Are routine breast and pelvic examinations necessary for women starting combined oral contraception?

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Millions of women worldwide use combined oral contraception (COC). Most of them are in good health and have no contraindications to using any contraceptive method. Although extremely safe for the vast majority of women and even though the absolute risk of complications is very small, COC is associated with an increased relative risk of serious conditions including cardiovascular disease and breast and cervical cancer. In many countries, breast and pelvic examinations are routinely undertaken annually for all women using hormonal contraception. Breast and pelvic examination have low detection rates for abnormality and may yield clinically irrelevant results, causing anxiety and inconvenience to the patient for no obvious gain. There is no good evidence to support routine breast or pelvic examination either for women starting hormonal contraception or for monitoring long-term use.

Key words: breast/contraception/hormonal/pelvic/screening

Introduction

Millions of women worldwide use hormonal contraception. Most of them have no contraindications to using any contraceptive methods including hormonal methods. Combined oral contraception (COC) is not, however, without risk. The risks include venous thromboembolism and cerebrovascular accident [World Health Organization (WHO, 1998)], myocardial infarction (Khadra et al., 2003), cervical cancer (Smith et al., 2003) and breast cancer (Collaborative Group on Hormonal Factors in Breast Cancer, 1996). For most women the absolute risk of any of these complications occurring is extremely small. However, when serious complications do occur it is devastating.

The additional risks of hormonal contraceptive use for women with pre-existing medical conditions (such as diabetes or hypertension) are well recognized, but the vast majority of women have no medical problems and they are young. In Europe the use of oral contraception declines quite rapidly after the age of 35 years (Table I). The over-riding concern of providers in Europe is to recognize, among healthy women, those who may be at risk of the rare but serious complications of hormonal contraception. Exactly which of these women will develop a complication is almost impossible to predict. Mostly we rely on identifying women who have other risk factors associated with the conditions of concern (e.g. smoking associated with cardiovascular disease or family history associated with breast cancer), and either informing them of the increased risks or advising them not to use COC. Taking a careful history (including family history) and observing obvious physical characteristics (such as obesity) provide much useful information and the measurement of blood pressure is routine. In some settings, however, detailed physical examination and a variety of blood tests have also become routine before starting a woman on a hormonal method of contraception, and while monitoring her use of it. In the USA, Japan and in some European countries, it is common practice to examine a woman’s breasts and pelvis prior to commencing hormonal contraception and to repeat these examinations annually. The contraceptive consultation is often seen as an opportunity to undertake other screening procedures such as the measurement of serum cholesterol or mammography and there is a danger that these too become part of routine screening for hormonal contraception.

The WHO (2002) distinguishes examinations and investigations that are essential for safe prescribing of contraception from those that ‘do not contribute substantially to safe and effective use of the contraceptive method’ but which are commonly done.

This paper reviews the evidence for undertaking routine breast and pelvic examination in women intending to use, or using, hormonal contraception.

Clinical breast examination

Breast cancer is the commonest malignancy in women in the developed world, accounting for some 18% of all female cancers. In the UK almost 20% of deaths among women aged 40–50 years are due to breast cancer (McPherson et al., 2000). Although women are much more likely to die from cardiovascular disease, they worry a lot about breast cancer. They often
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Table I. Percentage of women using oral contraception according to age

<table>
<thead>
<tr>
<th>Study</th>
<th>Age (years)</th>
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<tr>
<td>Italy</td>
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<tr>
<td>Oddens (1996)</td>
<td>30</td>
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<tr>
<td>France</td>
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<td>Toullemon and Leridon (1998)</td>
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<td>Larsson et al. (1997)</td>
<td>47</td>
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<tr>
<td>Oddens and Milsom (1996)</td>
<td>57</td>
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<tr>
<td>UK</td>
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<td>Oddens et al. (1994)</td>
<td>53</td>
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Data have been taken from a number of published European surveys.

*Value not published.

worry too about the relationship between hormonal contraception and breast cancer. There is a widespread belief that risk factors can be used as a screening tool for disease. Current or recent COC use is a risk factor for breast cancer (Collaborative Group on Hormonal Factors in Breast Cancer, 1996) but not a strong one [relative risk (RR) = 1.24]. Being elderly (RR > 10), living in a developed country (RR = 5), menarche before age 11 years (RR = 3), delaying childbearing until aged >40 years and excessive alcohol consumption (RR = 3) are all much stronger risk factors than taking the pill (McPherson et al., 2000). However, even strong risk factors do not necessarily make good screening tests (Wald et al., 1999).

The main justification for breast examination prior to starting hormonal contraception is to exclude pre-existing conditions that contraindicate its use or those that would be worsened by it. Benign breast disease is not regarded as a contraindication to the use of hormonal contraception, indeed the WHO (2004) regards benign breast disease as a category 1 condition (no restrictions for use of the method: it can be used in any circumstances). Furthermore there is some evidence that use of the COC pill is associated with a reduced risk of benign breast disease (Tzingounis et al., 1996; Rohan and Miller, 1999).

In contrast to benign disease, breast cancer is regarded as a contraindication (category 4) to all forms of hormonal contraception since these agents may enhance the progression of the disease. However, most women using hormonal contraception are young and at extremely low risk of breast cancer. In Scotland, there were only 161 cases of breast cancer in women aged <30 years between 1990 and 1999. The total number of breast cancers in all age groups during the same period was 33 190 (Scottish Cancer Intelligence Unit, 2003). Fewer than 18 women in every 10 000 at age 35 years will develop breast cancer, and the risk in younger women is even smaller. To undertake 10 000 breast examinations to detect 18 cancers is not cost-effective. Furthermore, even were clinical breast examination to be undertaken for all these women, not all of the 18 cancers would be detected. The Forrest Report (Department of Health and Social Security Working Group on Breast Cancer Screening, 1986) demonstrated that clinical examination alone was relatively ineffective in detecting tumours and in reducing mortality from breast cancer. The report calculated that 175 000 women would have to be screened by clinical examination in order to detect one case of breast cancer in women aged 20–24 years. The United Kingdom Trial of Early Detection of Breast Cancer Group (1992) confirmed the findings of the Forrest Report, demonstrating that the probability of a woman with a positive finding on clinical examination of the breast actually having cancer is only 2%. This trial included women aged 45–64 years. Since the population using hormonal contraception is substantially younger than this and the incidence of breast cancer even lower, the positive predictive value will be even less.

Despite much evidence against it, use of clinical breast examination as a screening tool for breast cancer remains controversial. In a recent review (Zoorob et al., 2001) of cancer screening guidelines published by seven professional organizations in North America, six of them mention clinical breast examination (CBE) in their guidelines. Two (including the Canadian Task Force on Preventive Healthcare, CTFPHC) recommend CBE from age 50 years, one from age 40 years, one from age 20 years, and one does not specify an age range in the guideline. However, the Centre for Chronic Disease Prevention and Control in Canada found that inclusion of CBE in an organized screening programme contributed ‘minimally’ to early detection. They made no comment regarding the incidence of false positive findings. The US Preventive Services Task Force (USPSTF) states that there is ‘insufficient evidence to recommend for or against using clinical breast examination alone’ and recommends it as an optional procedure for women aged >50 years. The authors of the review point out that only the CTFPHC and the USPSTF (both of which recommend CBE only in women >50 years) base their recommendations on explicit methodology for evaluating and weighing the strength of the evidence. The other professional organizations use literature review and expert opinion. It should be remembered that many of the members of professional organizations in countries where there is a ‘fee for service’ type of reimbursement have a financial interest in recommending regular health checks. Additionally, fear of potential litigation increasingly drives practice, particularly in the USA.

Routine breast examination cannot be justified for young women who are starting the pill, nor should it be used as part of routine monitoring once they are established on hormonal contraception. Certain clinicians (Stewart et al., 2001) will continue to...
argue that it should be done selectively (perhaps for women > 35 years), mainly because the pill is inextricably linked to breast cancer in the minds of both providers and users, and both find regular examinations reassuring. Not only may CBE provide false reassurance, but many women (especially younger women) find it invasive and thus may be deterred from attending for contraception. Any abnormality found on examination causes great anxiety and leads to costly and invasive investigations as a result of referral to specialists. Breast examination should be targeted according to personal history; if a woman complains of breast symptoms she should be examined, but not if she is asymptomatic.

Breast self-examination

In addition, women using hormonal contraception should not be advised to undertake regular breast self-examination, which has been widely advocated on the assumption that it can do no harm and must do good. However, the majority of breast lumps are detected during everyday activities such as washing and dressing. A large trial in Shanghai of > 250,000 women showed breast self-examination to be ineffective (Thomas et al., 2002). One group of women had intensive instruction, supervision and reminders regarding breast self-examination, yet there was exactly the same rate of breast cancer deaths in these women as in the group who were not educated about breast self-examination. More than that, breast self-examination can do harm. Women in the breast self-examination group had more surgical biopsies (3627 versus 2398). A recent Cochrane review (Kosters and Gotzsche, 2003) concluded that data from two large randomized trials do not demonstrate any benefit. On the contrary, there is evidence of harm in respect of generating anxiety and referral. The only recommendation that can be made in relation to breast disease and the use of hormonal contraception is that it is good clinical practice to discuss breast awareness with all women, especially those aged > 40 years.

Imaging of the breast

Since clinical breast examination cannot be recommended, it follows that imaging techniques such as mammography or breast ultrasound should not be considered for routine assessment of women using COC.

Pelvic examination

Pelvic examination is even more likely than breast examination to be considered a screening and monitoring tool for hormonal contraceptive users, particularly when the provider is a gynaecologist. Indeed in some countries annual pelvic examination is regarded as an important routine ‘health check’ whether or not contraception is being used. Pelvic examination is often used in conjunction with a Papanicolaou test for screening for cervical cancer. It may detect other cervical abnormalities such as ectropion or polyps; uterine pathology such as fibroids; or ovarian enlargement. Pelvic examination can also diagnose some genital tract infections, (such as candida, warts and syphilitic chancre) and pregnancy.

Cervical cancer is the second most common malignant disease among women, although nearly 80% of cases arise in developing countries (Waggoner, 2003). Although the median age of diagnosis is in the fifth decade, nearly half the cases diagnosed each year in North America are diagnosed before the age of 35 years. Cervical cancer is strongly associated with human papilloma virus (HPV) which is sexually acquired. In developed countries, macroscopic cervical cancer is a rare finding; most cancers are diagnosed at the pre-malignant stage (cervical intraepithelial neoplasia). Pelvic examination without cytological screening will miss CIN. Most organizations do not recommend pelvic examination as part of routine cervical screening. In the review of North American cancer screening guidelines (Zoorob et al., 2001) all organizations recommend regular Papanicolaou tests for screening for cervical cancer, but only two recommend pelvic examination in addition (the American College of Obstetricians and Gynecologists and the American Medical Association). While women using hormonal contraception are sexually active and while COC use certainly increases the risk of cervical cancer (Smith et al., 2003), especially in the presence of persistent HPV infection, pelvic examination to diagnose cervical cancer cannot be recommended as a screening test for hormonal contraception. Nor should it be used as a monitoring tool for women already using the method.

While visual inspection of the cervix will diagnose endocervical polyps (if they are visible at the os) and cervical ectropion, and while both are probably associated with use of COC, they are benign conditions which seldom cause symptoms (Critchlow et al., 1995). While a woman with symptoms suggestive of either ectropion or polyp (such as post-coital bleeding) should have a pelvic examination, neither condition warrants routine screening.

Uterine pathology is relatively uncommon in young women. Prevalence estimates for fibroids vary. Among a random sample of Swedish women screened using transvaginal ultrasound, the prevalence of fibroids was 3.3% at age 25–32 years and 7.8% at age 33–40 years (Borgfeldt and Andolf, 2000). A study among US women identified the presence of fibroids among almost 70% of white women by the age of 50 years (Baird et al., 2003). The Swedish study reported that uterine size was significantly smaller among women on the COC pill than in women with natural cycles. Furthermore a number of studies have suggested that the prevalence of fibroids is reduced among oral contraceptive users (Ross et al., 1986; Parazzini et al., 1988; Marshall et al., 1998). Whatever the prevalence of fibroids, the WHO (2004) regards uterine fibroids as category 1 for all hormonal contraception and states that oral contraceptive use has no effect on fibroid growth. Even if fibroids were diagnosed on pelvic examination, unless the woman was symptomatic no treatment or further investigation would be indicated. Uterine fibroids rarely transform to malignancy.

Pelvic examination may detect ovarian and uterine tumours, but ovarian and endometrial cancer tend to be diseases of postmenopausal women and the COC pill is associated with a reduction in risk (Beral et al., 1999). In Scotland there were 143 cases of cancer of the ovary in women aged < 30 years between 1990 and 1999, out of a total of 6061 cases in all age groups (Scottish Cancer Intelligence Unit, 2003). Pelvic examination has a low specificity for detecting ovarian enlargement when used without ultrasonography (Jacobs et al., 1988; Grover and Quinn, 1995). A positive finding on pelvic examination may not necessarily benefit the patient. For example, simple functional ovarian
cysts do not require treatment unless symptomatic and they often resolve spontaneously. Diagnosis of an ovarian cyst inevitably leads to repeat ultrasound examinations and often to surgery with attendant risks and costs.

Sexually transmitted infections (STI) are common among young sexually active women, many of whom use hormonal contraception. Genital examination, including pelvic examination, is not recommended as a screening tool for STI (including HIV) or pelvic inflammatory disease. Diagnosis of any of these conditions would nonetheless be in the woman’s best interest, aside from her contraceptive needs. Symptomatic infections and sexual lifestyles associated with an increased risk of STI should be evident from the woman’s history, which should be taken routinely prior to provision of contraception. Symptomless infections, such as Chlamydia trachomatis, will not be detected by clinical examination.

Very early pregnancy is difficult to diagnose on clinical examination and can usually be more accurately excluded by a menstrual history or laboratory pregnancy testing. Unless pregnancy is suspected on clinical grounds, pelvic examination should not be performed.

Thus it is hard to make the case for routine pelvic examination which, as with breast examination, may often yield false positive results causing needless anxiety and leading to more expensive and invasive investigations.

Some women, especially young women, find breast and pelvic examinations embarrassing (Larsen and Kragstrup, 1995) and may be deterred from starting hormonal contraception if examination is perceived as an essential prerequisite. One study undertaken in the USA (where pelvic examination has been regarded as mandatory) demonstrated a clear benefit, in respect of uptake of more effective methods of contraception and increased use of services, when pelvic examination was omitted from routine assessment of women attending for family planning advice (Harper et al., 2001). A careful history will identify most risk factors for serious disease and allow further discussion and appropriately targeted further examination and investigations if necessary. The current WHO recommendations indicate that only blood pressure measurement is necessary prior to prescription of hormonal contraception.

References


Scottish Cancer Intelligence Unit (2003) ISD, NHS, Scotland.


