QUERI

Screening Pelvic Examinations in Asymptomatic Average Risk Adult Women

EXECUTIVE SUMMARY

September 2013

Prepared for:
Department of Veterans Affairs
Veterans Health Administration
Quality Enhancement Research Initiative
Health Services Research & Development Service
Washington, DC 20420

Prepared by:
Evidence-based Synthesis Program (ESP) Center
Minneapolis, MN
Timothy J. Wilt, M.D., M.P.H., Director

Investigators:
Principal Investigator:
Hanna E. Bloomfield, M.D., M.P.H.

Co-Investigators:
Andrew Olson, M.D.
Amy Cantor, M.D., M.H.S.
Nancy Greer, Ph.D.

Research Associates:
Roderick MacDonald, M.S.
Indulis Rutks, B.A.

VA HEALTH CARE Defining EXCELLENCE in the 21st Century

PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) managers and policymakers, as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout VA.

QUERI provides funding for four ESP Centers and each Center has an active VA affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence,
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures, and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of QUERI Central Office and the four ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at nicole.floyd@va.gov.

Recommended citation: Bloomfield H, Olson A, Cantor A, Greer N, MacDonald R, Rutks I, and Wilt TJ. Screening Pelvic Examinations in Asymptomatic Average Risk Adult Women. VA-ESP Project #09-009; 2013

This report is based on research conducted by the Evidence-based Synthesis Program (ESP) Center located at the Minneapolis VA Medical Center, Minneapolis, MN funded by the Department of Veterans Affairs, Veterans Health Administration, Office of Research and Development, Quality Enhancement Research Initiative. The findings and conclusions in this document are those of the author(s) who are responsible for its contents; the findings and conclusions do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. No investigators have any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

EXECUTIVE SUMMARY

BACKGROUND

The routine pelvic examination has been a usual part of preventive care for women for many decades. In 2008, 63.4 million pelvic examinations were performed in the United States. Many women and providers believe that the routine pelvic exam should be included in an annual comprehensive well-woman visit. The exam consists of inspection of the external genitalia, speculum examination of the vagina and cervix, bimanual examination, and sometimes rectal or rectovaginal examination. Traditionally, the examination in the asymptomatic average risk women has been used to screen for pathology through palpation, visualization, and specimen collection.

Pathology potentially detectable on the pelvic examination includes malignancies (e.g., cervical, ovarian, uterine, bladder, vaginal or vulvar); infections (e.g., Chlamydia, gonorrhea, warts, candidiasis, bacterial vaginosis); pelvic inflammatory disease (PID); or other pathology (e.g., atrophic vaginitis, cervical polyps, uterine prolapse, fibroids). In addition, pelvic examinations are often performed prior to the provision of hormonal contraception. Recent high quality evidence-based reviews and guidelines have concluded that pelvic examinations are not required for Chlamydia and gonorrhea screening or for hormonal contraception initiation and up-to-date evidence-based guidelines for cervical cancer screening are also available. However, we are unaware of any systematic reviews that have investigated the utility of the pelvic examination for the other indications.

This systematic review was undertaken to evaluate the benefits and harms of the routine screening pelvic examination in asymptomatic, average risk, non-pregnant, adult women. For cervical cancer and sexually transmitted infection (i.e., Chlamydia and gonorrhea) screening and for initiation of hormonal contraception we summarize the results of recent reviews and guidelines from major US health organizations. For all other indications, we performed and report results from a comprehensive search of the medical literature.

Summary of Recommendations for Cervical Cancer, Chlamydia, and Gonorrhea Screening and Initiation of Hormonal Contraception

According to the United States Preventive Services Task Force (USPSTF), cervical cancer screening (Pap smears) should be performed every 3 years in average risk women with a cervix who are 21 to 65 years old. Pap smears are not recommended for women under 21 regardless of sexual activity level. In women aged 30 to 65 years, the screening interval may be lengthened to 5 years when simultaneous human Papillomavirus testing is performed. Pap smears should not be performed in women over 65 years of age who have had adequate and negative prior screening and are not otherwise at high risk for cervical cancer or in women who do not have a cervix.

Pelvic examinations are not necessary prior to prescribing hormonal contraception. Only a medical history and blood pressure measurement are required to rule out contraindications.

Pelvic examinations are not required to test for Chlamydia and gonorrhea. This testing can be performed on either self-obtained vaginal swabs or urine specimens.

Key Questions

Key Question #1. How accurate is the screening pelvic exam for detection of malignancy (other than cervical), pelvic inflammatory disease (PID), or other benign gynecologic conditions?

Key Question #2. What are the benefits (reduced mortality and morbidity) and harms (overdiagnosis, over-treatment, diagnostic procedure-related) of the routine screening pelvic examination performed for the detection of malignancy, PID, or other benign gynecologic conditions?

Key Question #3. What are the examination-related harms and indirect benefits of a screening pelvic examination in asymptomatic women**?**

Key Question #3a. Do these harms vary by patient or provider characteristics?

METHODS

We searched MEDLINE (OVID) for articles published from 1946 through July 2013 (Appendix A). Our search was designed to identify studies of any design other than case series or case reports. We limited the search to studies involving human subjects published in the English language. To supplement our literature search, we selected nine references that we considered highly relevant to the topic and used the "Related Citations" feature of PubMed, to identify any additional abstracts. Additional articles were identified from hand-searching reference lists of existing systematic reviews and pertinent studies and from suggestions by members of the Technical Expert Panel and peer reviewers.

The full text of each article identified as potentially eligible was independently reviewed by two investigators or research associates. Study characteristics, patient characteristics, and outcomes data were abstracted from articles meeting inclusion criteria. We assessed the quality of the studies of diagnostic accuracy based on patient representativeness, quality and administration of the reference (gold standard) test, quality and administration of the index test, and data analysis. We assessed the quality of survey studies based on the population sampling method, the survey instrument, and the analysis methods used.

DATA SYNTHESIS

We compared the characteristics, methods, and findings of included studies. Pooled analyses of data were not possible due to limited reporting and heterogeneity of methods and outcomes across studies. Therefore, findings were summarized in narrative form. We identified and highlighted findings from studies involving Veterans.

PEER REVIEW

A draft version of this report was reviewed by technical experts, as well as VA clinical leadership. Reviewer comments were incorporated into this report, as appropriate, and a summary of our responses may be found in Appendix B.

RESULTS

From the primary literature search, we identified 1523 abstracts. From the "Related Citations" literature search, we identified 826 unique abstracts for a total of 2349 abstracts. We reviewed the full text of 156 references and 13 met inclusion criteria. An additional 39 references were identified by hand-searching or from suggested references.

Key Question #1. How accurate is the screening pelvic exam for detection of malignancy (other than cervical), pelvic inflammatory disease (PID), or other benign gynecologic conditions?

We identified three studies that investigated the diagnostic accuracy of the pelvic examination for detecting ovarian cancer and one for bacterial vaginosis. There were no diagnostic accuracy studies of other malignancies, PID, or any other benign gynecologic conditions in this population.

Ovarian Cancer

The 3 ovarian cancer studies enrolled a total of 5633 average risk asymptomatic women. Since not all subjects underwent the gold standard test (biopsy), sensitivity and specificity could not be calculated. One study did not identify any cases of ovarian cancer. In the other 2 studies the positive predictive value of the pelvic examination for ovarian cancer was 1.2 to 3.6%.

Bacterial Vaginosis

We identified one study of diagnostic accuracy of the pelvic examination for the detection of bacterial vaginosis that reported a sensitivity of 69% and specificity of 93%. However this study included both symptomatic and asymptomatic women and had a high prevalence of bacterial vaginosis. Furthermore, the clinical significance of this diagnosis is uncertain.

Key Question #2. What are the benefits (reduced mortality and morbidity) and harms (overdiagnosis, over-treatment, diagnostic procedure-related) of the routine screening pelvic examination performed for the detection of malignancy, PID, or other benign gynecologic conditions?

Benefits

Ovarian Cancer

We identified no studies that evaluated the mortality and morbidity benefits of the routine pelvic examination (specifically the bimanual examination) as a screening test for ovarian cancer in asymptomatic average risk women. Indeed the bimanual examination was not included as a screening modality in either of the 2 large contemporary trials of ovarian cancer screening. In the Prostate Lung Colorectal and Ovarian cancer (PLCO) study, a randomized controlled trial of over 78,000 women aged 55 to 74 years followed for a median of 12.4 years, the bimanual exam was initially included in the screening protocol but was dropped after 5 years because no cancers were detected solely by this examination. The second screening trial, the United Kingdom Collaborative Trial for Ovarian Cancer Screening (UKCTOCS), does not include pelvic examination in its screening protocol. This study of 202,638 post-menopausal women

ages 50 to 74 years is comparing no screening, screening with annual CA-125 with transvaginal ultrasound as a second-line test, or transvaginal ultrasound and is expected to report mortality results in 2015.

Other Conditions

We identified no studies investigating the benefits of the screening pelvic examination for the diagnosis of other malignancies, PID, or other benign gynecologic conditions (e.g., ovarian cysts, fibroids)

Harms

Direct harms of the pelvic examination itself (e.g., pain, discomfort, embarrassment) are discussed under Key Questions #3. We include here harms related to false reassurance, over-diagnosis, over-treatment, or diagnostic procedure-related harms that result from findings on the pelvic examination performed in asymptomatic women. We identified no studies that directly investigated any of these harms. However, one of the studies on diagnostic accuracy of the pelvic examination for detection of ovarian cancer in asymptomatic average risk women provides some indirect evidence. In this study there were 174 abnormal screening pelvic examinations in 2000 women (8.7%). These 174 women received follow-up with either a transvaginal or transabdominal ultrasound plus a serum CA-125. Based on the results of these follow-up tests, 31 women (18%) underwent either open or laparoscopic surgery which revealed ovarian cancer in 2 women (6.5%). Thus screening pelvic examination led to unnecessary surgery in 29/2000 or 1.5% of women.

Key Question #3. What are the examination-related harms and indirect benefits of a screening pelvic examination in asymptomatic women?

Examination-related Harms

We identified 15 studies that examined women's attitudes towards and/or experiences of the routine pelvic examination: 14 surveys and 1 longitudinal cohort study. These studies included more than 13,000 women. Outcomes included fear, anxiety, embarrassment, pain, discomfort, and global assessment of the pelvic examination experience. Since all the studies used different outcome measures, it was not possible to pool the data.

The percentage of respondents endorsing fear, embarrassment, or anxiety during or in advance of the pelvic examination ranged from 10 to 80% (median 34%, 7 studies, N=10,702). The percentage endorsing pain or discomfort during the pelvic exam ranged from 11 to 60% (median 35%, 8 studies, N=4,576). Women who endorsed pain or discomfort were less likely to return for another visit.

Indirect Benefits

It has been suggested that the annual pelvic examination might serve as an incentive for women to access the healthcare care system and thereby receive recommended evidence-based preventive care. Our literature search did not identify any studies that tested this hypothesis.

Key Question #3a. Do these harms vary by patient or provider characteristics?

We looked for studies investigating factors that might moderate the association between pelvic examinations and psychological harms. Patient factors include demographics and physical traits, history of sexual trauma and/or post-traumatic stress disorder, and veteran status. Provider factors include gender and specialty.

Patient Factors

Obesity

We identified only one study that reported pelvic examination-associated psychological harms in women of varying body weights. In this study, heavier women were significantly more likely than thinner women to endorse feelings of disrespect and embarrassment during a gynecology visit.

History of Sexual Violence (SV)

We identified nine studies that investigated the association between a history of SV and experience of the pelvic examination or receipt of gynecologic services. Two of four studies found significantly higher rates of pelvic examination related pain and discomfort in women with a history of SV compared to women without a history of SV. Two of three studies found a significant association between history of SV and fear, anxiety, or embarrassment during a pelvic examination. Women with a history of SV who also had a diagnosis of PTSD had significantly more distress, fear, and embarrassment than either SV+ or SV- women without PTSD.

Provider Factors

Although studies have reported patient preferences for provider characteristics (especially gender), we identified no studies that investigated the association between provider characteristics and psychological harms.

CONCLUSION AND FUTURE RESEARCH

In conclusion, there are no data supporting the effectiveness of the screening pelvic examination (including speculum and bimanual examinations) in the asymptomatic average risk woman for any indication other than periodic cervical cancer screening. The procedure causes pain, discomfort, fear, anxiety, and/or embarrassment in about a third of women and can lead to unnecessary, invasive, and potentially harmful diagnostic procedures. Conducting a pelvic examination requires additional clinician time, especially in primary care settings, and often requires the presence of a chaperone in the examination room, thus incurring resource and opportunity costs.

The most important area for future research is development and testing of strategies to reduce inappropriate use of the pelvic examination. The implementation literature suggests that passive education alone is unlikely to be effective; a variety of strategies employed at multiple levels within the healthcare system will likely be required.

ABBREVIATIONS

ACOG	American College of Obstetricians and Gynecologists
ACS	American Cancer Society
ASCP	American Society for Clinical Pathology
ASCCP	American Society for Colposcopy and Cervical Pathology
BMI	Body mass index
CA-125	Cancer antigen-125
CDC	Centers for Disease Control and Prevention
CI	Confidence interval
HMO	Health maintenance organization
HPV	Human Papilloma virus
NAA(T)	Nucleic acid amplification (test)
PID	Pelvic inflammatory disease
STI	Sexually transmitted infection
SV	Sexual violence
USPSTF	United States Preventive Services Task Force
UTI	Urinary tract infection
VA	Veterans Affairs
VHA	Veterans Health Administration
WHO	World Health Organization