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Title **First and Second Trimester Antenatal Screening for Down's Syndrome: The Results of the Serum, Urine and Ultrasound Screening Study (SURUSS)**

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Aim

To identify the most effective, safe, and cost-effective method of antenatal screening for Down's syndrome using nuchal translucency (NT), maternal serum, and urine markers in the first and second trimesters of pregnancy, maternal age in various combinations.

Conclusions and results

The false-positive rates (FPR) for an 85% detection rate (DR) were as follows: integrated test 1.2%, serum integrated test 2.7%, combined test 6.1%, quadruple test 6.2%, triple test 9.3%, double test 13.1%, NT measurement 20%. With the serum integrated test, 10 weeks is the preferred time in pregnancy for the PAPP-A measurement. For the integrated test and the combined test this timing is less critical. The lower FPR with the integrated test compared with other tests means that at an 85% DR there would be 9 diagnostic procedure-related unaffected fetal losses per 100 000 women screened compared with 44 using the combined test or 45 with the quadruple test. Screening using the integrated test is less costly because savings in the cost of diagnosis due to low FPR may offset extra screening costs. To achieve an 85% DR, the estimated cost to the UK NHS would be £15 300 per Down's syndrome pregnancy detected. The corresponding cost using the second trimester quadruple test would be £16 800, and using the first trimester combined test it would be £19 000.

Recommendations

Screening performance in the first trimester of pregnancy was similar to that in the second trimester, and in either it was much less effective than integrating screening measurements from both trimesters into a single test. The evidence in this report does not support retaining the double test, the triple test, or NT measurement on its own (with or without maternal age) - each would lead to many more women having invasive diagnostic tests, without increasing the proportion of Down's syndrome pregnancies detected.

Methods

A prospective study of women booked for antenatal care at about 9–13 weeks of gestation, with followup to identify pregnancies with Down's syndrome ascertained through second trimester screening or at birth. NT measurements were included if obtained between 9 and 13 weeks of pregnancy. A pair of serum and urine samples was collected in the second trimester and included if obtained between 14 and 20 weeks. Urine and serum samples from each affected pregnancy and five matched controls were tested. The matching criteria were gestation, duration of storage, and center. Screening performance of individual markers and combinations of markers together with maternal age was assessed by standard methods. Serum samples from 600 controls collected between 9 and 22 weeks' gestation were tested to secure a larger set to determine screening performance using distribution parameters based on dates.

Further research/reviews required

Described in the main report.

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