

The predictive value of the presence of an amniotic sac without a visible embryonic heartbeat in the diagnosis of early embryonic demise

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INTRODUCTION

Current NICE¹ and American Institute for Ultrasound in Medicine² criteria state that an early embryonic demise (EED) cannot be diagnosed unless there is an empty gestational sac measuring ≥ 25 mm in the mean diameter or an embryo with no cardiac activity with the crown rump length ≥ 7 mm.

These criteria include a high safety margin, which helps to prevent misdiagnosis, but a significant proportion of women need to attend for follow-up visits until a conclusive diagnosis is made. This diagnostic uncertainty has been shown to have a significant impact on women's anxiety levels.³

Previous small studies have reported that women who had an ultrasound scan in early pregnancy demonstrating an amniotic sac which did not contain an embryonic pole all were later confirmed to have an EED.^{4,5}

The aim of our study was to assess the predictive value of visualising an amniotic sac without a live embryo ('amniotic sac sign') for the diagnosis of EED. We also looked to determine whether incorporating the amniotic sac sign into current diagnostic algorithms could have a significant effect on the rate of follow-up visits in EPU.



GS= Gestational sac
Y= Yolk sac
A=Amniotic sac



METHODS

This was a prospective cohort study assessing all pregnant women attending a single specialist early pregnancy unit from July 2017 to November 2018 with symptoms of pain, bleeding, or a history of ectopic pregnancy or miscarriage, at less than 14 weeks' gestation. The initial ultrasound findings were documented, including whether an amniotic sac was present in the absence of a live embryo. Women were followed-up until a conclusive diagnosis was made.

RESULTS

The study included 6012 women. A conclusive diagnosis was reached on the initial scan in 4221 (70.2%), whilst 1135 (18.9%) had pregnancies of uncertain viability and 656 (10.9%) had pregnancies of unknown location.

An amniotic sac in the absence of a live embryo was found in 174/1135 (15.3%) of women with pregnancies of uncertain viability at their initial ultrasound scan.

The presence of amniotic sac without a live embryo at the initial visit had a specificity of 100% (95% CI 98.4-100) and positive predictive value of 100% (95% CI 97.2-100) in the diagnosis of early embryonic demise.

By using the presence of amniotic sac without a live embryo to diagnose miscarriage at the initial visit, the number of follow-up scans for pregnancies of uncertain viability would be reduced by 14.4%; which accounted for 11% of all follow up scans during the study period.

Morphology on initial scan	Live pregnancy, n (%)	EED, n (%)	Incomplete miscarriage, n (%)	Complete miscarriage, n (%)	Completed follow up
Empty gestational sac <25mm	80 (25.4)	147 (46.7)	51 (16.2)	37 (11.7)	315
Gestational sac <25mm, yolk sac, no visible embryo	110 (48.0)	76 (33.2)	31 (13.5)	12 (5.2)	229
Gestational sac, yolk sac, embryo <7mm, -no visible heartbeat	41 (20.6)	101 (50.8)	40 (20.1)	17 (8.5)	199
Gestational sac, yolk sac, amniotic sac, embryo <7mm, no visible heartbeat	0 (0)	71 (62.8)	32 (28.3)	10 (8.8)	113
Gestational sac <25mm, yolk sac, empty amniotic sac, no visible embryo	0 (0)	15 (71.4)	5 (23.8)	1 (4.8)	21
Total	231	410	159	77	877

Table showing initial ultrasound findings and final diagnosis in cases of pregnancy of unknown viability, who completed follow-up, n=877.

Results show that no women progressed to have a live pregnancy, where an amniotic sac was visualised in the absence of a live embryo on initial scan.

CONCLUSION

Our study showed that the finding of an amniotic sac without a live embryo on ultrasound is a reliable marker of early pregnancy failure and could reduce the number of follow-up scans by 11% in cases of diagnostic uncertainty.

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