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First-trimester Down syndrome screening: free beta-human chorionic gonadotropin and pregnancy-associated plasma protein A.

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OBJECTIVE: Our purpose was to determine the feasibility of a first-trimester Down syndrome screening protocol including free beta-human chorionic gonadotropin and pregnancy-associated plasma protein A. **STUDY DESIGN:** First-trimester maternal blood samples from 22 Down syndrome and 483 control cases were assayed for free beta-human chorionic gonadotropin and pregnancy-associated plasma protein A by enzyme-linked immunosorbent assay procedures. False-positive and detection rates were determined on the basis of Down syndrome risks calculated from the levels of biochemical markers and maternal age. Because 11 of the 22 Down syndrome cases were from older pregnancies (> or = 35 years old), rates were recalculated with the United States age distribution of live births to get a more representative estimate of false positives and detection efficiency. **RESULTS:** The median free beta-human chorionic gonadotropin and pregnancy-associated plasma protein A levels in cases of Down syndrome was 2.09 (95% confidence interval 1.69 to 2.62) and 0.405 multiples of the median (95% confidence interval 0.28 to 0.67), respectively. At a 5.0% false-positive rate, 15 (68.2%) Down syndrome cases were detected. By the use of the age distribution of live births, 63% of cases could be expected to be detected at a 5.0% false-positive rate. **CONCLUSION:** First-trimester free beta-human chorionic gonadotropin and pregnancy-associated plasma protein A screening for Down syndrome can achieve detection rates as high as those associated with alpha-fetoprotein and human chorionic gonadotropin or alpha-fetoprotein, human chorionic gonadotropin, and unconjugated estriol screening in the second trimester. Prospective studies are needed to further assess first-trimester screening.