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PELVIC MASS RISK ASSESSMENT; IS IT CANCER?

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Objective: Each year over 2 million patients globally will undergo surgery for an adnexal mass. Of these patients approximately 200,000 (~11%) will ultimately be diagnosed with epithelial ovarian cancer (EOC). Multiple studies in the US and Europe have demonstrated that patients with EOC managed by high volume surgeons and at institutions experienced in the management and treatment of EOC will have improved survival. Despite these facts, less than 50% of patient diagnosed with EOC are cared for by these physicians and at these centers. The Risk of Ovarian Malignancy Algorithm (ROMA) was developed to assist in the triage of women at high risk for EOC who are diagnosed with a pelvic mass. This presentation will focus on the performance of ROMA in patient diagnosed with a pelvic mass.

Methods: An analysis was conducted by pooling data from 5 pelvic mass trials performed by the PI. This study was IRB-exempt due to secondary use of preexisting data. Data was combined into one cohort for analysis of ROMA. As per ROMA design, the sensitivity, PPV and NPV were calculated at a set specificity of ~75%.

Results: A total of 2,004 patients were included in the analysis. There were 448 EOCs (89 stage I, 45 stage II, 284 stage III, 24 stage IV and 6 un-staged), 83 Borderline/LMP tumors, 1,224 benign masses, 23 non-epithelial ovarian cancers, 165 other gynecological cancers, 59 non-gynecologic metastatic cancers, and 2 mesotheliomas. At a set specificity of 75.0%, ROMA had a sensitivity of 91.3% with a NPV of 95.9%. In the evaluation of early-stage disease (Stage I & II) there were a total of 1358 patients with benign versus early stage EOC. At a set specificity of 75.0% ROMA differentiated benign verses early stage EOC with a sensitivity of 76.1% and a NPV of 96.6%.

Conclusions: ROMA has been shown in multiple independent prospective trials to be an accurate tool for pelvic mass risk assessment. ROMA should be used as one of the tools for pelvic mass risk assessment to assist in the triage of patient at high risk for EOC.

Statistical performance of ROMA

Total (N)	Premenopausal (N=739)	Postmenopausal (N=933)	Total (N=1672)
Sensitivity	85.5%	92.3%	91.3%
Specificity	74.8%	75.3%	75.0%
PPV	25.9%	71.9%	57.2%
NPV	98.0%	93.5%	95.9%

Biography

Richard G. Moore, MD, FACS, FACOG: Is a Professor of Obstetrics and Gynecology at the University of Rochester, the Chief of Gynecologic Oncology at the Wilmot Cancer Institute, and the director of the Targeted Therapeutics Laboratory at the Wilmot Cancer Institute. His research interests include investigation of oncogenic pathways, the development biomarkers and targeted therapeutics. His significant contribution to the development of the novel biomarker HE4 has led to USFDA clearance of HE4 as a biomarker for the management of women with ovarian cancer. Dr. Moore was the national PI on two project developing biomarker assays to detect malignancies in women with pelvic masses. He led the team that developed the Risk of Ovarian Malignancy Algorithm (ROMA) that was cleared by the USFDA for the detection of ovarian cancer. ROMA has also gained clearance in Europe, Canada and China and is currently being used clinically