

## Comment on: “Negative Pressure Wound Therapy Reduces Wound Breakdown and Implant Loss in Prepectoral Breast Reconstruction”

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Sir,

We have read the article entitled “Negative Pressure Wound Therapy Reduces Wound Breakdown and Implant Loss in Prepectoral Breast Reconstruction” by Irwin et al<sup>1</sup> published in *Plastic Reconstructive Surgery Global Open*. The authors found a significant benefit using a 1-time negative pressure wound therapy (NPWT) dressing (PICO) compared with standard dressing; however, we believe there are critical methodological flaws that bias the presentation of the results. We aim to highlight some of the issues with the investigation’s methodology but will focus on the proposed interpretation of results and its clinical applicability.

Several methods are used to describe risk and changes in risk. The rate ratio has been traditionally used in evidence-based medicine to compare the rate of events in an exposed group with that in an unexposed group. We have presented the rate ratio for wound breakdown in a traditional 2 × 2 contingency table (Table 1). The estimated relative rate of wound breakdown is 6.96 (95% confidence interval, 0.90–53.7;  $P = 0.062$ ) with the use of standard dressing versus the PICO dressing. As such, we fail to reject the null hypothesis as the confidence interval includes the ratio of 1. This suggests that the evidence is indeterminate about the effect of PICO on wound breakdown incidence in this patient population. In fact, the PICO dressing may potentially cause harm and increase the rate of wound breakdown events by as much as 10%.

Additionally, the authors suggest that due to the nature of the study, a double-blind randomized controlled trial (RCT) was not possible. Within surgery, there are many questions that cannot be answered by RCTs due to inability to randomize patients; however, an RCT is the most appropriate study design for this clinical question. Why did the authors omit reporting their decision to forgo an RCT study design? As it is randomization, not necessarily blinding, that

**Table 1. 2 × 2 Contingency Table: Patient Rate Ratio Wound Breakdown**

	Group		<i>P</i>
	Standard Cohort	NPWT Cohort	
Wound breakdown	10	1	
Nonevents	171	125	
Total wounds	181	126	0.030*
Incidence proportion	0.055	0.008	
Rate ratio	6.96 (95% CI, 0.90–53.7; $P = 0.062$ )		

\*Fisher’s exact test.

provides evidence which can be trusted.<sup>2</sup> Pooled results from a review of 7 meta-epidemiological studies found that intervention effect estimates are exaggerated by 10% when there is no allocation concealment and exaggerated by 7% when there is no randomization process.<sup>3</sup> This bias is greater when evaluating subjective outcomes such as wound breakdown.<sup>3</sup> In cases where randomization is not possible, bias can be reduced by adjustment for relevant covariates. Considering the prospective nature of this study, laterality (unilateral versus bilateral) is an important prognostic factor that should have been considered for adjustment.

In conclusion, due to the high amount of systematic error within the study (some of which was not discussed in this letter), the intervention effect estimate is likely to be different than the one reported. The effect estimate is imprecise, and despite the article’s title, the evidence presented does not permit readers to reject the null hypothesis that there is any difference in risk between patients who receive the PICO dressing versus those who receive standard dressings in prepectoral breast reconstruction.

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### DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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