

## Fragile Data Requires High Statistical Caution

To the Editor:

The article looking at the effect of a bundled intervention on hospitalized patients with community acquired pneumonia concludes that the bundled care resulted in increased gastrointestinal bleeding (GIB).[\(1\)](#) The authors state in their discussion that the increased bleeding almost certainly was due to the corticosteroid component of the bundled intervention. The data presented, however, are highly fragile making such a conclusion regarding corticosteroids tenuous at best.

To support their conclusion of increased GIB in the intervention group, the authors calculated confidence intervals of the unadjusted difference between 2.2% (9 out of 401 intervention group patients) and 0.7% (3 out of 415 control group patients) showing a statistically significant result. However, this statistical analysis is highly fragile, having a fragility index of 0. This indicates a highly unstable result for which statistical inferences probably should not be made at all, but if done, should be viewed cautiously.[\(2\)](#)

Perhaps most importantly, the use of corticosteroids wasn't 100% in the intervention group. In the 9 intervention group patients with a GIB (supp table 8), only 7 of 9 received any corticosteroids at all. Therefore, out of all patients experiencing a GIB (total = 12), only 7 of these 12 received corticosteroids. This rate of 58% is not statistically different than a rate of 50% which would be expected if no association between corticosteroid administration and GIB existed.

Finally, these results almost certainly would be affected by the type of prophylaxis given for deep venous thromboembolism and whether or not gastrointestinal protective agents were used. These variables did not appear to be accounted for in the authors' analysis, increasing

uncertainty over exactly what was responsible for the difference in GIB observed between the control and intervention groups.

## Bibliography

1. Lloyd M, Karahalios A, Janus E, Skinner EH, Haines T, De Silva A, et al. Effectiveness of a Bundled Intervention Including Adjunctive Corticosteroids on Outcomes of Hospitalized Patients With Community-Acquired Pneumonia: A Stepped-Wedge Randomized Clinical Trial. *JAMA Intern Med.* 2019 Jul 8;
2. Walsh M, Srinathan SK, McAuley DF, Mrkobrada M, Levine O, Ribic C, et al. The statistical significance of randomized controlled trial results is frequently fragile: a case for a Fragility Index. *J Clin Epidemiol.* 2014 Jun;67(6):622–8.

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