General Overview of the Model

Our model is a computer-simulation state-transition Markov model of the risks and benefits of hysterectomy in women 18-65 years of age. The base-case analysis was constructed to represent a woman requiring hysterectomy without a preoperative diagnosis of cancer who would be a potential candidate for one of three modalities of hysterectomy: total abdominal hysterectomy, laparoscopic hysterectomy (either total laparoscopic hysterectomy or laparoscopic assisted vaginal hysterectomy) or a laparoscopic hysterectomy with use of electric power morcellation to facilitate removal of the uterus. Given that the prevalence of cancer is highly dependent on age, all models were stratified into the following age groups: <40, 40-49, 50-59 and ≥60 years.[1]

The general model has three components: perioperative events, risk of cancer and dissemination, and outcomes of cancer in women with an underlying malignancy. The perioperative phase of the model included all events within 6 weeks of the index procedure (hysterectomy).[2] The risk of cancer dissemination phase of the model is based on age-specific risks of underlying malignancy and histology-specific estimates of the risk of dissemination at the time of hysterectomy.[1] Women who underwent abdominal and laparoscopic hysterectomy with their uteri intact were assumed to not be at risk for tumor dissemination while women who underwent electric power morcellation are at risk for tumor dissemination through fragmentation of the uterus.[1,3-7] Finally, the outcomes of cancer phase of the model estimated outcomes in women ultimately diagnosed with cancer.[8]

Model Assumptions

Perioperative Complications

Perioperative complications analyzed included the major intraoperative injuries and short-term complications defined as outcomes in a recent Cochrane review of hysterectomy for benign gynecologic diseases.[2,9,10] Intraoperative visceral injuries included bladder injury, ureteral injury, bowel injury, and vascular injury. Short-term outcomes and complications included abdominal wall and wound complications, pelvic hematomas, vaginal cuff infection, urinary tract infections, pulmonary infections, and pulmonary embolism/venous thromboembolism (Table 1).[2,9,10] Probabilities for each complication were determined through review of published literature.[11-29] Estimates of the risk of each complication were derived from prospective clinical trials for both abdominal and laparoscopic hysterectomy.[11-29] As data specifically describing the risks of complications for laparoscopic hysterectomy with electric power morcellation are lacking, we assumed the risk of complications was similar to that of laparoscopic hysterectomy.

Perioperative Resource Utilization

Metrics of resource utilization included transfusion, 30-day readmission, return to work, and unintended laparotomy for surgical approaches not involving routine laparotomy (i.e., conversion to laparotomy in women who underwent laparoscopic hysterectomy).[2,9,10] Like complications, estimates for abdominal and laparoscopic hysterectomy were derived from published, prospective studies.[2,11-29] Resource utilization for laparoscopic hysterectomy with morcellation was assumed to be similar to those of laparoscopic hysterectomy. The influence of length of stay is captured in the analysis of cost including hospitalization cost and cost associated with loss of productivity. Women who underwent unintended laparotomy were assumed to have the cost as those women in the primary abdominal hysterectomy group.

Perioperative Mortality

Estimates of procedure-associated mortality in the literature are highly variable. Perioperative death is rare with any type of hysterectomy for apparent benign gynecologic disease and, as such, accurate estimates could not be obtained from prospective studies. We utilized data from large observational studies and registries to estimate the risk of perioperative death by modality of hysterectomy.[30-36] However, many of these sources are based on billing data, therefore, patients whose surgery is initiated as a laparoscopic procedure and who experience a catastrophic intraoperative complication are likely to undergo emergent laparotomy and subsequently have their procedure coded as a laparotomy and abdominal hysterectomy.

Risk of Malignancy

The risk of malignancy at the time of hysterectomy for presumed benign gynecologic disease was based on prevalence estimates from population-based analyses of women who underwent minimally invasive hysterectomy (Table 2).[1] In this report, the prevalence of malignancy was 0.27% (95% CI, 0.22-0.32%).[1] While the prevalence of occult malignancy likely differs for each of the three modalities of hysterectomy, this discrepancy is due to differences in patient selection. Our base case model was predicated on the premise that a patient was potentially a candidate for any of the three types of hysterectomy, and we therefore assumed that the risk of underlying malignancy was similar for the three surgical approaches.

Malignancies in women undergoing hysterectomy for benign gynecologic disease may be either epithelial endometrial tumors or uterine sarcomas. Population-level data demonstrated that endometrial hyperplasia, a precursor to epithelial endometrial tumors is found in 0.84% of women who undergo electric power morcellation, suggesting that a substantial portion of these tumors may be endometrial cancers.[1] Among women with an occult cancer, our base-case model assumed that 50% of the tumors were uterine sarcomas and 50% were epithelial endometrial cancers. A scenario analysis in which a higher percentage of the tumors was assumed to be sarcomas was undertaken. We also conducted sensitivity analyses and examined outcomes based on varying estimates of the prevalence of malignancy. Prevalence estimates of occult uterine leiomyosarcomas which range from 0.09-1.0% at single institution studies, and 0.28% (all sarcomas) to 0.20% (leiomyosarcoma) by the United States Food and Drug Administration.[3,6,37]

Risk of Tumor Dissemination

Women who underwent either abdominal or laparoscopic hysterectomy were assumed to have had their uteri removed intact without disruption of any occult malignancies. In contrast, women who undergo laparoscopic hysterectomy with electric power morcellation are at risk for tumor dissemination from disruption of the uterus within the abdominal cavity. A study of women with apparent stage I leiomyosarcomas who underwent hysterectomy with morcellation noted clinically apparent disseminated intraperitoneal tumors in 28.6% of patients who underwent re-exploration.[4] Data describing the risk of tumor dissemination in women with epithelial endometrial tumors who underwent hysterectomy with morcellation are largely lacking. Our base-case scenario assumed a risk of dissemination of 28.6% for women with leiomyosarcomas and 20.0% for those with epithelial endometrial tumors. Patients with tumor dissemination were classified as metastatic (stage IV) cancer. Given the limited data for these estimates, we performed scenario analyses in which the risk of dissemination was modeled from 10-60% for leiomyosarcomas and 10-40% for epithelial endometrial tumors.

Indeterminate Smooth Muscle Tumors

The classification of uterine smooth muscle tumors follows a spectrum from benign leiomyoma to leiomyosarcoma.[6,38,39] A number of variants including smooth muscle tumors of uncertain malignant potential (STUMP), mitotically active leiomyoma and atypical leiomyoma that have some worrisome histologic features (increased mitotic active, atypia, tumor necrosis) but do not meet the diagnostic criteria for leiomyosarcoma have been described.[39] Although not clearly malignant, these neoplasms may recur. At the time of recurrence, the neoplasm may be classified as a leiomyosarcoma, or, alternatively, these neoplasms may recur with histologic features that do not clearly warrant classification as a leiomyosarcoma.[38]

From population-based data we estimated that the prevalence of indeterminate smooth muscle tumors at the time of hysterectomy was 0.11% (95% CI, 0.07-0.14%) (Table 2).[1] A prior report that examined women with smooth muscle tumors of uncertain malignant potential who underwent re-exploration after hysterectomy and morcellation noted a rate of dissemination of 25.0%.[4] Among women with these neoplasms, we estimated a recurrence rate of 7.3%.[38] Among those women who recur, one third of neoplasms are classified as leiomyosarcomas and two thirds as indeterminate smooth muscle neoplasms.[38] Treatment for recurrent smooth muscle tumors consists of repeat surgical resection.[38] Those women who recurred with a sarcoma were then classified as a metastatic leiomyosarcoma.

Tumor Stage Distribution and Survival

Estimates of tumor distribution and survival were derived from the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) database (Tables 3 and 4).[8] SEER is a population-based tumor registry that captures detailed clinical, demographic, and outcomes data on 28% of the U.S. population. Stage distributions as well as survival were estimated separately for each age strata and for each histologic tumor subtype. The percentage of women surviving from surgery until five-years was calculated at yearly intervals.

Costs

Total costs were modeled from a societal perspective. The cost of each modality of hysterectomy was captured using data from the Perspective database (Premier, Inc).[40-42]

Perspective captures direct hospital costs and not charges. Costs are measured within the database using an itemized log of all services a patient receives. Cost data from Perspective has been validated and utilized for a number of outcomes studies, including studies of hysterectomy.[40-44] Further, unlike other data sources, the structure of the Perspective database allows the capture of women who underwent hysterectomy with electric power morcellation so costs of morcellator-associated procedures can be directly captured.[1] Among women who experienced perioperative complications, the adjusted excess cost of each complication was estimated from the same data source. Similarly, the costs associated with resource utilization were obtained in a similar manner and verified through a search of published literature.

The cost of cancer care was estimated based on the phases of care paradigm and incorporated both health-related costs and time costs.[45-47] Briefly, the care of cancer patients is divided into three clinical phases: initial, continuing, and last year of life.[45-47] The initial phase of care occurs in the first 12 months after diagnosis, the last year of life phase as the final 12 months of life, and the continuing phase encompasses all of the time in between.[45-47] Phase of care costs for women with uterine cancer were estimated based on the data of Yabroff and colleagues. The health-related cost of the initial phase of care for all patients with uterine cancer was $16,268 (95% CI, $15,597-$16,939), the annual cost of continuing care was $916 (95% CI, $810-$1023), and the last year of life cost for those women with cancer who died was $24,651 (95% CI, $23,769-$25,532).[47] These cost estimates represent the excess cost of cancer-related care relative to non-cancer controls.[47] The perioperative costs, including hysterectomy, were assumed to be included in the initial phase of care to avoid double counting of procedure-associated costs.

The U.S Department of Labor Bureau of Statistics data was used to define the median cost of lost wages per week for women.[48] Women were assumed to have lost wages during the acute perioperative recovery period (until time to return to work) and from patient time costs associated with cancer care, including outpatient physician visits, emergency room visits, chemotherapy, radiation therapy, hospitalizations, and ambulatory surgery.[49] We used reported patient time in hours and weekly wage to calculate the time-related costs of uterine cancer for the initial phase, continuing phase, and last year of life.[49] All cost data was adjusted to 2013 U.S. dollars using the Bureau of Labor Statistics Consumer Price Index for Medical Costs. All costs were discounted 3% annually.

Utilities

Quality-of-life weights (utilities) were applied to post-surgery health states (abdominal hysterectomy, laparoscopic hysterectomy, laparoscopic hysterectomy with morcellation) and cancer outcomes from the available literature.[50-59] Utility values ranged from 0.0 to 1.0, where death is assigned a value of 0.0 and full health a value of 1.0. Utilities for abdominal hysterectomy were discounted compared to minimally invasive procedures. We applied the post-surgery utility for 6 weeks after surgery, at which point patients return to baseline if no cancer is identified (utility=1), or assume the utility of cancer. Studies evaluating the health utility of leiomyosarcoma were lacking, so we assumed the utility of soft tissue sarcoma.[54,57] We utilized a value of 0.83 for endometrial cancer (stages I-III), 0.60 for leiomyosarcoma (stages I-III), and 0.52 for metastatic disease.

Probabilistic Sensitivity Analyses of Model Parameters

Probabilistic sensitivity analyses using Monte Carlo simulations were utilized to estimate the uncertainty around our parameters. We performed probabilistic sensitivity analysis on the cost of surgery using a gamma distribution that incorporated the range of costs generated by estimates of the risk of complications from the literature. Estimates of mortality, the risk of underlying cancer, age-specific stage distribution of cancer, stage and histology-specific estimates of survival and utilities were assumed to follow a beta distribution. The cost of cancer care and follow up was assumed to follow a normal distribution.[47,49] We performed 1000 simulations and report the mean and standard error for each estimate.

Scenario Analyses

We modeled the outcomes of the three modalities of hysterectomy in women undergoing hysterectomy for presumed benign gynecologic disease. The base-case model was stratified by age: <40, 40-49, 50-59 and ≥ 60 years and the underlying risk of occult malignancy estimated to be 0.06%, 0.13%, 0.60%, and 2.4% for each age cohort, respectively.[1]

We conducted a series of scenario analyses in which the underlying assumptions about the risk and behavior of the occult malignancy were varied. First, we developed a simulation in which the risk of malignancy was reduced by 25% for each age group, and, alternatively, increased by 25% for each age group. A second scenario analysis simulation was conducted in which the risk of tumor dissemination in women with an underlying malignancy was altered. For this model, we first estimated outcomes if the risk of dissemination was increased to 40% in women with epithelial endometrial tumors and 60% in women with uterine sarcomas. We then developed a model in which the risk of dissemination was lowered to 10% for both tumor types. Finally, a third scenario analysis was undertaken in which the distribution of tumor types was varied. In this model, we assumed that 75% of the tumors were sarcomas and 25% epithelial endometrial tumors.

Relative to performance of abdominal hysterectomy, we projected the change in cost, change in life years, change in quality adjusted life years (QALYs), and the incremental cost effectiveness ratio (ICER, additional cost divided by change in QALYs or change in life years) for laparoscopic hysterectomy with electric power morcellation. We also report the impact of modality of hysterectomy on outcomes per 10,000 women. Outcomes analyzed included complications, cases of metastatic cancer, all cause mortality, perioperative mortality, and mortality from cancer.

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