Presidential Symposium dedicated to Professor Seiichiro Fujimoto:
Clinical Trials for Lymphadenectomy in Endometrial Cancer in the Post-ASTEC/Post-SEPAL Era

5) Risk Assessment of Nodal Metastasis before Surgery in Endometrial Cancer: Do We Need A Clinical Trial for Low-risk Patients?

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The Korean Gynecologic Oncology Group (KGOG) recently proposed new pre-operative criteria to identify a low-risk group for lymph node metastasis in endometrial cancer (Kang et al., J Clin Oncol, 2012). In the multi-center study, serum CA125 levels and three MRI parameters were found to be independent risk factors for nodal metastasis among 360 Korean patients. The model classified 53% of patients as part of a low-risk group, and the false negative rate was 1.7%. In the validation cohort including 180 Korean patients, the model classified 43% of patients as low-risk, and the false negative rate was 1.4%. The negative likelihood ratio of our low-risk criteria was 0.11 (95% confidence interval [CI] = 0.04 - 0.29), which was equivalent to the false negative rate of 1.3% (95% CI = 0.5% - 3.3%) at the assumed prevalence of nodal metastasis of 10%. In addition, the KGOG low-risk criteria were validated in 319 Japanese patients with endometrial cancer. The criteria identified 181 of 319 patients as a low-risk group (51%), and three false-negative cases were found (1.9%). Among the entire study population, the adjusted false-negative rate was 1.4% (95% confidence interval, 5% to 4.3%), which was similar to that of 1.3% in previous Korean multi-center study. These results indicate that we are able to identify low-risk patients with negligible false negative rate before surgery. However, the low rate implies that it would be very difficult to perform a randomized trial determining the efficacy of routine lymphadenectomy in the low-risk group. Based on these data, the challenges and the possible solutions for developing consensus on optimized management of low-risk endometrial cancer will be discussed in this lecture.