Study supports new standard of treatment for women with advanced ovarian cancer

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Results of a phase III, international randomized clinical trial demonstrate a new standard of care for treating advanced ovarian cancer that significantly reduces side-effects and post-operative deaths compared to the previously established treatment course. The study, presented at the 12th Biennial Meeting of the International Gynecologic Cancer Society (IGCS) in Bangkok in October, has a major impact on many countries where the new standard represents a more practical course of treatment.

The prospective study was presented by Professor Ignace B. Vergote of University Hospital Leuven, EU, on behalf of the European Organization for Research and Treatment of Cancer-Gynaecological Cancer Group (EORTC-GCG) and the National Cancer Institute Canada-Clinical Trial Group (NCIC-CTG).

A total of 718 patients from 60 institutions with advanced ovarian cancer were enrolled in the study. The women were randomized to receive either primary debulking surgery (PDS) prior to receiving six cycles of chemotherapy (329 patients as per protocol), or interval debulking surgery (IDS) performed after three of six cycles of neoadjuvant chemotherapy (339 patients as per protocol). The current treatment guidelines for stage IIIc and IV disease recommend debulking surgery prior to administering chemotherapy. This study represents the first randomized phase III neoadjuvant clinical trial ever reported for ovarian cancer treatment.

"Most women diagnosed with ovarian cancer have advanced stage

disease. Surgery before chemotherapy is not a practical course of treatment for patients in many countries because of difficulty scheduling surgery for patients with extensive cancer and associated complications," said the study's author, Prof. Vergote. "Because of this trend in treatment, our trial was designed to validate the administration of chemotherapy prior to surgery. In addition to establishing acceptability for this strategy, our study demonstrates fewer complications when chemotherapy is administered prior to surgery."

The median follow-up for all participants was 4.8 years. Overall survival and progression free survival were similar in both arms of the study, but a statistically significant reduction in complications, including postoperative deaths (2.7 percent in PDS versus .6 percent in IDS) was observed. The PDS arm of the study demonstrated a higher rate of hemorrhage (7 percent versus 1 percent) and blood clots (2.4 percent versus .3 percent).

"It was concluded that in patients with very extensive disease, as included in our study, neoadjuvant chemotherapy followed by interval debulking surgery can be considered as the preferred treatment. However, chemotherapy before surgery should not be used in patients with less than FIGO stage IIIc ovarian cancer, or small IIIc ovarian cancers, as these patients were not well-represented in the study" said Prof. Vergote. "Aggressive debulking surgery to no residual tumor remains the most important prognostic factor, underscoring the importance of a maximal surgical effort whenever the surgery is performed, whether the surgery is performed before or after chemotherapy."

Worldwide, nearly 200,000 women are diagnosed of ovarian cancer each year and every year, over 100,000 women die of the disease.

Source: Fox Chase Cancer Center