

Title: Ovarian-sparing hysterectomy: Is it right for your patient? J Fam Pract. 2009;58:478-480.	
Potential PURL Review Form: Cohort study	
SECTION 1: IDENTIFYING INFORMATION FOR NOMINATED POTENTIAL PURL	
1. Citation	Parker WH, Broder MS, Chang E, et al. Ovarian conservation at the time of hysterectomy and long-term health outcomes in the Nurses' Health Study. <i>Obstet Gynecol.</i> 2009;113:1027-1037.
2. Hypertext link to PDF of full article	http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3159&itool=AbstractPlus-def&uid=19384117&db=pubmed&url=http://meta.wkhealth.com/pt/pt-core/template-journal/lwwgateway/media/landingpage.htm?doi=10.1097/AOG.0b013e3181a11c64
3. First date published study available to readers	May 2009
4. PubMed ID	19384117
5. Nominated By	Sarah-Anne Schumann
6. Institutional Affiliation of Nominator	University of Chicago
7. Date Nominated	April 28, 2009
8. Identified Through	OB/Gyn
9. PURLS Editor Reviewing Nominated Potential PURL	Bernard Ewigman
10. Nomination Decision Date	May 1, 2009
11. Potential PURL Review Form (PPRF) Type	Cohort study
12. Other comments, materials or discussion	
13. Assigned Potential PURL Reviewer	Umang Sharma
14. Reviewer Affiliation	University of Chicago
15. Date Review Due	May 14, 2009
16. Abstract	OBJECTIVE: To report long-term health outcomes and mortality after oophorectomy or ovarian conservation. METHODS: We conducted a prospective, observational study of 29,380 participants of the Nurses' Health Study who had a hysterectomy for benign disease; 16,345 (55.6%) had hysterectomy with bilateral oophorectomy, and 13,035 (44.4%) had hysterectomy with ovarian conservation. We evaluated incident events or death due to coronary heart disease (CHD), stroke, breast cancer, ovarian cancer, lung cancer, colorectal cancer, total cancers, hip fracture, pulmonary embolus, and death from all causes. RESULTS: Over 24 years of follow-up, for women with hysterectomy and bilateral oophorectomy compared with ovarian conservation, the multivariable hazard ratios (HRs) were 1.12 (95% confidence interval [CI] 1.03-1.21) for total mortality, 1.17 (95% CI 1.02-1.35) for fatal plus nonfatal CHD, and 1.14 (95% CI 0.98-1.33) for stroke. Although the risks of breast (HR 0.75, 95% CI 0.68-0.84), ovarian (HR 0.04, 95% CI 0.01-0.09, number needed to treat=220), and total cancers (HR 0.90, 95% CI 0.84-0.96) decreased after oophorectomy, lung cancer incidence (HR=1.26, 95% CI 1.02-1.56, number needed to harm=190), and total cancer mortality (HR=1.17, 95% CI 1.04-1.32) increased. For those never having used estrogen therapy, bilateral oophorectomy before age 50 years was associated with an increased risk of all-cause mortality, CHD, and stroke. With an approximate 35-year life span after surgery, 1 additional death would be expected for every 9 oophorectomies performed. CONCLUSION: Compared with ovarian conservation, bilateral oophorectomy at the time of hysterectomy for benign disease is associated with a decreased risk of breast and ovarian cancer but an increased risk of all-cause mortality, fatal and nonfatal CHD, and lung cancer. In no analysis or age group was oophorectomy associated with increased survival. LEVEL OF EVIDENCE: II.

SECTION 2: CRITICAL APPRAISAL OF VALIDITY

1. The study addresses an appropriate and clearly focused question.	Well covered
2. The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.	Well covered Comments: Pts who underwent bilateral oophorectomy tended to be older at the time of surgery (46.8 vs 43.3 years) and older overall (51.9 vs 50.3 years). As might be expected, they were also much more likely to have used estrogen therapy (78.3% vs 36%).
3. The study indicates how many of the people asked to take part did so, in each of the groups being studied	Well covered
4. The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis.	Well covered
5. What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed?	Response rate was approximately 90% for each survey point: every 2 years over 24 years
6. Comparison is made between full participants and those lost to follow up, by exposure status.	Not applicable
7. The outcomes are clearly defined.	Well covered
8. The assessment of outcome is made blind to exposure status.	Not addressed
9. Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome.	Not addressed

<p>10. What are the key findings of the study?</p>	<p>Hazard ratios for bilateral oophorectomy: 1.12 for total mortality (95% CI 1.03-1.21) 1.17 for CHD (95% CI 1.02-1.35) 1.14 for CVA (95% CI 0.98-1.33) 0.75 for breast cancer (95% CI 0.68-0.84) 0.04 for ovarian cancer (95% CI 0.01-0.09), NNT=220 0.90 for total cancers (95% CI 0.84-0.96)</p> <p>With an approximate 35-year life span after surgery, 1 additional death would be expected for every 9 oophorectomies performed.</p>
<p>11. How was the study funded? Any conflicts of interest? Any reason to believe that the results may be influenced by other interests?</p>	<p>Funded by grants from Ethicon Women's Health and Partnership for Health Analytic Research. No apparent conflict of interest.</p>
<p>SECTION 3: REVIEW OF SECONDARY LITERATURE</p>	
<p>1. DynaMed excerpts</p>	
<p>2. DynaMed citation/access date</p>	<p>Hysterectomy In: Dynamed [database online]. Available at: www.DynamicMedical.com. Last updated: April 26, 2009. Accessed May 10, 2009.</p>
<p>3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences)</p>	<p>Insufficient evidence to recommend for or against bilateral oophorectomy.</p>
<p>4. UpToDate excerpts</p>	
<p>5. UpToDate citation/access date</p>	<p>Valea and Mann. Oophorectomy and ovarian cystectomy In: UpToDate [database online]. Available at: http://www.uptodate.com. Last updated: January 28, 2009. Accessed May 10, 2009.</p>
<p>6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences)</p>	<p>Benefits of oophorectomy outweigh risks in postmenopausal women. Decision should be individualized in premenopausal women.</p>
<p>7. PEPID PCP excerpts</p>	<p>None found</p>
<p>8. PEPID citation/access data</p>	
<p>9. PEPID content updating</p>	<p>1. Do you recommend that PEPID get updated on this topic? No, this topic is current, accurate, and up to date.</p>

<p>10. Other excerpts (USPSTF; other guidelines; etc.)</p>	<p>ACOG:</p> <ul style="list-style-type: none"> • Strong consideration for retaining normal ovaries in premenopausal women who are not at increased genetic risk of ovarian cancer. • Given the risk of ovarian cancer in postmenopausal women, ovarian removal at the time of hysterectomy should be considered for these women.
<p>11. Citations for other excerpts</p>	<p>http://www.guideline.gov/summary/summary.aspx?doc_id=12190&nbr=006287&string=oophorectomy</p>
<p>12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)</p>	<p>Consider ovarian removal in postmenopausal women and ovarian retention in premenopausal women not at risk for ovarian cancer.</p>
<p>SECTION 4: CONCLUSIONS</p>	
<p>1. Validity: How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)</p>	<p>2</p>
<p>2. If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?</p>	<p>The baseline characteristics of the groups were a bit different—ie, mean age was 3 years older in the bilateral oophorectomy group. This was adjusted for in the outcomes.</p>
<p>3. Relevance: Are the results of this study generalizable to and relevant to the health care needs of patients cared for by “full scope” family physicians? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly)</p>	<p>3</p>
<p>4. If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.</p>	<p>94% of patients were white—authors point out that results may have limited applicability to other racial/ethnic groups.</p>
<p>5. Practice changing potential: If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice? Give one number on a scale of 1 to 7 (1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice)</p>	<p>3</p>
<p>6. If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.</p>	<p>Individualize the decision based on a patient's history (as with current recommendations), but with additional information probably not incorporated previously in this discussion—increased risks of CHD and overall mortality with oophorectomy.</p>

<p>7. Applicability to a Family Medical Care Setting: Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention? Give one number on a scale of 1 to 7 (1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)</p>	4
<p>8. If you coded 4.7 as a 4, 5, 6, or 7, please explain.</p>	Debatable whether this is in the scope of primary care.
<p>9. Immediacy of Implementation: Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market? Give one number on a scale of 1 to 7 (1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)</p>	4
<p>10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.</p>	Many primary care providers may view this as a specialist decision.
<p>11. Clinical meaningful outcomes or patient oriented outcomes: Are the outcomes measured in the study clinically meaningful or patient oriented? Give one number on a scale of 1 to 7 (1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)</p>	1
<p>12. If you coded 4.11 as a 4, 5, 6, or 7, please explain why.</p>	

<p>13. In your opinion, is this a Pending PURL? Give one number on a scale of 1 to 7 (1=definitely a Pending PURL; 4=uncertain; 7=definitely not a Pending PURL) Criteria for a Pending PURL:</p> <ul style="list-style-type: none"> · Valid: Strong internal scientific validity; the findings appears to be true. · Relevant: Relevant to the practice of family medicine · Practice changing: There is a specific identifiable new practice recommendation that is applicable to what family physicians do in medical care settings and seems different than current practice. · Applicability in medical setting: · Immediacy of implementation 	3
<p>14. Comments on your response in 4.13</p>	<p>If the consensus is that this falls in the scope of primary care, I think it could be a practice changer. The individualized decision part is already recommended, but I think this study provides a lot of additional information with which to flesh out this conversation.</p>
<p>SECTION 5: EDITORIAL DECISIONS</p>	
<p>1. FPIN PURLs editorial decision (select one)</p>	Pending PURL
<p>2. Follow-up issues for Pending PURL Reviewer</p>	
<p>3. FPIN PURLs Editor making decision</p>	Bernard Ewigman
<p>4. Date of decision</p>	May 14, 2009
<p>5. Brief summary of decision</p>	<p>This well-done cohort study shows that for women having hysterectomy and bilateral oophorectomy for benign disease (eg, fibroids) compared with ovarian conservation, with an approximate 35-year life span after surgery, 1 additional death would be expected for every 9 oophorectomies performed. Our discussion revolved around whether the family physician has a role in referring patients to gynecologists who would choose ovarian conservation and informing patients about the advantages of ovarian conservation or whether this should be left up to the gynecologist. We concluded that family physicians need to know this and advocate on behalf of their patients to help ensure that they obtain the appropriate surgical intervention.</p>