Is this patient pregnant: can you reliably rule in or rule out early pregnancy by clinical examination?

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Authors' objectives
To determine the value of patient history or physical examination features in determining the probability of early pregnancy.

Searching
MEDLINE was searched from 1966 to 1996 using the terms 'pregnancy', 'diagnosis' and 'pregnancy tests'. The bibliographies of retrieved articles and textbooks were also examined. Only English language publications were considered.

Study selection
No inclusion criteria relating to study design were specified, and no details of the primary study designs were reported in the review.

Specific interventions included in the review
No inclusion criteria were specified with respect to the index test. The included studies evaluated the diagnostic performance of elements of clinical history, symptoms and physical examination. For clinical history these were delayed menses, use of birth control and patient opinion; for symptoms, these were morning sickness and any pregnancy symptoms; for physical examination, these included Chadwick sign, breast signs, vaginal examination signs, presence of palpable fundus and presence of uterine artery pulsation. Studies of home pregnancy testing kits were also reported.

Reference standard test against which the new test was compared
The included studies were required to evaluate index test performance against a reference standard: serum or urine human chorionic gonadotrophin (HCG), or pregnancy outcomes (delivery).

Participants included in the review
No inclusion criteria were specified with respect to participant characteristics, and no participant characteristics were reported for the included studies.

Outcomes assessed in the review
The included studies had to report sufficient data to construct 2x2 contingency tables. This data were used to calculate the sensitivity, specificity and likelihood ratios (LRs) for the included studies.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

Assessment of study quality
The articles were graded A, B or C by the authors according to the study design and level of evidence. The authors do not state how the papers were assessed for validity, or how many of the reviewers performed the validity assessment.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction. Only outcome data and level of evidence were reported in the review.
Methods of synthesis

How were the studies combined?
The studies were combined both narratively and statistically, with statistical pooling of studies using LRs.

How were differences between studies investigated?
Between-study heterogeneity was assessed using the Breslow-Day test for homogeneity (see Other Publications of Related Interest), and pooled LRs were calculated only when this was not significant (P > 0.05).

Results of the review

Nine studies were included. The total number of patients was unclear, as the studies contributed different numbers of patients to different tables depending on the review question to be addressed.

Accuracy of history and symptoms for pregnancy diagnosis.

A delayed menstrual period yielded statistically significant results for predicting pregnancy in 3 out of 4 reported studies: positive LRs of 1.13 (95% confidence interval, CI: 1.05, 2.92), 1.56 (95% CI: 1.40, 1.74) and 2.06 (95% CI: 1.65, 2.57). However, the results were inconsistent and, therefore, represent an unreliable symptom of pregnancy.

Typical early symptoms of pregnancy were more consistent across studies and slightly increased the likelihood of pregnancy: the positive LR was 2.43 (95% CI: 1.71, 3.44) for any symptoms and 2.70 (95% CI: 2.19, 3.33) for morning sickness. The absence of early symptoms, however, did not rule out pregnancy: the negative LR was 0.71 (95% CI: 0.67, 0.76) for absence of morning sickness and 0.63 (95% CI: 0.52, 0.77) for absence of any pregnancy symptoms.

The use of birth control decreased the likelihood of pregnancy (pooled negative LR 0.29, 95% CI: 0.16, 0.53), but not sufficiently to rule it out. Patient suspicion of pregnancy statistically altered the likelihood of pregnancy, but not sufficiently to be reliable.

Accuracy of the physical examination.

No studies were found to have examined the inter- or intra-observer reliability. The most useful findings on physical diagnosis appeared to be the Chadwick sign (positive LR 28.7, 95% CI: 4.10, 200.00) and palpable uterine artery pulsation (positive LR 10.98, 95% CI: 5.63, 21.4), though the 2 studies from which these estimates were derived were of relatively lower methodological quality. In addition, the absence of these signs did not rule out pregnancy.

Accuracy of home pregnancy tests.

Narrative information was presented from 2 studies. In one study of 3 kits, positive and negative LRs of 2.5 and 0.29, respectively, were found. In the second study of 11 kits, the sensitivity and specificity were 100% under ideal laboratory conditions. However, a diagnostic study in 638 volunteers found 5 of the 11 kits had 100% specificity, whilst the others had specificities between 77 and 94%. Two kits had a high diagnostic sensitivity (greater than 90%), while 2 were found to have a low sensitivity (less than 10%).

Authors’ conclusions

To establish a diagnosis of early pregnancy, a clinician should order a urine or serum hCG test. The evidence suggests that some historical features are fair, but not reliable, for ruling out pregnancy.

CRD commentary

The review addressed a clear research question, which was defined by the inclusion criteria, in terms of acceptable reference standards and outcome measures. However, details of the included participants and study designs were vague. The search strategy was poor and restricted to English language publications, leaving the review open to publication bias and biases introduced due to incomplete retrieval of the available published evidence. The methodology was poorly reported, making it difficult to judge the extent to which the findings may have been biased by poor conduct of the review process. The validity assessment of the included studies was limited to the assignment of a grade of evidence; although these grades were reported, their derivation was not described and no further use was made of them in the review. It is therefore difficult to judge the extent to which the results reported in the review may have been influenced
by the quality of the primary studies.

The presentation of the majority of results as a narrative summary seems appropriate, as was the use of a statistical test of heterogeneity to determine the appropriateness of pooling. However, the review lacked any discussion of potential sources of heterogeneity, and insufficient details of the included studies were presented to allow assessment by the reader. In addition, the method used to pool the LRs was not described, and its appropriateness cannot therefore be assessed. In general, the review was of insufficient quality to allow any firm conclusions to be drawn from the evidence presented.

**Implications of the review for practice and research**

Practice: The authors state that, when diagnosing pregnancy, the patient or clinician should not rely on symptoms, signs of pregnancy or a home pregnancy test - a laboratory test should be requested.

Research: The authors make no recommendations for further research.

**Bibliographic details**

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**Other publications of related interest**


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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.