

APPENDIX 2

REPORT OF THE TASK FORCE ON THROMBOEMBOLIC DISORDERS

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A. THROMBOEMBOLISM AND ORAL CONTRACEPTIVES: AN EPIDEMIOLOGICAL CASE-CONTROL STUDY^{1, 2, 3}PHILIP E. SARTWELL, ALFONSE T. MASI,⁴ FEDRICO G. ARTHES,
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The suspicion that oral contraceptives might predispose women toward vascular occlusive phenomena arose about 1961, largely from the publication of case reports. An *ad hoc* committee (1) in 1963 advised that "comprehensive and critical" studies to look into the possibility be conducted. Nevertheless, little was done in this direction, despite the great increase in the use of these potent drugs. By the time the Advisory Committee on Obstetrics and Gynecology of the Food and Drug Administration began to prepare its first report on the oral contraceptives in 1965, it was evident that an epidemiologic study was even more urgently needed than in 1963. The present study was begun in November, 1965, in direct response to this need.

The primary aim of this study has been to evaluate the reported association between taking oral contraceptives and development of thromboembolism. The retrospective (case-control) approach was used. This was appropriate in view of the low incidence for idiopathic thromboembolism at the reproductive ages, which made a prospective approach extremely difficult, costly and slow to yield results. A series of previously hospitalized cases of idiopathic thromboembolism in women of reproductive age was identified, matched controls were secured from among other hospitalized women, and both groups were interviewed to ascertain whether they had used oral contraceptives before the hospitalization.

The term "idiopathic thromboembolism" is used in this report to refer to cases in women who at the time they developed thromboembolism did not have any medical, surgical or traumatic condition that is associated with this disease.

MATERIALS AND METHODS

A pilot study was first conducted at the Johns Hopkins Hospital. Ten suitable cases were found, and 20 matched controls were selected. One finding of the pilot trial was that a high proportion of women, even at these relatively young ages, who were hospitalized with thromboembolism had medical, surgical or traumatic features in their histories that made them ineligible for study. Another important result was that they knew, or at least stated, quite confidently their histories of use of oral contraceptives. This finding was consistent with the opinions of workers who had done surveys of contraceptive practices, and justified proceeding with the study. To be sure, the statements of respondents, although given with assurance in most cases, could have been wrong, but it was not feasible to attempt to verify them from independent sources. The finding of six cases who had used oral contraceptives out of a

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