Venous Leg Ulcers: Wound Risk Assessment and Prevention

Prof. Helen Edwards, OAM

Queensland University of Technology, Brisbane
Prof. H. Edwards, Dr K. Finlayson, M. Gibb, C. Parker

Royal District Nursing Service, Victoria
Dr R. Ogrin, C. Miller, J. Anderson, S. Kapp

Blue Care, Sunshine Coast
G. Webby, P. Burrows, C. Roberts, R. Tennent

Royal Brisbane Hospital, Qld Health
Dr D. Smith, L. Daniels, T. Edward, M. Francis

Aims

• Develop and validate a risk assessment tool for non-healing venous leg ulcers;

• Develop and validate a risk assessment tool for recurrence of venous leg ulcers; by
  - analysing databases to identify predictors of delayed wound healing and recurrence
  - combining this information with evidence from the literature and advice from an expert panel
  - developing risk assessment tools and testing reliability
  - multi-site prospective studies to determine whether the RATs accurately predict those at high risk of not healing or recurrence
Methods & Findings

Study 1: RAT for non-healing VLUs

- A review of the literature undertaken to identify the current evidence on risk factors for delayed healing of venous leg ulcers, and evaluate any risk assessment tools previously developed.

- Risk factors found in the literature were:
  - Age
  - Ulcer duration
  - Ulcer area
  - Inadequate compression
  - Past DVT
  - Poor socio-economic status

- 4 risk assessment tools found – however, most relied on vascular measures difficult to access in the community and/or had limited predictive power.

Methods & Findings

- Secondary analysis was conducted on data from a sample of 316 patients from outpatient clinics and community nursing services.

- Clinical, venous, ulcer, healing, health and psychosocial data collected prospectively for 24 weeks in previous studies.

- Inclusion Criteria
  - Ulcers of primarily venous aetiology
  - ABPI $\geq 0.8$ and $< 1.3$

- Exclusion Criteria
  - Patients with cognitive impairment
**Methods & Findings – Generalised linear mixed model**

<table>
<thead>
<tr>
<th>Independent Variable</th>
<th>Coefficient</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.016</td>
<td>-0.015 - 0.047</td>
<td>0.302</td>
</tr>
<tr>
<td>Lives Alone</td>
<td>0.932</td>
<td>0.069 – 1.794</td>
<td>0.034 *</td>
</tr>
<tr>
<td>Any venous surgery (study leg)</td>
<td>0.723</td>
<td>-0.252 – 1.698</td>
<td>0.145</td>
</tr>
<tr>
<td>Any DVT (study leg)</td>
<td>0.446</td>
<td>-0.600 – 1.492</td>
<td>0.401</td>
</tr>
<tr>
<td>Rheumatoid Arthritis</td>
<td>0.523</td>
<td>-0.829 – 1.876</td>
<td>0.447</td>
</tr>
<tr>
<td>Compression therapy &lt;30mmHg</td>
<td>1.481</td>
<td>0.604 – 2.357</td>
<td>0.001 *</td>
</tr>
<tr>
<td>PUSH score</td>
<td>-0.243</td>
<td>-0.386 - 0.100</td>
<td>0.001 *</td>
</tr>
<tr>
<td>&lt; 25% area reduction in 2 weeks</td>
<td>-1.882</td>
<td>-2.744 - 1.019</td>
<td>&lt;0.001 *</td>
</tr>
</tbody>
</table>

Model:  $F = 5.4$, $p = <0.001$,  Nagelkerke $R^2$  0.44

**Methods & Findings**

**Study 1:** RAT for non-healing VLUs

- Development of Risk Assessment Tool
  - Evidence in literature
  - Significant predictors of non-healing from data analysis
  - Model coefficients used to determine item points in RAT
  - Expert Wound Advisory Group
Methods & Findings

**Study 1**: RAT for non-healing VLUs

Retrospective validation of tool

- The model had good discrimination and goodness-of-fit in predicting failure to heal of venous leg ulcers at 24 weeks
  
  Total score: ROC 0.84 (95% CI, 0.74-0.94)  \( p<0.001 \)

- Random sample of 200 patients
  
  Total score: ROC 0.86 (95% CI, 0.73-0.99)  \( p<0.001 \)

**Methods & Findings**

**Study 1**: RAT for risk of non-healing VLUs

- Prospective validation study commenced mid 2012, will continue until mid 2014

- Tool is being validated in 10 clinical sites across Australia (RDNS, Victoria; Blue Care, QUT and Qld Health)

- Currently 172 participants recruited
**Progress – Study 1**

**Study 1:** RAT for risk of non-healing VLUs

- At end of April 98 participants had reached 24 weeks follow up
- 72% of these healed by 24 weeks, 28% unhealed
- In this interim sample:
  - 92% of participants who scored at high risk on RAT failed to heal,
  - 86% of those who scored at low risk on RAT healed
Study 2 – RAT for recurrence of venous leg ulcers

- Retrospective analysis of data from 270 patients of medical, clinical, venous, ulcer, recurrence, physical activity, self-management activities, health and psychosocial data.
- These predictors + evidence from literature + expert advisory group utilised to develop a risk assessment tool.
- Tool is being validated in a multi-site prospective study.
- Patients recruited on healing and followed up for 12 months.

Methods & Findings

Study 2: RAT for recurrence of VLUs

- A review of the literature undertaken to identify the current evidence on risk factors for recurrence of venous leg ulcers, and any risk assessment tools previously developed.
- Risk factors found in the literature were:
  - Ulcer duration
  - Ulcer area
  - Poor mobility
  - Past DVT
  - Multiple previous ulcers
- No risk assessment tools found.
Methods & Findings

Secondary analysis was conducted on data from a sample of 250 patients from outpatient clinics and community nursing services.

Venous, ulcer, health, preventive strategies and psychosocial data collected prospectively for 6 to 36 months after healing (median follow-up time = 12 months).

Inclusion Criteria:
- Ulcer of primarily venous aetiology which healed within 4 weeks of recruitment
- ABPI ≥ 0.8 and <1.3

Exclusion Criteria:
- Patients with cognitive impairment

Study 2: RAT for recurrence of VLUs

Cox proportional hazards regression model found:
- more than one previous ulcer
- longer ulcer duration
- < 5 days/week compression hosiery (Class 2 or higher)
- decreased mobility
- lower levels of self efficacy were associated with a higher risk of recurrence

Model: $\chi^2 = 109.9$, $p = <0.001$
Methods & Findings

Study 2: RAT for recurrence of VLUs

Retrospective validation of tool

- The model had good discrimination and goodness-of-fit in predicting recurrence by 12 months
  
  ROC AUC 0.898 (95% CI, 0.85 - 0.94)  p<0.001

Progress - Study 2

Study 2: RAT for risk of recurrence of VLUs

- Prospective multisite validation study commenced in mid 2012, will continue until mid 2014

- 12 months follow-up after healing, data collected 3 monthly

- Currently 111 participants recruited
Progress - Study 2

- At end of April around 50 participants had reached 3 months follow up & 31 had reached 6–9 months follow up
- Recurrence rate at 3 months: 25% (12/48)
  6 months: 38% (13/29)
- In this early sample, looking at recurrence by 6 months:
  94% of participants who scored at high risk (>8) on RAT recurred,
  72% of those who scored at low risk did not recur

Next steps

- Completion of prospective validation of the tools for their effectiveness in predicting non-healing and recurrence – including inter-rater reliability
- Refinement and development of the tools as IT Applications for phones/tablets to enable efficient and accurate use
- Early detection of patients at high risk, leading to early tailored interventions
- Improved healing rates and decreased recurrence rates for patients with venous leg ulcers, leading to cost savings for consumers and health care system
Thank you