

Letter to the Editor

# Comparing strength of evidence: a rebuttal to *A cluster-controlled clinical trial of two prophylactic silicone sacral dressings to prevent sacral pressure injuries in critically ill patients*

Brindle T and Wright E

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Dear Editor

We thank Stankiewicz and colleagues for their recent study assessing the performance of two prophylactic silicone sacral dressings in the prevention of sacral pressure injuries in critically ill patients<sup>1</sup>. However, we have a number of concerns and would like to highlight that the researchers' study design and results do *not* support the conclusions. Additionally, the conclusions may put patients at risk of pressure injury unless viewed in comparison with established *in vitro* and clinical evidence.

Our concerns with the study are:

1) The methodology and recruited population do not support a fair comparison of product performance.

The patients were allocated to two different sacral foam dressings on a 3-month cluster basis. The authors indicated that this was to reduce the potential for seasonal variation of patients; however, this design actually increased the

potential variation of patients and risk between the two dressing groups. The authors could have used a balanced 1:1 randomization design to assess performance based on the predetermined sample size calculation.

In addition, the method used in the study prevents true comparison, as the study was designed as a superiority study but was interpreted as a non-inferiority study, without any sample size re-calculation. Initially, the authors indicated they would require at least 400 patients to test for a significant difference in pressure injury incidence rates between the groups. However, the study only recruited a total of 302 patients, 98 patients short of the required sample. Despite this, the authors still reported conclusions regarding perceived differences between the products. Unfortunately, the non-significant results were wrongly interpreted for a superiority designed study and erroneously concluded there was no difference between the dressings.

2) The study excluded specific high risk patients.

The setting of the study did *not* include the high risk intensive care populations of neurosurgical, cardiothoracic, burn or major trauma. By not including patients at highest risk for ulceration, this study design contrasts the demonstrated benefit of previous studies assessing Mepilex Border (Mölnlycke Healthcare, Gothenburg, SE) dressings, including two RCTs assessing high risk intensive care cardiac, medical and trauma patients<sup>2,3</sup>. In the study by Stankiewicz and colleagues, if the sample population were at lower risk of pressure injury, it is likely that a much larger sample size would have been necessary to determine significant differences between dressings.

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3) There are significant concerns regarding the cost effectiveness calculations.

The economic evaluation does not appear to be accurate and is misleading. Initially, the authors reported the use of Allevyn Gentle Border Sacrum® (Smith & Nephew, Watford, UK) in the original published version of the study, when in fact, Allevyn Life Sacrum® was utilized. We note that this error has been revised in the updated version of the paper and trust that this error was not reflected in actual dressing use or price calculations as there are differences in dressing construction which would have impacted performance and price per unit.

Additionally, the authors reported that the dressing use per patient day was the same in both groups (0.5), the average duration of the study was the same (2 days in ICU), and the incidence of new pressure injury/100 dressing days was also the same (0.44). However, the dressing cost per patient was calculated based on patients in the Mepilex Border Sacrum® group using double the amount of dressings, which is contradictory.

Whereas the cost effectiveness of Allevyn Life Sacrum® for pressure injury prevention appears unproven, the cost effectiveness of Mepilex Border Sacrum® and Heel® were demonstrated in an RCT where the dressing group was shown to be 3.6 times less costly than the non-dressing control group<sup>4</sup>.

The dressings compared in this study can be further differentiated in terms of their respective evidence and construction from peer-reviewed published literature. Stankiewicz and colleagues stated that there were 5 studies supporting the effectiveness of Mepilex Border Sacrum® with its Deep Defense Technology®. However, along with Mepilex Border Heel®, the dressings have demonstrated reduced pressure, shear, microclimate and friction, resulting in pressure injury prevention and mitigation of pressure and shear at the muscle-bone interface in numerous studies. The results are supported by 4 systematic reviews/meta-analyses, 5 RCTs, 7 prospective studies, 32 retrospective studies, 8 case series, and 28 *in vitro* or expert opinion papers.

We welcome that Stankiewicz and colleagues have attempted to compare a foam dressing with the established research of Mepilex Border Sacrum® and Heel® and we agree that proper selection of the right products to assist pressure injury prevention is essential and that comparative level one studies are a necessity. An RCT is currently being performed with sufficient scientific methodology through an independent, investigator initiated study to investigate the difference between Mepilex® and Allevyn® dressings (NCT03442777). We look forward to seeing the data published and providing clinicians with further evidence to guide their practice.

## Conflict of interest

Brindle: Is the United States Medical Director for Molnlycke Health Care.

Wright: Is the Chief Medical Officer for Molnlycke Health Care.

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Not applicable.

## References

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