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Conservative versus Interventional Treatment for Spontaneous Pneumothorax

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ABSTRACT

BACKGROUND

Whether conservative management is an acceptable alternative to interventional management for uncomplicated, moderate-to-large primary spontaneous pneumothorax is unknown.

METHODS

In this open-label, multicenter, noninferiority trial, we recruited patients 14 to 50 years of age with a first-known, unilateral, moderate-to-large primary spontaneous pneumothorax. Patients were randomly assigned to immediate interventional management of the pneumothorax (intervention group) or a conservative observational approach (conservative-management group) and were followed for 12 months. The primary outcome was lung reexpansion within 8 weeks.

RESULTS

A total of 316 patients underwent randomization (154 patients to the intervention group and 162 to the conservative-management group). In the conservative-management group, 25 patients (15.4%) underwent interventions to manage the pneumothorax, for reasons prespecified in the protocol, and 137 (84.6%) did not undergo interventions. In a complete-case analysis in which data were not available for 23 patients in the intervention group and 37 in the conservative-management group, reexpansion within 8 weeks occurred in 129 of 131 patients (98.5%) with interventional management and in 118 of 125 (94.4%) with conservative management (risk difference, −4.1 percentage points; 95% confidence interval [CI], −8.6 to 0.5; P=0.02 for noninferiority); the lower boundary of the 95% confidence interval was within the prespecified noninferiority margin of −9 percentage points. In a sensitivity analysis in which all missing data after 56 days were imputed as treatment failure (with reexpansion in 129 of 138 patients [93.5%] in the intervention group and in 118 of 143 [82.5%] in the conservative-management group), the risk difference of −11.0 percentage points (95% CI, −18.4 to −3.5) was outside the prespecified noninferiority margin. Conservative management resulted in a lower risk of serious adverse events or pneumothorax recurrence than interventional management.

CONCLUSIONS

Although the primary outcome was not statistically robust to conservative assumptions about missing data, the trial provides modest evidence that conservative management of primary spontaneous pneumothorax was noninferior to interventional management, with a lower risk of serious adverse events. (Funded by the Emergency Medicine Foundation and others; PSP Australian New Zealand Clinical Trials Registry number, ACTRN12611000184976.)

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*A complete list of the PSP investigators is provided in the Supplementary Appendix, available at NEJM.org.

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