Letter to the Editor

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

Stankiewicz M, Gordon J, Dulhunty JM, Brown W, Pollock H and Barker-Gregory N

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Dear Editor

In response to the critical review of our study by Brindle and Wright[1,2], we take the opportunity to provide several points of clarification. First, sample size calculations in our trial were based on a 'superiority vs. null hypothesis' two-sided test, and not a non-inferiority approach as suggested by Brindle and Wright, which often employs use of a one-sided test[3]. Given our use of a two-sided test for sample size calculations, this distinction is arguably irrelevant[4]. However, we agree with Brindle and Wright that our findings of no difference between the two dressings need to be interpreted with caution given the chance of a type 2 error associated with a smaller than estimated sample. We also agree that our findings may not be extrapolated to specific Intensive Care Unit (ICU) sub-populations not featured in this study that may be at higher risk of pressure injury development. We disagree with Brindle and Wright that our conclusions are not supported by our study design or findings taking into account the stated limitations[2].

Monica Stankiewicz* RN, MAppSc (Research) MNSc (NP), Grad Dip WM, Grad Cert STN
Nurse Practitioner
Royal Brisbane and Women's Hospital
Brisbane, QLD, Australia
Email mon.stankiewicz@gmail.com

Jodie Gordon RN, MClinSpec (WM) MHealthAdmin, Grad Cert STN
Clinical Nurse Consultant
Wound Management, Stomal Therapy
Redcliffe Hospital, QLD

Joel M Dulhunty MBBS, MTH, PhD
Director of Research and Medical Education
Redcliffe Hospital, QLD

Wendy Brown RN, Cert ICN
Research Assistant, Intensive Care Unit
Redcliffe Hospital, QLD

Hamish Pollock BM, MRCP, FRCA, DICM(UK) FCICM, FANZCA, PGDipCU
Director, Caboolture-Redcliffe Intensive Care Unit
Redcliffe Hospital, QLD

Nicola Barker-Gregory RN, Grad Cert ICU Grad Cert Adult & Wkplace Ed, M Edu
Project Officer, Redcliffe Hospital, QLD

** Corresponding author*

Brindle and Wright have queried the cluster design and its potential interaction with seasonal variables in our study. We acknowledge this remains a possibility, although there was no direct overlap with the recognised seasons in Australia[5]. The three-month intervention cycles in our study were commenced on 17 February 2016 (Dressing 1), 11 May 2016 (Dressing 2), 17 August 2016 (Dressing 1), 16 November 2016 (Dressing 2), 15 February 2017 (Dressing 1) and 17 May 2017 (Dressing 2). All seasons were represented to some degree in both groups, although Dressing 1 (Allevyn Life™) was used more often in the Summer-Autumn period and Dressing 2 (Mepilex Border Sacrum™) in the Autumn-Winter period. While block allocation was chosen for logistical reasons in our ICU setting, we agree that individual patient randomisation allows for a higher degree of bias minimisation. Nevertheless, we found no evidence of difference between the two periods in terms of the baseline characteristics measured.

Brindle and Wright note a typographical error in our manuscript

relating to the dressing used in one of the treatment arms (Dressing 1) that was corrected by an erratum[6]. The comparator dressing to Mepilex Border Sacrum™ (Dressing 2) was Allevyn Life™ as previously stated in the study protocol[7], and not Allevyn Gentle Border Sacrum™ as initially reported in our paper[2]. The product description, dimensions and cost are, however, correctly reported.

We note the query by Brindle and Wright as to the difference in the total number of dressings per patient by study group (i.e. 1 and 2 dressings), despite similar patient daily dressing use (0.5 dressings) and dressing duration (2 days) in both treatment arms[2]. The reason for this apparent discrepancy is that median values are reported (in Table 2) for these variables due to their non-normal distribution.

Finally, we believe our paper is important because it provides comparative evidence from the first head-to-head comparison of two prophylactic sacral dressings in an ICU setting. Of note, our study has also been conducted independent of commercial sponsorship or affiliation. We thank Brindle and Wright for highlighting the significant healthcare cost savings that can be made by use of silicone foam dressings to prevent pressure injury development in comparison to standard care without dressings[8], and agree that further comparative randomised controlled evidence of efficacy and cost effectiveness will contribute to clinician confidence in appropriate product selection.

Conflict of interest

The authors declare no conflicts of interest.

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