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Review article

Physical examination prior to initiating hormonal contraception: a systematic review☆

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Abstract

Background: Provision of contraception is often linked with physical examination, including clinical breast examination (CBE) and pelvic examination. This review was conducted to evaluate the evidence regarding outcomes among women with and without physical examination prior to initiating hormonal contraceptives.

Study Design: The PubMed database was searched from database inception through March 2012 for all peer-reviewed articles in any language concerning CBE and pelvic examination prior to initiating hormonal contraceptives. The quality of each study was assessed using the United States Preventive Services Task Force grading system.

Results: The search did not identify any evidence regarding outcomes among women screened versus not screened with CBE prior to initiation of hormonal contraceptives. The search identified two case–control studies of fair quality which compared women who did or did not undergo pelvic examination prior to initiating oral contraceptives (OCs) or depot medroxyprogesterone acetate (DMPA). No differences in risk factors for cervical neoplasia, incidence of sexually transmitted infections, incidence of abnormal Pap smears or incidence of abnormal wet mount findings were observed.

Conclusions: Although women with breast cancer should not use hormonal contraceptives, there is little utility in screening prior to initiation, due to the low incidence of breast cancer and uncertain value of CBE among women of reproductive age. Two fair quality studies demonstrated no differences between women who did or did not undergo pelvic examination prior to initiating OCs or DMPA with respect to risk factors or clinical outcomes. In addition, pelvic examination is not likely to detect any conditions for which hormonal contraceptives would be unsafe.

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Keywords: Physical examination; Clinical breast examination; Pelvic examination; Hormonal contraception; Systematic review

1. Introduction

Unintended pregnancy continues to be a significant problem in the United States, with 50% of pregnancies being unintended [1]. Approximately 4.5 million women are at risk for unintended pregnancy but are not using contraception [2]. Increasing access and reducing unnecessary barriers to contraception are important measures in the effort to reduce unintended pregnancy. Many health care providers require physical examination prior to provision of contraceptives [3,4]. Such examinations are often linked to contraceptive encounters with the rationale that the contraceptive visit provides a good opportunity to perform other necessary physical examinations and counseling. However, requirement of physical examination may represent a logistical, emotional or economic barrier to contraceptive access for some women, particularly adolescents and low-income women, who have high rates of unintended pregnancies [1,5,6]. Systematic reviews were conducted to evaluate the evidence regarding outcomes among women with and without physical examination, including clinical breast examination (CBE) and pelvic examination, prior to initiating hormonal contraceptives.

☆ Disclaimer: The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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2. Methods

We searched the PubMed database for all peer-reviewed articles in any language published from database inception through March 2012. The search strategies are shown in Appendix A. References from identified articles were hand-searched to identify any additional relevant articles. Abstracts of conference presentations and unpublished studies were not considered.

2.1. Study selection

Because women with breast cancer should not use hormonal contraceptives, we sought direct evidence comparing adverse health outcomes among women who were screened versus not screened with CBE prior to initiation of hormonal contraceptives. For pelvic examination, all hormonal contraceptives were considered, with the exception of the levonorgestrel-releasing intrauterine device, as pelvic examination is essential for insertion [7]. We considered studies that assessed risk factors or adverse health outcomes in women without pelvic examination prior to contraceptive initiation compared to women with pelvic examination.

2.2. Study quality assessment and data synthesis

The evidence was summarized and systematically assessed by all authors. The quality of each individual piece of evidence was assessed using the United States Preventive Services Task Force grading system [8]. Summary measures of association were not computed.

3. Results

For CBE and hormonal contraception, our search strategy identified 46 articles. After reviewing the titles and abstracts of these articles, as well as the full articles when necessary, no articles were identified with direct evidence pertaining to these searches. For pelvic examination and hormonal contraception, the search strategy identified 391 articles, of which two met inclusion criteria (Table 1) [6,9]. Both studies described programs which offered contraceptives without pelvic examination and compared outcomes to a group of women who underwent pelvic examination or were seen in traditional clinic settings. The programs offered oral contraceptives (OCs) not further specified [6,9] and one program additionally offered depot medroxyprogesterone acetate (DMPA) [9]. Outcomes assessed included risk factors for cervical neoplasia [9] and incidence of sexually transmitted infections (STIs) or abnormal Pap smears or wet mounts [6].

In a retrospective cohort study describing the Smart Start program conducted in Pennsylvania, all consenting non-pregnant teens under the age of 18 years were eligible to delay pelvic examination while receiving two 3-month supplies of OCs and/or non-prescription contraceptives [6]. Out of 390 teens who visited the three participating clinics, 197 were followed with telephone survey at 8 months, and 151 underwent medical record review to verify clinical outcomes. Among those 151 teens, 40 had elected to delay pelvic examination and 111 had received pelvic examination with contraception initiation. Medical record data from all clinic visits in the 7-month period after the first visit showed no significant differences in the incidence of gonorrhea, chlamydia, syphilis, abnormal Pap smear, or abnormal wet mount between those who delayed and those who underwent pelvic examination at baseline; however incidence rates and p values were not reported.

The other retrospective cohort study examined the First Stop program in California [9]. In 7 nonclinical locations, 2 hormonal contraceptives (OCs and DMPA) were offered without pelvic examination, with referral to traditional clinics if needed for other family planning or reproductive health reasons [5]. A comparison of medical records was conducted between a random subset of 400 women who sought contraception at the nonclinical locations matched by age, race and contraceptive method to 400 women who received contraceptives at traditional clinics. The vast majority of providers at the traditional clinics required that women undergo pelvic examination prior to initiating contraception [10]. Among all study participants, 71% were using OCs and 29% were using DMPA. No statistically significant differences were found between the group of women receiving contraception at the nonclinical locations compared with the group at the traditional clinic in certain risk factors for cervical cancer (history of abnormal Pap smears, history of STIs, early age at first intercourse, multiple partners and smoking).

4. Discussion

4.1. Clinical breast examination

Because women with breast cancer should generally not use hormonal contraceptives, an important question is whether screening should be performed prior to initiating these methods. The US Medical Eligibility Criteria for Contraceptive Use, 2010 (US MEC) states that hormonal methods should not be used by women with current breast cancer (US MEC 4) and should generally not be used by women with previous breast cancer (US MEC 3) [11]. Breast cancer is a hormonally sensitive cancer and there is theoretical concern that concurrent use of hormonal contraceptives could worsen the disease or prognosis. However, the effect of hormonal contraceptives on undiagnosed breast cancer is not known [12].

In addition, the yield of CBE in women prior to contraceptive use is uncertain. Overall, the proportion of breast cancer diagnosed among women of reproductive age is relatively small. From 2004–2008, the percent of breast cancers diagnosed among women less than 45 years of age

Table 1
Evidence for outcomes among women screened and not screened with pelvic examination prior to initiation of hormonal contraceptives

Author, year, location	Study design	Population	Hormonal contraceptive type(s)	Outcomes	Results	Strengths	Weaknesses	Quality
Armstrong and Stover [6], 1994 United States	Retrospective cohort	*Smart Start* program offered in Title X funded clinics; teens ages <18 years offered OCs and non-prescription contraceptives, option to delay pelvic exam up to 6 months 151 teens who completed initial and 8 month follow-up surveys and had medical record review: - 40 who delayed pelvic exam - 111 who did not delay pelvic exam	OCs	Incidence of STIs, abnormal Pap, abnormal wet mount results	No significant differences between delay and no delay groups in incidence of gonorrhea, syphilis, chlamydia, abnormal Pap smear, or abnormal wet mount results (p values not reported).	Reported distribution of covariates at baseline Medical record verification of clinical outcomes	Determination of subjects selected for 8-month follow-up not specified (197 out of 390 total) Small number who delayed pelvic exam Percentages and p values not reported for outcomes of interest Did not adjust for potential confounders	II-2, fair
Sawaya et al. [9], 2001 United States	Retrospective cohort	*First Stop* project operated in 7 nonclinical locations; offered OCs, DMPA, condoms and other over-the-counter methods, did not offer pelvic exam [5] Women randomly selected by computer and matched on age, race, and contraceptive method: - 400 *First Stop* clients - 400 traditional clinic clients	OCs, DMPA	Differences in risk factors for cervical neoplasia	Risk factors for cervical neoplasia compared between *First Stop* and traditional clinic clients: Characteristic / First Stop *N* (%) / Traditional *N* (%) / p value Previous abnormal Pap: 29 (7.4) / 28 (7.2) / 0.90 <16 years at first intercourse: 69 (24.7) / 58 (23.3) / 0.70 History of STIs: 32 (8.2) / 38 (9.6) / 0.48 Current multiple sex partners: 22 (7.9) / 24 (7.4) / 0.82 Parity ≥3: 103 (27.8) / 57 (16.8) / 0 Current cigarette smoking: 34 (8.9) / 49 (12.4) / 0.12 History of abnormal Pap plus at least one other risk factor above: 21 (5.2) / 20 (5.0) / 1.00	Sample size sufficient as assessed by power calculation to detect 5% difference in history of abnormal Paps Medical record review for risk factors	Type of OCs not specified Small numbers with certain risk factors for comparisons Did not adjust for potential confounders	II-2, fair

Abbreviations: DMPA, depot medroxyprogesterone acetate; OC, oral contraceptive; STI, sexually transmitted infection.

was approximately 12%, and the percent of breast cancer deaths occurring in this age group was approximately 7% [13]. One study reported the prevalence of breast disorders among women who had CBE performed annually at a family planning clinic [14]. Among 13,456 women examined during a 5-year period, only 12 women had invasive carcinoma, none in women less than 35 years of age and 10 of the 12 in women greater than 40 years of age. Few studies have examined the accuracy of CBE alone as a screening modality for breast cancer. One study found that among women ages 40–49 years screened with CBE alone, the positive predictive value was only 5%, signifying that most of the women with positive findings referred for additional testing did not have breast cancer [15]. This predictive value may decrease even further among younger women, in whom the disease prevalence is lower [16]. In fact, there is evidence that CBE may lead to harm, either in unnecessary additional testing (e.g., false positives) or delay in cancer diagnosis (e.g., false negatives) [13].

4.2. Pelvic examination

The systematic review indicates that, within the two demonstration projects, women who obtained contraceptives without pelvic examination had similar risk factors for cervical cancer and similar rates of STIs, abnormal Pap smears and abnormal wet mount results when compared to women who did not delay the pelvic examination or who obtained contraceptives at traditional clinics. A strength of the studies is that both utilized medical record review to identify and verify outcomes. The studies are of fair quality and are subject to several limitations. In one study, it was not specified how subjects were selected for follow-up [6]. In the other study, it is not stated whether all women in the comparison group underwent pelvic examination prior to contraceptive initiation [9], although the vast majority of providers at the traditional clinics required pelvic examination prior to contraception initiation [10]. In addition, both studies included small numbers of women for comparisons and one study did not report percentages or p values for clinical outcomes of interest [6].

Two considerations exist for the need to link pelvic examination with provision of hormonal contraceptives: (1) to identify women who should not use hormonal contraceptives, and (2) to monitor possible effects of hormonal contraceptives on other health conditions [12]. According to the US MEC, the conditions for which women should not use (US MEC 4) or generally should not use (US MEC 3) hormonal contraceptives include breast cancer, hypertension, heart disease, vascular disease, smoking and age ≥ 35, migraine headaches with aura and certain liver diseases [11]. None of these conditions are likely to be detected by pelvic examination [12]. In one study of 1021 potential OC users, 51 women were excluded from use of OCs for possible contraindications, none based on pelvic examination [17]. Pelvic examination is sometimes used as a screening tool for conditions such as uterine fibroids or ovarian enlargement [18,19]. However, there is little evidence that pelvic examination is an effective screening modality for these conditions, particularly in asymptomatic women [19]. In addition, women with gynecologic conditions which might be detected by pelvic examination (e.g., uterine fibroids, ovarian masses, ovarian cancer, endometriosis) can safely use hormonal contraceptives [11]. With respect to effects of hormonal contraceptives on other health conditions, pelvic examination is not likely to detect status changes in asymptomatic women which would preclude hormonal contraceptive initiation or continuation [12].

5. Conclusions

The performance of CBE and pelvic examination likely do not enhance safe initiation of contraceptives. Although hormonal contraceptives are not recommended for use in women with known breast cancer, no evidence exists to determine whether screening for breast cancer with CBE is necessary prior to initiation of hormonal contraceptives. Two fair quality studies demonstrated no differences between women who did not undergo pelvic examination versus women who did undergo pelvic examination prior to initiating OCs or DMPA with respect to risk factors for cervical neoplasia, and incidence of sexually transmitted diseases, abnormal Pap smears or abnormal wet mount results. In addition, pelvic examination is not likely to detect any conditions for which hormonal contraceptives would be unsafe for use. Reducing the need for unnecessary physical examination prior to initiation of contraception may improve access and use of contraception with the ultimate goal of reducing unintended pregnancy.

Appendix A

Search strategy for clinical breast examination and hormonal contraceptives:

((breast exam* OR clinical breast exam*)) AND (“Contraceptive Agents, Female”[Mesh] OR oral contracept* OR hormonal contracept* OR “Ortho Evra”[Supplementary Concept] OR ortho evra OR “contraceptive patch” OR “transdermal patch” OR “NuvaRing”[Supplementary Concept] OR nuvaring OR “vaginal ring” OR ((depot medroxyprogesterone OR depo medroxyprogesterone OR depotmedroxyprogesterone OR depomedroxyprogesterone OR dmpa OR depo-provera OR “net en” OR norethisterone-enanthate) OR ((Medroxyprogesterone 17-Acetate[mesh]) AND (contracept* OR inject* OR depo OR depot))) OR (norplant* OR ((levonorgestrel OR etonogestrel) AND implant*) OR implanon) OR ((progestin OR Progestins [MeSH] OR Progesterone[MeSH]) AND contracept* AND (oral OR pill OR pills OR tablet OR tablets)) OR ((levonorgestrel AND (intrauterine devices[mesh] OR iud

OR iucd OR ius OR iuc OR intrauterine system OR intra-uterine system OR intrauterine device OR intra-uterine device OR intrauterine contraceptive OR intrauterine contraception)) OR mirena)).

Search strategy for pelvic examination and hormonal contraceptives:

((“pelvic examination” OR “pelvic exam” OR “physical examination” OR “physical exam”)) AND (“Contraceptive Agents, Female”[Mesh] OR oral contracept* OR hormonal contracept* OR “Ortho Evra”[Supplementary Concept] OR ortho evra OR “contraceptive patch” OR “transdermal patch” OR “NuvaRing”[Supplementary Concept] OR nuvaring OR “vaginal ring” OR ((depot medroxyprogesterone OR depo medroxyprogesterone OR depotmedroxyprogesterone OR depomedroxyprogesterone OR dmpa OR depo-provera OR “net en” OR norethisterone-enanthate) OR ((Medroxyprogesterone 17-Acetate[mesh]) AND (contracept* OR inject* OR depo OR depot))) OR (norplant* OR ((levonorgestrel OR etonogestrel) AND implant*) OR implanon) OR ((progestin OR Progestins[MeSH] OR Progesterone[MeSH]) AND contracept* AND (oral OR pill OR pills OR tablet OR tablets)))

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