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Female Pelvic Medicine & Reconstructive Surgery

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Original Article: Cost-Utility of Routine Endometrial Evaluation Before Le Fort Colpocleisis

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1. *The introduction is relevant and appropriate. Please comment on what prompted this investigation.*

This study was prompted by a resident and fellow debate in our urogynecology clinic following the evaluation of an elderly woman, > 80 years old, who was considering a Le Fort colpocleisis for the treatment of her advanced prolapse. Two research questions arose from this debate. What is the likelihood that a low-risk, elderly, asymptomatic woman would have a malignancy? Would an undetected malignancy be detrimental to her health? Endometrial biopsy is often recommended prior to Le Fort colpocleisis (1), but how many endometrial biopsies needed to be done to detect one cancer? The literature did not have much data on this matter. Because the outcome is rare, a decision analysis is helpful in analyzing this type of problem.

2. *Please comment on factors considered when choosing a Le Fort colpocleisis and factors that may affect counseling regarding future endometrial malignancy.*

Le Fort is often considered for patients with advanced prolapse who are at high risk for perioperative complications because it can be performed relatively quickly using regional anesthesia. Historically, Le Fort colpocleisis may have a shorter operative time and less morbidity than total colpocleisis with concomitant hysterectomy, which is an alternative option to Le Fort colpocleisis.

Obliterative procedures should only be considered in women who are comfortable with the resultant inability to engage in vaginal intercourse. Uterine preservation should

be individualized based on patient's risk factors for endometrial malignancy. Postmenopausal bleeding should be evaluated. However, in one cohort study, even with a negative workup, 13% of postmenopausal women with abnormal bleeding undergoing pelvic floor reconstruction had either premalignant or malignant findings on final pathology (2). For this reason, uterine preservation in the presence of any postmenopausal bleeding is probably less than ideal.

It is difficult to determine what combination of risk factors confers the greatest risk of future endometrial malignancy in this population, and we are unaware of any studies that characterize this risk. Uterine preservation should probably not be the first choice for women who have a personal or family history suggestive of Lynch syndrome, where the lifetime cumulative risk of endometrial cancer is 40-60% (3). In the absence of postmenopausal bleeding or a history of Lynch syndrome, the decision for uterine preservation should be made after patients are counseled about other risk factors of future malignancy such as age, unopposed estrogen use, and obesity. Patients should be aware that any future bleeding would need to be evaluated and may require hysterectomy by either the abdominal or laparoscopic routes.

3. *Please comment on why the intervention of performing a D&C at the time of Le Fort colpocleisis was not incorporated into the model?*

Performing a D&C at the time of Le Fort colpocleisis is certainly an additional option that some surgeons advocate for. Abnormal pathology detected in the operating room on frozen section may guide the surgeon to consider colpocleisis with concomitant hysterectomy. However, performing a D&C on a postmenopausal cervix can be difficult and puts a patient at risk for uterine perforation and/or infection. For this reason, D&C should probably be used selectively for patients in whom there may be a higher suspicion of malignancy rather than as a routine method of evaluation. Therefore, we opted not to include it as an option for routine evaluation in the asymptomatic, low-risk woman.

4. *Please comment on why EM biopsy or TVUS were incorporated as the default intervention?*

Based on available reviews that recommend EM biopsy as preoperative evaluation prior to Le Fort colpocleisis, we opted to use EM biopsy as the default intervention. In the era of minimally invasive technology, we opted to add TVUS as an alternative option. An ACOG Committee Opinion (4) also recommends the use of either EM biopsy or TVUS to evaluate postmenopausal bleeding. Providers may order TVUS and utilize its high negative predictive value in order to offer a noninvasive option to their patients.

5. *Considering an incremental cost-effectiveness ratio, the ratio of the difference in costs over the difference in outcomes for the interventions being compared, would have been valuable. Was this considered as part of the analysis?*

The incremental cost-effectiveness ratio (ICER) is useful in cost-effectiveness analysis when quality-adjusted life years (QALYs) are the units used to measure the outcomes (effects) (5). Because this was a cost-utility analysis and we used costs and utilities, not QALYs, the ICER was not calculated. QALYs are simply the utility of a health state multiplied by the number of remaining life years. By researching life years remaining for healthy women and those with treated or untreated endometrial cancer, one can calculate the QALYs for each health state in the decision tree and, subsequently, calculate the ICER. But because the outcome is so rare and the utilities were relatively similar, the life years would have to be significantly different to see a detectable difference between the groups.

6. *Figure 3 shows a cost-effectiveness acceptability curve, which plots the probability that one health intervention is more cost-effective than alternatives. Please comment on how this figure can impact your clinical decision towards “no evaluation”. What other factors would be important to consider?*

This figure shows that regardless of what society is willing to pay to prevent one case of endometrial cancer in this population, the cost-utility of no evaluation is superior to the other options. This figure also shows that biopsy is more cost-effective than TVUS in our hypothetical low-risk population. Other things to consider when looking at this figure are the risk of concurrent endometrial cancer in the patient and options other than biopsy or TVUS, such as intraoperative D&C when applying it to populations other than our hypothetical cohort.

7. *Describe limitations as to the generalizability of this study. The “bottom line” of the study is highly dependent on specific factors, mainly a highly selective hypothesized population.*

The main limitation to the generalizability of this study is the nature of our hypothetical population: low-risk, asymptomatic, elderly patients. This population serves as a starting point in the discussion regarding the need for preoperative endometrial evaluation. Most patients undergoing obliterative procedures for advanced prolapse do fall into this category, so the results of the analysis would apply. However, as with any intervention, there is also a need for clinical judgment. Low-risk women in this age group probably do not need to undergo routine endometrial biopsy. The provider needs to decide what he/she considers higher risk and may consider biopsy under those conditions.

8. *Please comment on the future steps needed to have the current study affect and/or influence guidelines for evaluation prior to Le Fort.*

A multi-center study evaluating pathology and long-term postoperative outcomes (i.e. the development of endometrial cancer after a negative biopsy) would be ideal. However, given the rare outcome (endometrial cancer) and the length of follow-up needed, this study would likely be cost-prohibitive. A national Le Fort registry would be useful to track outcomes for these women. Data from such a registry might provide more accurate predictors/probabilities to enter into the decision analysis model. Based on our study, because endometrial cancer is rare, both in asymptomatic women and after Le Fort, providers can feel comfortable being more selective in whom they perform preoperative uterine evaluation and eliminating it as a routine practice.

References:

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