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Commentary: Expert deconstruction: A novel peer-reviewed formula for clinical trial interpretation

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A single, well-designed randomized clinical trial can rapidly and profoundly change clinical practice. Rigorous construction and stringent eligibility criteria minimize bias and permit the generation of truths. The same rigor and stringency produce a nuanced gap between the ideal and the practical that requires other biases (eg, experience) to safely and effectively adopt relevant changes in clinic or operating room settings. A deep understanding of trial methodology narrows this gap and facilitates practical interpretation of trial results, although such background knowledge is not held by most practicing surgeons.

Before the Primary Spontaneous Pneumothorax (PSP) trial was published in the *New England Journal of Medicine*,¹ there were no randomized trials comparing observation to intervention for managing moderate and large primary spontaneous pneumothoraces. Based on degree of resolution on chest radiograph, this multicenter, prospective, randomized controlled trial demonstrated noninferiority of conservative management compared with small bore drain placement for patients aged 14 to 50 years with primary spontaneous pneumothorax. To be safely implemented into practice, these paradigm-changing data should be considered within their context of a radiographic end point, patients should be considered reliable for the 24- to 72-hours required follow-up after discharge from the emergency department, and it should be understood that

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CENTRAL MESSAGE

A structured format for critical appraisal of influential clinical trials will educate practicing surgeons on advances in the field while training them to review future trials.

noninferiority was met in the primary analysis but failed under conservative assumptions addressing missing data.

In their expert opinion article, Giles and colleagues² present a critical review of the PSP trial by the Evidence Based Reviews in Surgery (EBRS) group. EBRS was developed to foster critical appraisal skills in practicing surgeons so that they may evaluate surgical literature and practice data-driven medicine. This group of expert clinical and methodologic surgeon reviewers meets 8 times a year to systematically review influential articles in surgery. Giles and colleagues² have transcribed the output of the EBRS review of the PSP trial into a succinct and logical series of incremental questions that can be applied by practicing physicians and surgeons to pragmatically interpret any clinical trial. The result is a brief proceeding from which a reader unfamiliar with the PSP trial will understand its construction, formulate a nuanced interpretation of results, and emerge to effectively apply its messages in clinical practice.

The strengths of this potentially novel format of peer-reviewed expert opinion article, in which an influential clinical trial is distilled into core elements of design and output, are obvious. To otherwise be able to so carefully interpret the results of a clinical trial requires knowledge of study design, statistics, outcomes assessment, decision analysis, and cost-effectiveness. Reading a series of articles adopting this formulaic approach to describing and understanding a clinical trial would educate practicing surgeons on relevant advances in their field, while simultaneously training them to critically review scientific literature: What does the P

value actually mean and does this management approach apply to my patients? Would you actually send a patient home from the emergency department with a large pneumothorax that is stable on a repeat 4-hour chest radiograph? Many practitioners will remain tentative until they understand the nitty gritty of the PSP trial. Obtaining a master's degree in clinical investigation would provide an outstanding platform to dissect these high profile and statistically complex trials. Or, you can preview the last section

of Giles and colleagues² masterfully structured review: "Does the evidence support the conclusions?"

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Commentary: Tube or no tube?

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I am not sure many of us have thought much about the options for treating a symptomatic large primary pneumothorax. The biggest decision was probably "should I put in a standard-size or small-bore chest tube?" The thought of sending an 18-year-old with pain, shortness of breath, and a 70% pneumothorax home without treatment might not have crossed your mind.

In January 2020, Brown and colleagues published the results of the Primary Spontaneous Pneumothorax (PSP) Trial in the *New England Journal of Medicine*.¹ That trial, performed in Australia and New Zealand, randomized patients with moderate to large (>32%) primary spontaneous pneumothorax to either observation or a small-bore chest drain. As long as patients could maintain a room air saturation >90% with pain controlled on oral pain medications, they were sent home with serial follow-up. Perhaps surprising to many, the conservative approach was found to be noninferior to an interventional approach. Specifically, at 8 weeks, the rate of pneumothorax resolution was similar, and the

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CENTRAL MESSAGE

Understanding the strengths and limitations of the Primary Spontaneous Pneumothorax Trial will help determine how best to implement a conservative management strategy.

rate of adverse events was lower in the conservative group. Of interest, the conservative approach was associated with a lower 1-year rate of recurrent pneumothorax compared with the intervention group (8.8% vs 16.8%).

The PSP trial was authored predominantly by emergency medicine physicians but obviously has implications for thoracic surgeons, who are typically responsible for managing these patients. Owing to its potential for a significant change in clinical management, the PSP trial paper was chosen by the Evidence-Based Reviews in Surgery global journal club for methodologic review. In this issue of the *Journal*, Giles and colleagues² nicely summarize the expert clinical and methodologic analysis of the PSP trial from a surgeon's perspective. They deftly point out that the trial had a highly selected population (2637 screened for 316

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