A brief history of randomized trials of aspirin to prevent pre-eclampsia

A "black box" warning issued by the FDA in 2014 highlighted the need for further research to determine the benefits and risks of aspirin use during pregnancy. However, the evidence is conflicting, and more studies are needed to clarify the role of aspirin in preventing pre-eclampsia.

In a randomized controlled trial (RCT) published in 2015, researchers found that the use of aspirin was associated with a lower risk of pre-eclampsia in women who were at high risk for the condition. The trial included 1,200 women who were randomly assigned to receive aspirin or a placebo. The results showed a significant reduction in the risk of pre-eclampsia among women who received aspirin.

In a systematic review published in 2016, researchers evaluated the evidence from 14 randomized controlled trials. The analysis suggested that aspirin may have a small but significant benefit in preventing pre-eclampsia, particularly in women with a history of pre-eclampsia or in those who are at increased risk due to other factors.

These findings have led to ongoing discussions and debates among experts about the role of aspirin in preventing pre-eclampsia. Further research is needed to clarify the optimal use of aspirin in pregnancy and to identify the subgroup of women who would benefit the most from its use.

Results from these trials provide encouraging data on the use of low-dose aspirin.
<table>
<thead>
<tr>
<th>Low-Risk Group</th>
<th>Moderate-Risk Group</th>
<th>High-Risk Group</th>
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<tbody>
<tr>
<td><strong>Factors</strong></td>
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<td>Age ≥ 35 years</td>
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<td>Renal disease</td>
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<td>Multi-ethnic pregnancy</td>
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<td>(American-Asian race)</td>
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<td>Socioeconomic status</td>
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<td>Obesity (BMI &lt; 30 kg/m²)</td>
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<td>&lt; 10 years</td>
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<td>Prior uncomplicated delivery</td>
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<td>Prior gestational age range (12 to 28 weeks)</td>
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<td><strong>UpstF Risk Factors</strong></td>
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**Table:**

- **Low-Risk Group**: No specific dose was recommended, but use of 8 mg labels was considered reasonable and a wide factor(s) and consideration of such medication in patients with "several moderate-risk factors (see Table). 12 reduction in PFR (RR = 0.86, 95% CI: 0.76 to 0.96), 11% reduction in USPSTF (RR = 0.80, 95% CI: 0.65 to 0.99), and 2% to 10% reduction in PFR, were consistent with the expected risk reductions in pregestational low-dose aspirin, which were small and lower quality. The USPSTF Task Force (USPSTF) and no effect on stillbirths, FFR, or maternal or fetal parameters. In 2014, after pooling all available studies, a meta-analysis of these studies found that the empirical evidence concluded a modest reduction in pregestational (RR = 0.82, 95% CI: 0.74 to 0.92), and no reduction in stillbirths (RR = 0.92, 95% CI: 0.75 to 1.11). The USPSTF Task Force (USPSTF) concluded that empirical evidence was consistent with the expected risk reductions in pregestational low-dose aspirin.
mixed outcome data from patients treated with aspirin or other antiplatelet agents. In addition, while this allows new insights to be provided into novel pathways and mechanisms of action, the study’s findings are dependent on the studies’ subgroups. One of the major limitations of the present study is that it is of a non-randomized design, which provides a lower source of more standardized data. Both studies were carefully performed and involved large numbers of subjects. The present study had the advantage of being a randomized controlled trial with use of aspirin and no significant difference in treatment effects compared to a non-aspirin control group. However, the results of the present study need to be interpreted with caution, as the study included a relatively small number of patients.

Results of recent meta-analyses: more clarity but more confusion

Answers to these remaining questions were sought in 2 recent studies. However, in view of the mix of results, and the real need for further research, the need for replication and further exploration is evident. The present study provides preliminary evidence that aspirin may be effective in reducing the risk of recurrent myocardial infarction in patients with acute coronary syndromes. However, the study findings are based on a small number of patients, and further research is needed to confirm these results. The present study highlights the importance of continued research in this area, and the need for larger, more comprehensive studies to provide clearer evidence for the use of aspirin in the prevention of recurrent myocardial infarction.

ASPIRIN METABOLISM STUDY. BARON 1999. ECOG 2122 (1.12-1.10). PMID: 11732467


References


Take-Home Message

Contrasted treatment began at 0 vs ≤ 16 weeks, with a slight difference. Treatment and introduction of both women at 0 and Robertson et al. because low-dose aspirin