.1; 19.7) at three months is similar to that (11.8%) reported by Kapp and colleagues (2013). Our results show little variation between all measurement points assessing

self-efficacy, social support and VLU-HRQoL. Over the study period the scores remained relatively unchanged for the total study population as well as the subgroups (gender, recurrence). The mean score for self-efficacy at baseline was 28.70 (SD 1.9) which is comparable with the self-efficacy score (29.28, SD 4.6) of a standard German population reported by Schwarzer (1993). It is surprising that that the average self-efficacy score of our population of elderly persons with a chronic condition is so similar to that of a much younger population without chronic conditions.

The observed mean social support score at baseline of our study population was 29.6 (2.7). Comparing to other studies with cardiac patients (29.9 , SD 5.7 (Mitchell et al., 2003); 26,0, SD 4.3 (J. Vaglio et al., 2004)) our participants had a similar social support score. One reason might be because 63,4% reported to live with a spouse.

The HRQoL mean score was 1276.38 (SD 216.56). Our results demonstrate that the HRQoL mean scores remained unchanged and are comparable to those (1435, SD 843) reported by Araujo et al. (2014) in a similar population.

Limitations

This study shows a selection bias as all participants had to give their consent. Nothing is known about patients not participating in this study. Participants not visiting the participating outpatient clinics could not have been represented. The used concepts of self-efficacy, social support and quality of life are measured through validated instruments. Because the data are self-reported there is a possibly of an information bias.

CONCLUSION

The results of this mixed method study suggests that the VLU recurrence is lower than previously reported in other studies. Further, this study provides insights that the VLU recurrence is the result of skin damage following an accident. The scores for self-efficacy, social support and VLU-HRQoL did not

differ between all measurement points. Recommended therapeutic measures such as wearing compression stockings were not consistently carried out. Other measures such as leg elevation, exercises or high-protein diet were not reported. Possibly, VLU patients were not aware of other measures than compression stockings. More research is needed to investigate if improvements in patient knowledge could help optimise recurrence prevention.

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Table 1: demographic characteristics of the study populations

Characteristics*	Quantitative study part (n=145)		Qualitative part study (n=17)	
	n	%	n	%
Sex				
male	59	40.7	9	52.9
female	86	59.3	8	47.1
Mean age (SD)				
all	68.0 (11.0)	Min 41 Max 95	71 (15.0)	Min 42 Max 92
male	68.1 (10.9)	Min 46 Max 95	67.66 (14.5)	Min 52 Max 92
female	67.9 (11.2)	Min 41 Max 95	75.25 (15.5)	Min 42 Max 89
Marital status				
single	6	4.1	3	17.6
married	92	63.4	8	47.2
divorced	25	17.2	3	17.6
widowed	22	15.2	3	17.6

*The values present either means or standard deviations (SD) or absolute or relative frequencies.

Table 2: Self-efficacy, social support and HRQoL during all measurement points (n = 145)

		Time				
Characteristics		T0	T1	T2	T3	T4
Self-efficacy	Mean (SD*)	28.7 (1.9)	28.7 (1.9)	28.8 (1.9)	28.7 (1.9)	27.6 (2.2)
	Minimum	20	20	20	20	20
	Maximum	40	40	40	40	38
Social support	Mean (SD*)	29.6 (2.7)	29.6 (2.7)	28.8 (2.4)	29.6 (2.7)	29.3 (2.8)
	Minimum	20	20	20	20	18
	Maximum	34	34	34	34	34
HRQoL	Mean (SD*)	1276.38	1276.38	1276.38	1276.38	1273.10
		(216.56)	(216.56)	(216.56)	(216.56)	(211.10)
	Minimum	700	700	700	700	700
	Maximum	1850	1850	1850	1850	1825

* SD= Standard deviation

Table 3: Occurrence of VLU associated pain, burning and stinging of the wound (n = 145)

Characteristics*	Time				
	T0	T1	T2	T3	T4
Wound pain					
Yes	70	70	70	70	70
%	48.3	48.3	48.3	48.3	48.3
Burning/stinging in the wound					
yes	91	91	91	91	72
%	62.8	62.8	62.8	62.8	49.7
Wound burning/stinging OR ulcer pain					
yes	98	98	98	98	93
%	67.6	67.6	67.6	67.6	64.1
Wound burning/ stinging AND ulcer pain					
yes	63	63	63	63	49
%	43.4	43.4	43.4	43.4	33.8

*the values are absolute or relative frequencies

Table 4: The relation between the occurrence of a recurrence, self-efficacy, social support and HRQoL (n = 145)

Characteristics*	Recurrence		Absolute difference and 95% CI
	No (n=97)	Yes (n=48)	
Self-efficacy	27.64	27.63	0.014 [-0.75; 0.78]
Social support	29.16	29.52	-0.356 [-1.23; 0.52]
Quality of life	1281.44	1256.25	25.19 [-48.67; 99.06]

*comparison of means