INAHTA Briefs

Issue 2003/39

Title **Antenatal Screening for Heritable Thrombophilia – August 2002**

Agency **MSAC, Medical Services Advisory Committee**

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Reference MSAC Reference 9B. ISBN 0642 82105 4. January 2003

Aim

To assess screening for heritable thrombophilia, antenatally, in unselected high-risk women (with history of obstetric complications) for safety, effectiveness, and cost effectiveness.

Conclusions and results

No studies have compared a group of women screened antenatally for heritable thrombophilia with a group of unscreened women.

Prevalence and risks associated with heritable thrombophilia. Heterozygous factor V Leiden (FVL), prothrombin, and homozygous MTHFR C677T mutations are relatively common in unselected women, while protein C, S, or antithrombin deficiencies are rare. Limited evidence suggests that unselected FVL carriers are 8 times more likely to suffer venous thromboembolism during pregnancy than non-carriers (absolute risk increase of 1%). They may have a 5-fold increased risk of fetal loss, but this must be confirmed by higher quality studies. No association was found between either FVL or homozygous MTHFR and intrauterine growth restriction. Good quality data on assessing outcomes in high-risk women were unavailable.

Diagnostic accuracy of the tests: No high-level evidence on test accuracy. Protein S deficiency should not be investigated antenatally due to likelihood of inaccurate diagnosis.

Safety and effectiveness of prophylaxis: No substantive evidence that prophylaxis effectively prevents or reduces maternal adverse events in high-risk pregnant women with thrombophilia. Limited level III-2 evidence suggests that heparinization of these women will reduce fetal loss at clinically significant levels. The data on the impact of prophylaxis on perinatal mortality, gestational age at delivery, and intrauterine growth restriction were inconclusive, but improvements were observed in the prophylaxed groups. Good quality, but limited, evidence showed that low-molecular-weight heparinization was associated with nearly 4 times the risk of increased blood loss (>600 ml) during delivery and of postpartum anemia. Good quality data were unavailable on prophylaxis in unselected women.

Cost effectiveness: Costs and consequences of antenatal screening for heritable thrombophilia could not be analyzed since epidemiological or primary research evidence are lacking.

Recommendations

On the strength of evidence on antenatal screening for heritable thrombophilia, public funding should not be supported for systematic screening of all pregnant women. Since the evidence on high-risk women with obstetric indications is insufficient, selective antenatal screening should not receive public funding at this time. This recommendation will be reviewed in 2 years. The Minister for Health and Ageing accepted the recommendation.

Methods

Systematic literature review based on search of MEDLINE, EMBASE, Current Contents, Cochrane Library, SSCI, ProceedingsFirst, internet databases and sites, and reference lists from 1966–2001. Studies were selected using a protocol. Evidence was assessed and classified using dimensions from the National Health and Medical Research Council. Quality was appraised using standard checklists, and clinical importance and relevance of benefit (or harm) were assessed.

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