Expectant, medical, or surgical treatment of spontaneous abortion in first trimester of pregnancy: a pooled quantitative literature evaluation

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Authors' objectives
To clarify the role of expectant, medical and surgical treatment in the management of spontaneous abortion.

Searching
MEDLINE was searched from 1966 to February 1998 using the keywords 'incomplete abortion', 'therapy', 'management' and 'curettage'; subject headings were also used for 'therapy', 'drug therapy', 'surgery', 'prevention' and 'control'. Details of other published or unpublished material were obtained by checking Best Evidence and the Cochrane Database of Systematic Reviews for citations, scanning bibliographies in identified studies, and by contacting two experts. Studies were restricted to those in the English language.

Study selection
Study designs of evaluations included in the review
Studies with more than 15 patients and a follow-up of at least 2 weeks were eligible. Included studies were of the following designs: randomised controlled trials (RCTs), case series, and non-randomised controlled trials.

Specific interventions included in the review
Eligible treatments included: expectant; medical treatment with prostaglandin or antiprogesterone agents; and surgical treatments including sharp or suction curettage and manual vacuum aspiration. Medical treatment included oral misoprostol (400 microg), gemeprost vaginal pessaries (up to 5 mg in total), and a single dose of sulprostone intramuscularly. Surgical treatment included dilatation, and sharp and suction curettage.

Participants included in the review
Patients with spontaneous inevitable or incomplete abortions in the first 13 weeks of pregnancy were eligible. Exclusion criteria were: patients with other types of abortion such as induced termination of pregnancy and missed abortion; spontaneous abortion beyond 13 weeks; patients with temperature higher than 100.4 degrees F, unstable blood-pressure and heart rate, uncontrolled vaginal bleeding, evidence of endometritis or pelvic inflammatory disease, or findings suggestive of ectopic pregnancy. Participants included women with: retained products of conception (15 to 50 mm anteroposterior diameter), blood clots or empty uterus by initial transvaginal scan; and those with dilated cervical os and palpable products of conception, or empty uterus on pelvic examination.

Outcomes assessed in the review
Studies that assessed objective outcomes, including evaluation of success in evacuating the products of conception from the uterus and rates of complications, were eligible. Different objective outcomes were assessed so interventions were classified as 'success' or 'failure' by forming a composite outcome for each study, with success indicated if the first option for each of the following outcomes were met: vaginal bleeding (up to and including 3 weeks versus after 3 weeks); products of conception (fully expelled by 2 weeks versus residual products after 2 weeks); and complications assessed as absent (indicating success) or present (infection, transfusion, uterine perforation, hospitalisation and death). Outcomes were assessed clinically on follow-up visits without the use of sonography. Where chorionic gonadotropin levels were monitored, success was defined as chorionic gonadotropin levels declining to zero by 30 days.

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
No formal assessment of validity was undertaken.
Data extraction
Two authors (one blinded to author, journal, title, and year) independently extracted the following data: sample size, treatment method, evaluation criteria, outcomes, adequacy of follow-up, complication rate, and overall success or failure. Any discrepancies were reconciled.

Methods of synthesis
How were the studies combined?
Pooled success averages and 95% confidence intervals (CIs), weighted by sample size, were estimated for each treatment category.

How were differences between studies investigated?
The outcomes from RCTs and observational studies were compared for the expectant and surgical groups. It was not possible to examine the influence of outcome variables on results due to lack of relevant follow-up data.

Results of the review
Eighteen studies (n=2,151), including 3 RCTs, were included.

The success rates for expectant and surgical treatment were similar. Success rates for RCTs of surgical treatment were similar to overall pooled success rates for surgical treatment, whilst success rates from RCTs of expectant treatment were lower than overall pooled success rates of expectant treatment.

Expectant treatment.
Overall pooled success weighted average (9 studies with 545 patients) = 92.5% (95% CI: 86.6, 98.4).

RCTs: pooled success weighted average (2 RCTs with 122 patients) = 79.5% (95% CI: 69.7, 89.3).

Clinical series: pooled success weighted average (7 case series with 423 patients) = 96.2% (95% CI: 90.3, 102.1).

Medical treatment.
Overall pooled success weighted average (3 studies with 198 patients) = 51.5% (95% CI: 51.7, 71.3).

Surgical treatment.
Overall pooled success weighted average (10 studies with 1,408 patients) = 93.6% (95% CI: 89.7, 97.5). RCTs: pooled success weighted average (3 RCTs with 95 patients) = 91.8% (95% CI: 82.0, 101.6).

Clinical series: pooled success weighted average (7 case series with 1313 patients) = 93.8% (95% CI: 89.9, 97.7).

Authors' conclusions
Expectant management of spontaneous abortion in the first trimester is safe and effective for many afebrile patients whose blood-pressure and heart rate are stable, and who have no excess bleeding or unacceptable pain. Transvaginal sonographic studies might be useful in patient selection, and serial chorionic gonadotropin monitoring should be considered while observing the initial course of expectant treatment. Currently there is insufficient evidence to support medical therapy of spontaneous abortion, and further research is needed to clarify the more limited role of surgical treatment.

CRD commentary
The aims were stated and the inclusion criteria were defined in terms of the participants, interventions, outcomes, and study design. Restricting the included studies to those published in the English language may have resulted in the
omission of other relevant studies, and methods used to select studies were not described. Attempts were made to locate unpublished material. Validity was not formally assessed. Details of the methods used to extract data were provided, and some relevant data were presented in tabular format. Data were pooled with weighting by sample size, and the influence of study design on the results was explored. There may be a misprint in the reporting of pooled success weighted average for medical treatment, since the lower 95% CI for success of medical treatment was greater than the average. Statistical heterogeneity was not assessed, and could not be assessed from the data presented. It was, therefore, not possible to determine whether pooling the data was appropriate. The discussion includes consideration of the following limitations of the review: formal comparison of medical, surgical and expectant treatments was not possible due to the small number of RCTs identified; only three studies evaluated medical treatment; the possibility of selection bias in selecting patients who were bleeding more heavily for surgical rather than expectant treatment; and the estimated pooled weighted averages did not allow statistical comparisons between treatments.

Without an assessment of validity, the quality of the evidence on which the conclusions are based cannot be determined, and without an evaluation of heterogeneity, the generalisability of the results cannot be judged.

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

**Practice:** The authors state that expectant management of spontaneous abortion in the first trimester is safe and effective for many afebrile patients whose blood-pressure and heart rate are stable, and who have no excess bleeding or unacceptable pain. Transvaginal sonographic studies might be useful in patient selection, and serial chorionic gonadotropin monitoring should be considered while observing the initial course of expectant treatment. There is not yet sufficient evidence for medical treatment of incomplete abortion. Surgical treatment is indicated in the presence of continued brisk vaginal bleeding, infection of unacceptable pain and probably for gestation greater than 13 weeks.

**Research:** The authors state that further research is needed to clarify the role of surgical treatment, including comparisons of expectant treatment with surgical approaches in larger RCTs with wider inclusion criteria for transvaginal sonography cut-offs, and patient preference studies incorporating the latest research.

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