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Evaluation of proposed criteria for research reporting of amniotic fluid embolism



OBJECTIVE: To examine the diagnostic performance of proposed criteria for the research reporting of amniotic fluid embolism (AFE).¹

STUDY DESIGN: The Amniotic Fluid Embolism Registry is an international database established at Baylor College of Medicine in partnership with the Amniotic Fluid Embolism Foundation and the Perinatal Research Branch of the Division of Intramural Research of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health. Charts submitted to the registry between August 1, 2013, and June 31, 2017, underwent 2 separate analyses. First, a group of maternal–fetal medicine specialists with expertise in critical care (S.L.C., G.A.D., M.A.B.) conducted a detailed analysis of medical records to categorize these women into 3 groups, based on their consensus diagnosis: (1) AFE; (2) a distinct diagnosis other than AFE; and (3) indeterminate/uncertain diagnosis. Next, each chart was independently analyzed by a physician with no obstetric training to determine whether the medical record did or did not contain each of the recently published criteria for the diagnosis of AFE¹ (Table). Agreement between expert record analysis and the presence of these strict, objective criteria was determined.

RESULTS: A total of 115 charts were reviewed. Expert review resulted in a diagnosis of AFE in 68 cases (59%), a clear alternative diagnosis in 26 cases (23%), and an indeterminate diagnosis in 21 cases (18%) (Figure). When analyzed according to the

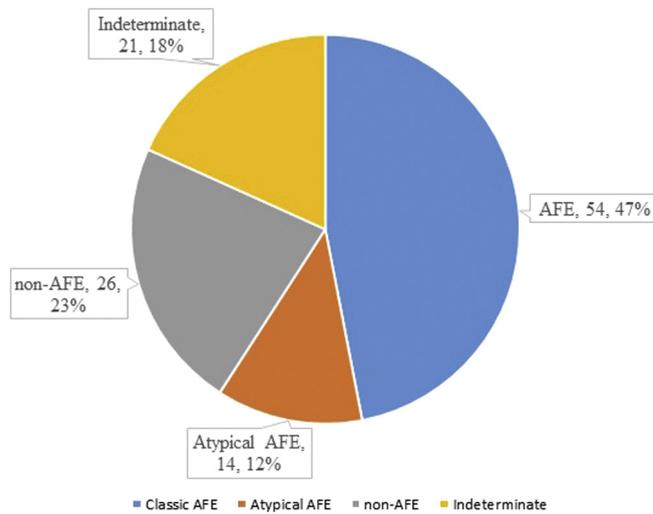
TABLE

Uniform diagnostic criteria for research reporting of amniotic fluid embolism¹

1. Sudden onset of cardiorespiratory arrest, or both hypotension (systolic blood pressure <90 mm Hg) and respiratory compromise (dyspnea, cyanosis, or peripheral capillary oxygen saturation [SpO₂] <90%)
2. Documentation of overt disseminated intravascular coagulation (DIC) following appearance of these initial signs or symptoms, using scoring system of Scientific and Standardization Committee on DIC of the International Society on Thrombosis and Haemostasis (ISTH), modified for pregnancy. Coagulopathy must be detected prior to loss of sufficient blood to itself account for dilutional or shock-related consumptive coagulopathy
3. Clinical onset during labor or within 30 min of delivery of placenta
4. No fever ($\geq 38.0^{\circ}\text{C}$) during labor

Stafford. Research reporting of amniotic fluid embolism. *Am J Obstet Gynecol* 2019.

FIGURE
Amniotic fluid embolism classification by diagnostic criteria



Stafford. Research reporting of amniotic fluid embolism. *Am J Obstet Gynecol* 2019.

presence or absence of the proposed objective criteria, 54 cases were identified as AFE. In each of these cases, expert review had also made the diagnosis of AFE. The 14 cases (21%) identified by the expert panel as AFE that did not meet the objective criteria are believed to represent atypical presentations of this condition. The diagnostic performance of this criteria set was as follows: sensitivity, 79.4% (67.9–88.3); specificity, 100% (94.1–100.0); positive predictive value, 100%; negative predictive value, 81.3% (73.7–87.4).

CONCLUSION: The guidelines for research reporting of AFE were developed by a multidisciplinary group in an effort to establish objective criteria that, if present, are not consistent with any known medical condition other than AFE.¹ The authors of these guidelines acknowledged that although the use of these criteria may provide a clean data set for research analysis, some atypical cases would be excluded. Our review supports this assumption. Each case meeting the objective criteria for AFE diagnosis was independently determined by the expert panel to have AFE. However, as anticipated, these criteria appear to exclude 21% of women with less typical presentations.^{1–3} In this analysis, we used consensus expert review as the standard against which the proposed objective criteria were measured. Although we recognize potential problems with the use of such review as a standard, such opinions have, to date, been the only available diagnostic standard, and we believe that these particular reviewers are as qualified as any to render such opinions.^{4,5} In light of these data, we encourage the adoption of these objective criteria as the standard for research reporting pending future identification of additional valid, objective criteria that would allow inclusion of less typical cases, and

further enhance our understanding of the spectrum of this condition.¹

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