breathing in an already compromised population. Given the limitations of pharmacotherapy in treating insomnia in returning soldiers, it may be more valuable to focus on nonpharmacologic therapies such as cognitive behavioral therapy and imagery rehearsal therapy. This has been used successfully in recent populations of veterans. A comprehensive sleep-medicine evaluation including polysomnography is critical given the high prevalence of obstructive sleep apnea in this population. Another potential option would be multidisciplinary clinics. Simultaneous input from pain medicine physicians, physical medicine and rehabilitation specialists, psychiatry, and sleep medicine would offer the most efficient route to managing polypharmacy. As these patients leave the care of the military health-care system and return to civilian life, they will be increasingly treated by nonmilitary physicians. Knowledge of the factors that impact their disease process is critical in providing effective care and will be for years to come.

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Randomized Trials and Bronchoscopy

To the Editor:

I read with interest about the randomized clinical trial of endobronchial ultrasound with and without aspiration in the recent article by Casal et al1 in CHEST (September 2012). In this study, neither participants, nor bronchoscopists, nor pathologists were randomly assigned to comparison groups. Instead, the study was designed as a prospective comparison of two different bronchoscopic techniques, with each participant serving as his or her own control subject. Easy to miss, save for a single sentence in the “Materials and Methods” section, the unit of randomization was which procedure was performed first. Although this was a potentially rigorous design, the relevant details were not adequately captured by the “randomized clinical trial” designation, which was somewhat misleading.

In addition, the unit of randomization differed from the unit of analysis, which was the individual lymph node, with a total of 192 nodes sampled in 115 participants. Positive correlations between lymph nodes within individual participants introduce bias, leading to overly optimistic estimates of diagnostic accuracy and yield in both groups. Furthermore, the authors did not report the baseline characteristics of the participants according to group assignment, leaving the reader to wonder whether the randomization process resulted in groups that were reasonably well balanced.

As a member of the CHEST editorial board, I believe these issues should have been identified and clarified during the peer review and editorial process. The accompanying editorial would have been a good place to provide clarification, but this opportunity was missed.

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Response

To the Editor:

We thank Dr Gould for his comments regarding our study of endobronchial ultrasound performed with and without aspiration. One of his main concerns is the denomination of “randomized clinical trial” that we gave to our study. There was, indeed, a randomization used in our study. Of note, instead of randomizing patients or lymph nodes (LNs) to one technique or another, we preferred to use both techniques in each LN and randomize the order in which they would be performed. This way, each LN would provide its own control, and, additionally, this type of randomization would prevent the first-pass bias. We call the first-pass...
bias the fact that the first sample, in our experience, provides the best quality material, since the LN has not been traumatized by the needle yet.

Dr Gould also points out that our unit of analysis differed from our unit of randomization, with which we agree. However, we do not think this has introduced any bias, since the number of LNs included in each randomization group and the LN size—probably one of the most important factors affecting yield—were comparable. In 98 LNs, passes one to three were performed without suction and two to four with suction; in 94 LNs, passes one to three were performed with suction and two to four without. Lymph node size in short axis (mean ± SD) was 10.45 ± 5.15 mm for LNs in which the initial pass was performed without suction vs 11.65 ± 5.82 mm for LNs in which the initial pass was performed with suction (\( P = .15 \)).

Regarding Dr Gould’s question about the baseline characteristics of participants in each group, we did not report them separately because all patients and LNs had both techniques performed, serving as their own controls. Patient and LN characteristics of the entire study population were described in Table 1 of our article.¹

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