Oral contraceptives for older women

The Fertility and Maternal Health Drugs Advisory Committee of the US Food & Drug Administration (FDA) recently (October 1989) decided to remove the upper age limit in the USA on oral contraceptive use for healthy, non-smoking women. A year earlier, the American College of Obstetricians & Gynecologists (ACOG) also decided that the Pill was safe for healthy non-smokers up to the age of 45.

History of Pill side-effects

Although it is widely believed that the FDA imposed age restrictions on Pill use, this is not exactly the case. In 1975, Mann and his colleagues published two articles which reported an increased risk of both fatal and non-fatal cardiovascular events (primarily myocardial infarction) in Pill users, especially older ones. (A later article by the same research group reported a relative risk of 3 in women over 40, which was lower than earlier reported.) The FDA then recommended (via the FDA Drug Bulletin, July 1975) that Pill users over 40 be made aware of the increased risk and be urged to use other forms of contraception. This became the first de facto age limit imposed on oral contraceptive users by the FDA. The age limit was included in Contraceptive Technology (5th edition, 1976).

In 1977, the FDA Advisory Committee recommended that labelling be revised to reflect variable risks for smokers and non-smokers. In January 1978, package inserts for users started to include the statement "Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use. This risk increases with age and with heavy smoking and is quite marked in women over 35 years of age. Women who use oral contraceptives should be strongly advised not to smoke." This labelling remains in place today.

Age as a contra-indication to Pill use was first introduced in 1975, while Pill use was first imposed, the incidence of acute myocardial infarction (MI) in Pill users, especially older ones. (A later article by the same research group reported a relative risk of 3 in women over 40, which was lower than earlier reported.) The FDA then recommended (via the FDA Drug Bulletin, July 1975) that Pill users over 40 be made aware of the increased risk and be urged to use other forms of contraception. This became the first de facto age limit imposed on oral contraceptive users by the FDA. The age limit was included in Contraceptive Technology (5th edition, 1976).

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towards family planning practice in the USA. What are the implications of this policy change for other countries? This question has two aspects: are the risks of cardiovascular events likely to be the same elsewhere? How do contraceptive choices vary among countries?

Risks of cardiovascular events vary substantially among countries. The risk of MI is typically low in many Asian countries (probably because of lifestyle differences), intermediate in Africa and Latin America, and highest in the developed countries. Thus the adverse consequences of OC use for cardiovascular disease are less in many (but not all) developing countries than in the USA.

The range of contraceptive options varies among countries. Two methods which are perhaps ideal for older women — Depo-Provera and Norplant — are not available in the USA. Safe abortion is not available in many developing countries, perhaps leading to a greater demand for highly effective contraceptive methods. In the USA, and in many other countries, both developing and developed, sterilization is the most popular method of family planning among older women. Whether the method is popular for its own sake, or as a response to a perceived lack of options, is not known. Experience in providing family planning services tells us that the greater the range of options, the greater the proportion of women who will choose to use contraception.

Conclusion

Finally, it is important to keep in mind that the risks associated with pregnancy are far higher for older women than for younger ones. Older women are more likely than younger ones to choose abortion which, in countries where it is not legal, carries a high risk of morbidity and mortality. The increased risk of congenital malformations in the fetus is well known. Even in developing countries with a low overall obstetric risk, the risk of maternal death is up to 10 times higher for women in their 40s than it is for younger women. In many developing countries the risk of death associated with pregnancy is a very significant one, and must be weighed against any risks associated with contraception.

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