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Strengths and Limitations of a Small Randomized Trial Comparing Manual and Vacuum Drainage in Thoracentesis

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To the Editor:

We thank Sagar *et al.* for their Letter to the Editor and appreciate this opportunity to highlight the contributions and limitations of our research examining the use of vacutainers when performing thoracentesis..

We acknowledge that our pilot study [1] is small and therefore prone to greater variability than the larger studies cited by Sagar *et al.* [2, 3]. We further acknowledge that our overall rate of pneumothorax of 3.0% (3 events among 100 procedures) is greater than the 0.6% reported by Sagar *et al.* (4 events among 709 procedures). Nonetheless, we assert that our rate of pneumothorax is not inflated with respect to those reported by other large sample studies. For example, Jones *et al.* report a rate of pneumothorax of 2.6% (24 events among 941 procedures) and Patel *et al.* report a rate of 2.8% (246 events among 8824 procedures) [4, 5]. Additionally, a meta-analysis of 24 studies that included 6,605 thoracenteses demonstrated an overall pneumothorax rate of 6.0% [6].

Given that this pilot study is intended to motivate larger, more comprehensive studies comparing the safety of manual and vacuum drainage, we are impressed with the consistency of our findings. If, for the sake of argument, we attribute the rate of pneumothorax in our study to a simple matter of sample size, it seems unlikely that the same participants randomized to the manual drainage arm would simultaneously exhibit a markedly lower rate of early termination as well as a significantly lower level of pain.

In summary, although we agree that our small sample size is a factor when examining “rare events” such as pneumothorax or hemothorax, it is very unlikely that it would uniformly bias the results from this carefully conducted RCT in favor of manual drainage. For this reason

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we stand by the last sentence in our abstract: “Although larger studies are needed, this pilot study suggests that manual aspiration provides greater safety and patient comfort.”

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