Regular Review

Contraceptive methods: risks and benefits

Despite the large amount of current research into new methods of fertility control,¹ British couples seeking reliable reversible contraception must still choose between the pill, the intra-uterine device (IUD), and one of the occlusive methods. What do we know about the risks and benefits of these different methods, and how can we use this information to counsel those seeking advice?

Contraceptive pills containing a progestogen alone have never been widely used and accordingly have not been the subject of epidemiological investigation. They will not be considered further in this article, and the terms "the pill" and "oral contraceptives" will refer to combined preparations in what follows.

The well-established major adverse effects of oral contraceptives are principally on the cardiovascular system—deep-vein thrombosis, pulmonary embolism, hypertension, stroke (both thrombotic and haemorrhagic), and acute myocardial infarction. In addition, however, use of the pill may lead to hepatocellular adenoma, gall bladder disease, and cervical erosion: while there may be temporary impairment of fertility after ceasing medication. On the credit side, pride of place must go to the high degree of efficacy and acceptability of the pill, but there are also non-contraceptive beneficial effects, notably suppression of menstrual disorders (resulting in a reduced risk of iron deficiency anaemia), fewer benign lesions of the breast (especially chronic cystic disease), and fewer retention cysts of the ovary. The recent suggestion from the Royal College of General Practitioners study that women using the pill may be at reduced risk of rheumatoid arthritis awaits confirmation.²

As far as malignant disease is concerned a World Health Organisation Scientific Group³ reviewed the epidemiological evidence in December 1977 and concluded that there was no clear indication of a relationship, either positive or negative, between using the pill and any form of cancer (though cancer of the body of the uterus may have been produced by the unopposed oestrogens in sequential preparations). While several reports have suggested that oral contraceptives taken inadvertently during (or even just before) pregnancy might increase the incidence of birth defects the evidence is uneven and difficult to interpret and the risk cannot be regarded as substantiated.⁴

Women relying on an IUD run a greater risk of accidental pregnancy than do those using the pill; and such pregnancies are especially likely to be extrauterine or to end in spontaneous abortion. Furthermore, work done in the United States⁵ has shown that spontaneous abortions occurring in women with an IUD in situ (especially a Dalkon Shield) are more likely than usual to be complicated by infection, which very occasionally is fatal for the mother. Women using an IUD also tend to experience an increase in menstrual disorders (and, consequently, iron deficiency anaemia) and pelvic inflammatory disease. Occasionally, insertion of an IUD is followed by uterine perforation and migration of the device into the peritoneal cavity; serious complications, such as intestinal

obstruction, may then follow, especially if the device is a copper-bearing one.

In general, occlusive methods of contraception are less effective than either the pill or the IUD, though highly motivated users may achieve remarkably good results. There is now reasonably firm evidence that use of the diaphragm (and, presumably, the condom) offers some protection from the risk of preinvasive carcinoma of the cervix,⁶ while wearing a condom certainly reduces the chance that a man will acquire gonorrhoea from his partner.⁷ The suggestion that pressure of the rim of the diaphragm on the female urethra increases the risk of urinary tract infection remains to be confirmed.⁸

Reasonably reliable information about the magnitude of most of the known hazards and benefits of the pill, the IUD, and occlusive methods of contraception is now available from two large British prospective studies, both of which started in 1968 and are still in progress. In the study by the Royal College of General Practitioners⁹ 23 000 users of the pill aged 15-49 years together with a similar number of controls using other methods or no method of contraception were brought under observation by 1400 general practitioners. During follow-up doctors record the diagnoses of episodes of illness, oral contraceptive prescriptions, and information about pregnancies and deaths. In the Oxford University-Family Planning Association study,⁸ 17 000 women aged 25-39 years using the pill, the diaphragm, or an IUD were recruited at one or other of 17 large family planning clinics. During follow-up information is collected about changes in contraceptive methods, pregnancies and their outcome, hospital attendances (outpatient and inpatient), deaths, and the results of cervical smears. From the two studies, morbidity data collected during about 150 000 woman-years of observation and mortality data collected during about 290 000 woman-years of observation have now been published.⁸⁻¹¹

Vessey and Doll¹² have used the morbidity data derived from these two studies to make comparisons between the different reversible methods of contraception. They used a very simple model, merely contrasting the experience of 100 000 women using the pill, 100 000 using an IUD, and 100 000 using a diaphragm, all of whom wanted to avoid pregnancy, during one year. Because the morbidity data obtained in the prospective studies had been published in the form of age-standardised rates, they were obliged to consider "women of child-bearing age" in their analysis. Looking first at non-obstetric morbidity, they concluded that the increased risk to oral contraceptive users of gall-bladder disease and cervical erosion was roughly offset by the reduced risk of benign lesions of the breast and ovary and of menstrual disorders. Hence it seems fair to focus particular attention on the increased risk of cardiovascular disease and hepatocellular adenoma in pill users, and of major gynaecological disease in IUD users. In considering obstetric morbidity, Vessey and Doll pointed out that it was necessary to take into account both the efficacy of the different methods of contraception and the outcome of the unplanned

pregnancies; accordingly, they produced a series of different estimates based on various sets of assumptions.

To provide some illustrative figures, let us assume that the failure rate experienced by women using the pill is 0.36 pregnancies per 100 woman-years (as observed in the RCGP study) and that the corresponding failure rates for users of the IUD and the diaphragm are 2 and 5 per 100 woman-years (these are reasonable representative figures for well-motivated women). Let us also assume that the outcome of unplanned pregnancies in users of different methods is as observed in the Oxford study, and that the cancelling-out of certain of the risks and benefits in pill users referred to in the last paragraph is valid. The 100 000 pill users would then have an excess of about 35 hospital admissions for stroke, 70 for venous thrombosis and embolism, and 10 for acute myocardial infarction. Data from the United States³ suggest that perhaps three admissions would be expected for hepatocellular adenoma also, but no such cases have yet been observed in the British prospective studies. On the obstetric side, our 100 000 pill users would experience 360 accidental pregnancies, of which 200 would result in a term birth, 45 in a spontaneous abortion, one in an ectopic gestation, and 94 in a termination. The 100 000 IUD users, on the other hand, would have about 50 admissions for uterine perforation and an excess of about 200 admissions for pelvic inflammatory disease. In addition, 2000 accidental pregnancies would be expected, of which 495 would result in a term birth, 775 in a spontaneous abortion, 120 in an ectopic gestation, and 605 in a termination. Our 100 000 users of the diaphragm would suffer no excess non-obstetric morbidity but would have 5000 accidental pregnancies, of which 3045 would end as a term birth, 640 as a spontaneous abortion, 20 as an ectopic gestation, and 1295 as a termination.

Similar calculations can be carried out on patterns of mortality. In addition, however, mortality data are available for different age groups. For women aged 20-34 years, the sum of the mortality attributable to the method and that attributable to accidental pregnancies is very low for each method of contraception (2-4 deaths per 100 000). For those aged 35-44 years, however, the pill compares unfavourably with the other methods: the approximate total attributable mortality per 100 000 for pill users is 20, for IUD users 2, and for diaphragm users also 2.

Simple analyses of the sort just described, while of value in providing crude comparisons between contraceptive methods, are subject to many limitations. Firstly, some of the morbidity estimates and all of the mortality estimates are based on small numbers of events and therefore subject to considerable sampling error. Secondly, restricting the analysis to counting deaths, hospital admissions, and obstetric events is very inadequate. To give just one example, this type of approach cannot take into account the anguish of a woman of 40 with grown-up children, well established in a good job, who finds herself accidentally pregnant and who cannot accept termination of pregnancy because of her religious beliefs. Thirdly, most of the data accumulated in the two British prospective studies relate to oral contraceptives containing 50 µg of oestrogen. Lower-dose preparations have now captured more than half the market and may be associated with lower risks. Furthermore, the progestogenic component of the pill is important; the RCGP study,¹³ for example, showed that the risk of hypertension increases, and the risk of benign breast disease decreases, with the dose of norethisterone acetate. Fourthly, at least some of the risks (and benefits) associated with oral contraception are related to duration of use—this is certainly so for hepatocellular adenoma, for

example.³ Fifthly, the risks of oral contraceptives (and probably IUDs as well) vary with the characteristics of the user—some account of this has been taken in the mortality analysis by subdividing the data by age, but the interaction between cigarette smoking and acute myocardial infarction has not been taken into consideration, to give but one example. Moreover, most of the estimates relate to healthy women—little is known about the hazards of the pill in those with diabetes, hypertension, and so on. Sixthly, the model is artificial, since not all methods of contraception are acceptable to all women. Furthermore, it has been assumed that the women continue with the initial method. This is certainly unrealistic, since roughly 30% of women choosing the pill and 15% of women choosing an IUD give up in the first year. Finally, the model applies principally to couples concerned with the problems of birth spacing who want to use reversible methods of contraception. For those who have completed their families and who seek to avoid further births at any time male sterilisation is the safest method, since vasectomy is associated with little morbidity and virtually no mortality. Female sterilisation is preferable to the continued use of reversible methods of contraception,¹⁴ though the procedure is not without hazard. Needless to say, it gives the best results in terms of morbidity and mortality if it is carried out at a reasonably young age (say, 35 years rather than 45 years).

Despite the substantial knowledge we now have about the risks and benefits of different methods of contraception, at least in the short and medium term, counselling the individual seeking advice still requires a considerable amount of experience and judgment on the part of the counsellor. Furthermore, the data discussed here have been derived largely from British studies; it would be quite wrong to extrapolate them to countries with a different pattern of disease and different risks associated with childbearing.

M P VESSEY

Professor of Social and Community Medicine,
University of Oxford

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³ World Health Organisation, Steroid contraception and the risk of neoplasia. *World Health Organisation Technical Report Series no 619.* Geneva, World Health Organisation, 1978.

⁴ Ambani, L M, et al, Are hormonal contraceptives teratogenic? *Fertility and Sterility*, 1977, **28**, 791.

⁵ Cates, W, et al, The intrauterine device and deaths from spontaneous abortion, *New England Journal of Medicine*, 1976, **295**, 1155.

⁶ Wright, N H, et al, Neoplasia and dysplasia of the cervix uteri and contraception; a possible protective effect of the diaphragm, *British Journal of Cancer*, 1978, in press.

⁷ Barlow, D, The condom and gonorrhoea, *Lancet*, 1977, **2**, 811.

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⁹ Royal College of General Practitioners, *Oral Contraceptives and Health.* London, Pitman Medical, 1974.

¹⁰ Royal College of General Practitioners, Mortality among oral-contraceptive users, *Lancet*, 1977, **2**, 727.

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¹³ Royal College of General Practitioners, Effect on hypertension and benign breast disease of progestagen component in combined oral contraceptives, *Lancet*, 1977, **1**, 624.

¹⁴ Tietze, C, Bongaarts, J, and Schearer, B, Mortality associated with the control of fertility, *Family Planning Perspectives*, 1976, **8**, 6.