

Screening Pelvic Examinations (PE) in Asymptomatic Average Risk Women

A Systematic Review of the Evidence

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January 23, 2014



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Rationale for Review

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Today's Presentation

- **Objectives and Methods**
- Results
- Limitations
- Context and Implications
- Conclusions
- Comment



Objectives

To determine for average risk* asymptomatic women:

1. The diagnostic accuracy of the PE for the detection of malignancy (other than cervical), pelvic inflammatory disease, or other gynecologic conditions
2. Whether routine screening PEs (not PAP smears) reduce mortality and/or morbidity from any condition
3. The harms and ancillary benefits of the routine screening PE

Full report at <http://www.hsrd.research.va.gov/publications/esp/>

* *not at increased risk of gynecologic malignancy, by history or genes*



What is NOT included

Pelvic examinations...

- For cervical cancer screening (see USPTF guidelines)
- For symptomatic women
- For women at high risk of gynecologic cancer
- For STI screening (can be done with self obtained specimens)
- Prior to provision of OCPs (need only BP and medical history)



Literature Search

- MEDLINE 1946→2013
- English language only
- Excluded case series or case reports
- Search terms: Gynecologic Examination, Women's Health, and Mass Screening
- “Related Citations” and hand searching of reference lists

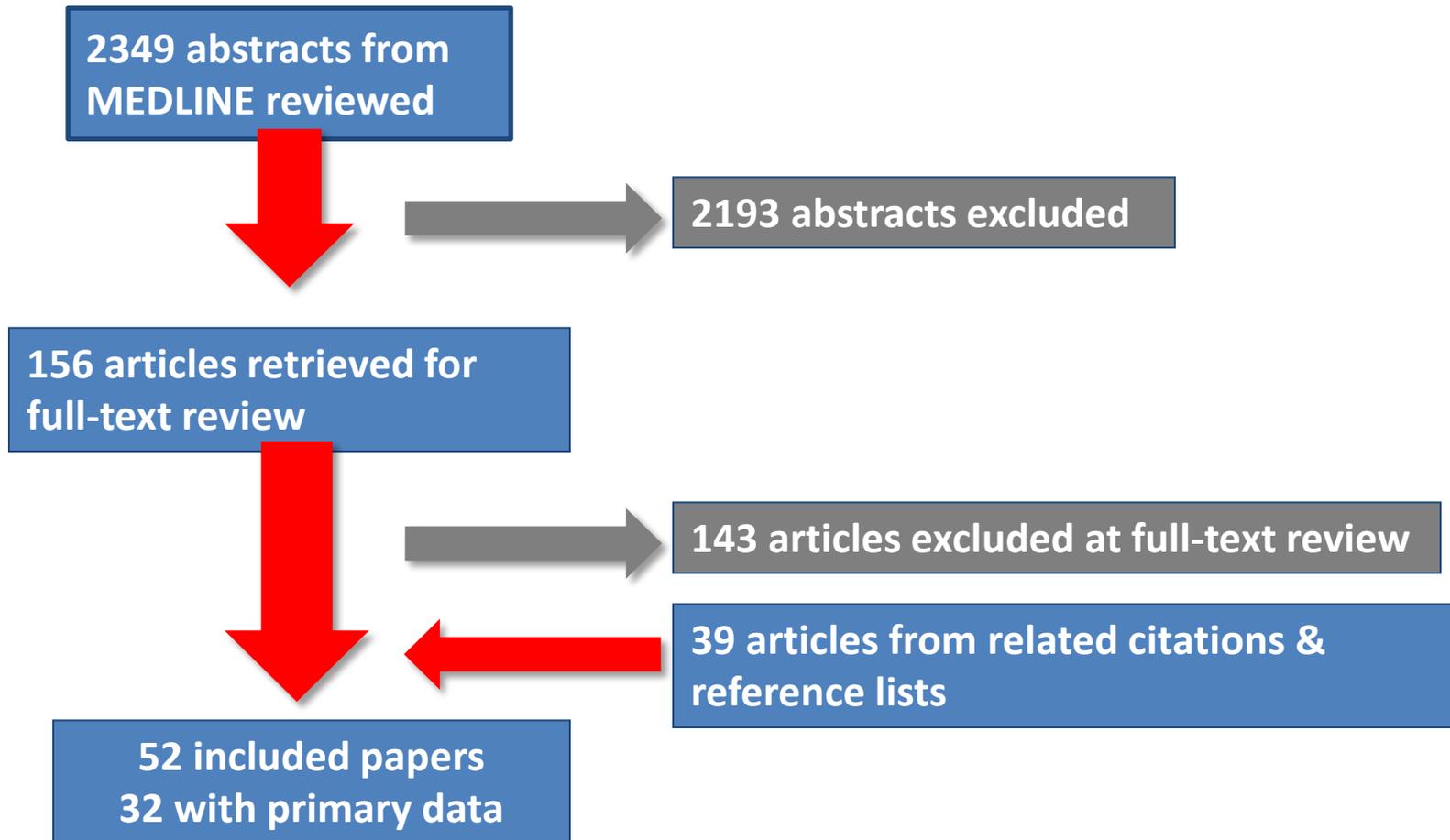


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Literature Flow



Objective 1: Accuracy of Pelvic Exam (PE) for detection of ovarian cancer

*Bimanual examination is the component of the
PE used to detect ovarian abnormalities*

Reference	Population	Abnormal or ambiguous exams	1 year incidence of ovarian cancer	Positive predictive value** of an abnormal PE
Adonakis 1996	N=2000 Mean age 58	174 (.09%)	2/2000 (0.1%)	1.2% (2/174)
Grover 1995	N=2623 Mean age 51	40 (1.5%)	1/2623* (0.04%)	0% (0/40)
Jacobs 1998	N=1010 Median age 54	28 (2.7%)	1/1010 (0.1%)	3.6% (1/28)

* The single case occurred in a woman with a normal PE

** Positive Predictive Value: true positives / all positives



Objective 2: Mortality and Morbidity Benefits

- No studies assessing the morbidity and mortality benefits of routine PEs in asymptomatic women for any condition
- The 2 large contemporary trials of ovarian cancer screening did not use the bimanual examination in their screening protocols because of its low diagnostic accuracy



Objective 3: Harms

- Potential Harms
 - Psychological harms of the exam: pain, discomfort, fear, anxiety, embarrassment
 - Indirect harms: false reassurance, over-diagnosis, over-treatment, diagnostic procedure related



Psychological Harms

Fear, Anxiety, Embarrassment, Pain, Discomfort

- 15 studies (14 surveys, 1 cohort)
- 9 in US
- Median sample size: 409 (40 to 7168)
- Overall study quality: Low
 - Un-validated surveys
 - Low response rates
 - Not population based



Psychological Harms

Fear, Anxiety, Embarrassment, Pain, Discomfort

- Pain/discomfort (8 studies, N=4576)
 - 11-60% (median 35%)
 - More common in younger, nulliparous women
 - Associated with poorer compliance with return visits in all 5 studies that examined the issue
- Embarrassment/fear/anxiety (7 studies, N=10,702)
 - 10-80% (median 34%)



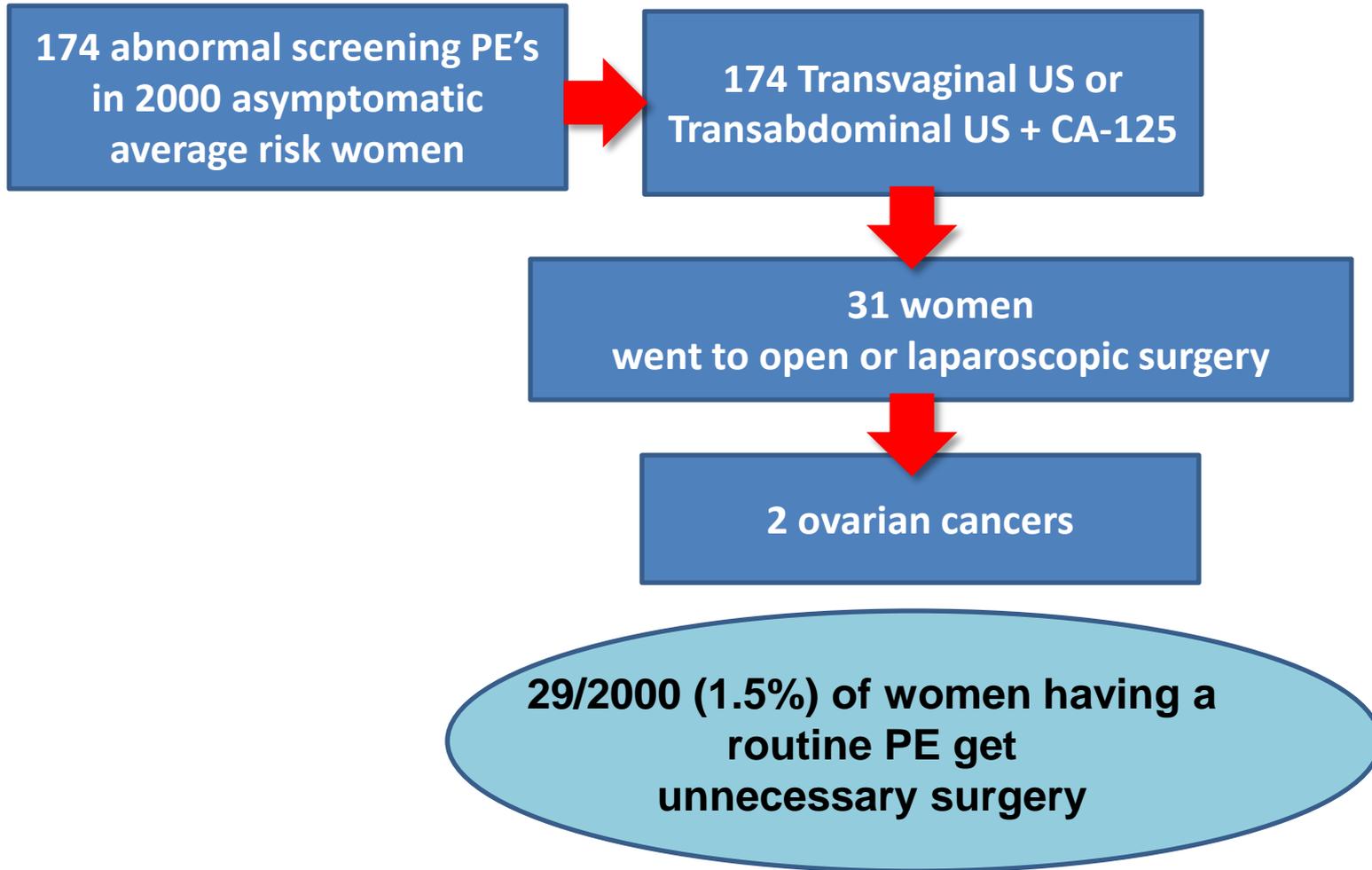
Indirect Harms

- False reassurance
 - Normal PE → pt ignores/delays evaluation for new symptoms
- Over-diagnosis
 - Diagnosis of an abnormality that would never have become clinically manifest
 - Psychological consequences
- Over-treatment
 - Treatment initiated for an abnormality that would have regressed or never caused problems
- Diagnostic procedure-related harms
- **No studies directly addressed these**



Indirect Harms

Diagnostic Procedure-related



Indirect Harms

Diagnostic Procedure-related

29/2000 (1.5%) of women having a
routine PE get
unnecessary surgery



Risk of major
complications may
be as high as 15%

Psychological Harms in Subgroups: Sexual Violence (SV)

- 9 studies, most of low quality, 8 with a control group
- Methodologically strongest Behavior Risk Factor Surveillance Study (BRFSS)

Outcome	# of studies	Results for women with h/o SV (c/w women without h/o SV)
Pain/ Discomfort	4 N=1344	<u>Inconsistent</u> : 2 reported significantly increased rates*, 2 no difference
Fear/Anxiety/ Embarrassment	3 N=333	2/3 reported increased rates*
Receipt of Gyn Services/Paps	5 N=40,007	<u>Inconsistent</u> : 2 reported decreased utilization*; 2 (including BRFSS) reported no difference; 1 reported increased utilization*

*This table includes the 8 studies with control groups; * p < 0.05*



Psychological Harms in Subgroups: Sexual Violence

- Methodologically strongest **BRFSS**
 - population-based
 - telephone survey
 - nationally representative US sample
 - 35,000+ women, 15 % w/ h/o SV
- Outcome: % reporting PAP w/in past 3 yrs
 - Did not differ between SV+ and SV- groups



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Limitations

- English language only
- Paucity of literature
 - Few studies on diagnostic accuracy or morbidity/mortality outcomes
 - No studies focused on over-diagnosis, over treatment, false reassurance
- Psychological Harms studies
 - Low quality
 - Did not focus exclusively on asymptomatic women
 - Selective reporting of “positive” results?



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Ovarian Cancer

- 2 large contemporary screening trials
- **PLCO** (*Buyts et al JAMA 2011;305:2295*)
 - RCT, N > 78,000, 12.4 yrs f/u
 - Bimanual exam dropped after 5 years
 - Serum CA-125, T-V ultrasonography
 - Increased detection of ovarian cancer
 - No decrease in OC mortality
- **UK-CTOCS** (*Menon et al Lancet Oncol 2009;10:327*)
 - Did not include bimanual
 - Due to report in 2015



Pelvic Inflammatory Disease

- Often presents with vague/minimal symptoms
- Can lead to infertility, ectopic pregnancy, chronic pelvic pain
- CDC recommends treatment only when a woman has both
 - Symptoms
 - PE findings (eg cervical motion tenderness)
- Symptom questionnaires can help determine which patients need a bi-manual *(Fisher et al Clin Pediatr 2004;43:153)*



Current Practice

- Survey of 1250 US MDs (*Stormo Arch Intern Med 2011 & Prev Med 2012*)
 - Perform PE as part of a well-woman exam
 - 54% internists
 - 90% FPs
 - 98% OB-GYNs
- Clinical Vignette, 521 ob-gyns (*Henderson Am J Ob Gyn 2013*)
 - 95% would do a bi-manual in asymptomatic women not due for a Pap



Reasons for Performing Routine PEs

Survey of 521 US Ob-Gyns

- Adherence to Standard Medical Practice (45%)
- Patient Reassurance (49%)
- Detection of Ovarian Cancer (47%)
- Identification of Benign Conditions (54-59%)

Henderson Am J Ob Gyn 2013



Cost

- \$38 for the exam
- Total annual cost in US for preventive gynecologic exams and associated labs/radiology: \$2.6 billion
 - 1/3 on cervical cancer screening in women under age 21
 - ?? % on other unnecessary exams
- Opportunity Costs

Mehrota et al Arch Intern Med 2007;167:1876

Morioka-Douglas et al JAMA Intern Med 2013;173:855



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Conclusions

- No data that a routine PE in asymptomatic average risk women reduces mortality or morbidity from any condition, other than cervical cancer
- Low quality data indicate that PEs may be associated with pain, discomfort, fear, anxiety, and/or embarrassment in about 30% of women



Cervical Cancer Screening

- Requires only speculum exam for visualization of cervix and collection of cervical specimen (for Pap, papilloma virus)
- Is not recommended
 - more often than every 3 years
 - in women under 21 or without a cervix
 - in women over 65 w/ prior negative exams
- Full recommendations available at <http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm>



Future Research Directions

- Development and testing of strategies to reduce the high rate of inappropriate use of PEs



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January 23, 2014

WOMEN VETERANS
HEALTH CARE



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in the 21st Century

Women's Health Services

- Deliver comprehensive, patient-centered care for women
- Promote preventive health care and wellness for women
- Ensure a safe and healing environment in which privacy is paramount
- Continue to enhance quality of care



Women's Health Services



- Enhancement of comprehensive care
 - 100% of VHA healthcare system delivering comprehensive primary care for women Veterans

Comprehensive Primary Care:

Preventive Services

Acute and Chronic Illness

Coordination of Care

Gender-specific Primary Care

Basic Mental Health Care

Comprehensive Women's Health

- Regular visits with primary care provider provides opportunity to address prevention and well woman care
 - Prevention
 - Preconception Care
 - Reproductive Life Planning
 - Basic Gynecology
- Specific symptoms may require further examination
 - May require visits for specialty gynecology or other specialty care

Pre-Pelvic Exam

- Before the patient has disrobed, while sitting up:
 - Ask if any problems with or discomfort during prior exams
 - Acknowledge exam may be stressful- *normalize, validate*
 - Reassure her it is your goal to make as comfortable and “least stressful” as possible
 - Elicit preferences (what has worked for her in the past, what has not)
 - Explain what the examination entails (e.g., show speculum, how it works/sounds)
 - Remind her she can terminate the examination at any time (give her direction on how you prefer to have this communicated)