Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic non-commercial multicentre randomised open label parallel group medical device trial.

BEECKMAN*1,2,3, A. FOURIE*1, C. RAEPSAET1, N. VAN DAMME1, B. MANDERLIER1, D. DE MEYER1, H. BEELE4, S. SMET4, L. DEMARRÉ5, R. VOSSAERT5, A. DE GRAAF6, L. VERHAEGHE7, N. VANDERGHEYNST7, B. HENDRICKX8, V. HANSSENS8, H. KEYMEULEN9, K. VANDERWEE10, J. VAN DE WOESTIJNE11, S. VERHAEGHE1, A. V. HECKE1, I. SAVOYE12, J. HARRISON12, F. VRIJENS12, F. HULSTAERT12.
The Belgian Health Care Knowledge centre (KCE) funded and sponsored the trial via the KCE Trials Programme (study ID KCE16012), a national public funding programme of non-commercial trials.

No funding from the manufacturers of the study devices was received.
Introduction

What’s already known?

The incidence of hospital-acquired pressure ulcers (HA-PUs) remains high despite the implementation of best practice recommendations.¹

A systematic review (2020), presents the pooled prevalence of HA-PUs (n=1,366,848) as 12.8%, a pooled incidence rate of 5.4 per 10 000 patient-days (n=681,885)and pooled rate of HA-PUs (n=1,893,593) as 8.4%.²

Introduction
What’s already known?

- The concept of using silicone foam dressings as an additional prophylactic strategy in PU prevention has been investigated in previous studies,* however with some limitations.
- At the time of publication there were no non-commercial, multicenter, multi-skin site, large scale results available to test the efficacy of using these dressings as adjuvant prophylactic therapy in further preventing HA-PUs.

* 5 systematic reviews; 7 RCTs – references available on request
Silicone foam dressings (depending on their construction),

- redistribute pressure over larger areas,
- mitigate external shearing forces on the skin (multiple layers),
- might assist with maintaining microclimate for the skin to function normally (foam structure/layers and film breathability)
- remove gently from the skin, and can be repositioned after visualising the skin (silicone-based adhesive)

Objective

Primary endpoint

Determine if silicone adhesive multilayer foam dressings applied to the sacrum, heels, and greater trochanters in addition to standard prevention, reduce PU incidence category 2 or worse compared to standard prevention alone.
Methods

Design

- Multi-centre, randomised controlled, open label, parallel group medical device trial
- February – December 2018
- Pragmatic vs. exploratory

Setting

- Eight hospitals in Belgium (university/teaching and regional)
- ICU and non-ICU (geriatrics, surgery, internal medicine, rehabilitation)
Methods

Participants

- Patients, > 18 years old, at risk for PU development (Braden score < 17)
- Hospitalised within the previous 48 hours
- No pre-existing PU at the sacral area or at least 3 of the 4 body sites accessible to observe
- No clinically relevant incontinence-associated dermatitis
Methods

Intervention

- Patients were centrally randomised to study groups based on a 1:1:1 allocation
- The control group (n=546) → Standard of care
- Experimental group 1: (n=542)
- Experimental group 2 (n=545)

Treatment group
Results

- In the intention-to-treat population (n=1605);
  - 4.8% developed a new PU category 2 or worse.
  - **4.0%** developed a PU category 2 or worse in the treatment group.
  - **6.3%** in the control group.
  - Statistically significant risk reduction (36%) to develop a new PU in the treatment group.
  - NNT is 43

<table>
<thead>
<tr>
<th></th>
<th>Experimental n/N (%)</th>
<th>Standard of Care n/N (%)</th>
<th>RR* (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>43/1066 (4.0)</td>
<td>24/539 (4.5)</td>
<td>0.64 (0.41-0.99)</td>
<td>0.04</td>
</tr>
<tr>
<td>Body site</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sacrum</td>
<td>30/1062 (2.8)</td>
<td>26/539 (4.8)</td>
<td>0.69 (0.35-0.98)</td>
<td>0.04</td>
</tr>
<tr>
<td>Any heel</td>
<td>15/1063 (1.4)</td>
<td>10/539 (1.9)</td>
<td>0.76 (0.34-1.66)</td>
<td>0.49</td>
</tr>
<tr>
<td>Any trochanter</td>
<td>1/1065 (0.1)</td>
<td>0/539 (0)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

RR* refers to Standard of Care group
n/a: not applicable
Results

- **Sacral pressure ulcers** were observed in 2.8% in the treatment group and 4.8% in the control group (RR=0.59, 95% CI 0.35-0.98, P=.04). The risk to develop a new PU on the sacrum was statistically significantly reduced by 41% in the treatment group (RR=0.59, 95% CI 0.35-0.98, P=.04).

- **Heel pressure ulcers** occurred in 1.4% and 1.9% of patients in the treatment and control group respectively - no statistical difference (RR=0.76, 95% CI 0.34-1.68, P=.49).

- One patient (0.1%) developed a pressure ulcer on the **trochanter**.
Results

- No serious adverse device effects were reported.
- 33 adverse device effects (ADEs) in 28 patients
- 246 device deficiencies (DDs) in 97 patients
  - Two patient-fall incidents, due to heel dressings being slippery on the floor, were reported.
  - Risk-benefit analysis for heel dressings?

<table>
<thead>
<tr>
<th>Device deficiency (DD)</th>
<th>Treatment group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Allevyn Life® (N=539)</td>
</tr>
<tr>
<td>All</td>
<td>168 (31.2)</td>
</tr>
<tr>
<td>Dressing layers separated</td>
<td>20 (3.7)</td>
</tr>
<tr>
<td>Poor adhesion/adhesion failure</td>
<td>75 (13.9)</td>
</tr>
<tr>
<td>Dressing causes floor to be slippery (increased fall risk)</td>
<td>19 (3.5)</td>
</tr>
<tr>
<td>Adhesive residue</td>
<td>10 (1.8)</td>
</tr>
<tr>
<td>Obstructs wearing footwear</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Backing film/liner: adhesive transfer/poor release</td>
<td>10 (1.9)</td>
</tr>
<tr>
<td>Rolled-up edges</td>
<td>33 (6.1)</td>
</tr>
</tbody>
</table>
Silicone adhesive multilayer foam dressings reduce the incidence of sacral pressure ulcers in addition to standard of care.
Conclusions

- The current standard guidelines for PU prevention remain the cornerstone of prevention.
- New protocols should stress the importance of
  - Education
  - Daily assessment underneath the dressing, and
  - Monitoring of the adherence to the protocol

Future research: Health-economic analysis
Conclusions
What does this study add?

This study was the first and unique:

- Multicenter (ICU and non-ICU)
- Multi-skin site (sacrum, heels and greater trochanters)
- Large scale (n=1633)
- Non-commercial
Thank you