Accuracy of first-trimester ultrasound in the diagnosis of early embryonic demise: a systematic review
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CRD summary
This review concluded that there was no good quality evidence for the accuracy of first-trimester ultrasound in diagnosing early embryonic demise. There were limitations to the review and the included studies, several of which the authors acknowledged. The conclusion drawn seems appropriate.

Authors’ objectives
To evaluate the accuracy of first-trimester ultrasound in diagnosing early embryonic death.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched up to 2011 without language restrictions; search terms were reported. Reference lists of included studies and review articles were searched.

Study selection
Studies evaluating the accuracy of first-trimester ultrasound for the diagnosis of early embryonic demise in women with or without symptoms of threatened first-trimester miscarriage, were eligible for inclusion. Studies with subjective ultrasound criteria for diagnosis were not included.

In the selected studies, most of the women had symptoms of threatened miscarriage. The sonographic criteria for diagnosis of early embryonic demise varied between studies, including crown-rump length with absent cardiac activity, empty gestational sac size, absent yolk sac with varied gestational sac sizes, and combined criteria. The reference standard used to confirm pregnancy success or loss varied, including miscarriage diagnosed on further scan or clinically, histopathology, failure of embryo development, falling levels of beta-human chorionic gonadotropin, and foetal status on second-trimester ultrasound.

Two independent reviewers applied the inclusion criteria to full papers; disagreements were resolved by consensus. It was unclear how many reviewers screened the titles and abstracts before accessing full papers.

Assessment of study quality
Study quality was assessed for direction of data collection, recruitment method, test description, blinding, appropriate reference standard, and follow-up. A prospective study with consecutive enrolment, full verification of the test result with a reference standard, and adequate description of the test, was considered to be of good quality. The authors did not report how many reviewers assessed study quality.

Data extraction
Data were extracted by two independent reviewers to construct 2x2 tables of test performance. Sensitivity, specificity, and positive and negative likelihood ratios, with 95% confidence intervals, were calculated.

Methods of synthesis
Studies were combined in a narrative synthesis. The differences between studies were discussed in the text. Study details were reported in tables, organised by the sonographic criteria. Results were also presented in forest plots, without a pooled estimate.

Results of the review
Eight cohort studies met the inclusion criteria, and four tests were evaluated, resulting in 18 data sets, with 872 women (range 55 to 211). All eight studies used an appropriate reference standard and duration of follow-up; six were prospective; six recruited consecutive women; three adequately described the tests being evaluated; and one blinded to allocation the interpreter of the index test.
Across the 18 data sets, sensitivity ranged from 14% to 100%; the highest estimate of sensitivity (100%, 95% CI 54 to 100) was from a study using sonographic criteria of the absence of embryo or cardiac activity in a gestational sac with a mean diameter of at least 16mm. Thirteen data sets had a specificity of 100%; specificity ranged from 57% to 88% in the other five studies. The positive likelihood ratio was over 10 in 13 studies, and the negative ratio was less than 0.1 in three studies.

Authors' conclusions
There were no high-quality prospective data to determine the accuracy of diagnosis of early pregnancy loss. There were few small studies, conducted before the introduction of new technology, and they included women with or without symptoms and used various reference standards.

CRD commentary
The review addressed a clear research question with reproducible inclusion criteria. Several relevant sources were searched, without language restrictions. There was no specific search for unpublished studies, so publication bias could be present. Study selection at the full paper stage and data extraction were conducted in duplicate; it was unclear whether similar methods to reduce error and bias were used during the title and abstract stage of study selection and in quality assessment. Study quality was assessed, but not for all relevant factors. Given the small number of studies and the clinical variation between them, a narrative synthesis seems to have been appropriate. As the authors acknowledged, the studies were published between 1986 and 1994 and, given the advancements in imaging technology, the results might not be generalisable to current clinical practice.

There were limitations to the review and the included studies, some of which the authors acknowledged. The authors reached an appropriate conclusion.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that an appropriately powered study, using up-to-date technology, with transvaginal ultrasound, and an appropriate reference standard for pregnancy success or loss, was urgently required before setting standards for the accurate diagnosis of early embryonic demise. They stated that a consensus on the appropriate methodological approach was needed before embarking on further projects.

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