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Oncologists Should Use Dual-Delivery Treatment More Often for Ovarian Cancer, Study Shows
Oncologists from six recognized cancer centers urge greater use of regimen for advanced ovarian cancer

COLUMBUS, Ohio – Fewer than half of ovarian cancer patients eligible for a combined chemotherapy regimen that can significantly improve survival actually receive it, according to a new study authored by researchers from six leading cancer centers, including The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James).

This study is the first outside of a clinical trial to analyze whether chemotherapy delivered using two routes -- one into the abdomen, or intraperitoneally (IP) and the other intravenously (IV) -- can improve survival in women with stage III ovarian cancer after surgery to remove the tumor.

The study showed an improvement in the overall survival with a three-year survival rate of 81 percent for IP/IV therapy versus 71 percent for IV chemotherapy alone, but that only 41 percent of eligible patients at six academic medical centers (OSUCCC – James, Dana Farber/Brigham and Women's Cancer Center, University of Arizona Cancer Center, University of Pennsylvania, City of Hope Comprehensive Cancer Center, University of Michigan Comprehensive Cancer Center, University of Texas MD Anderson Cancer Center and Fox Chase Cancer Center) were treated using the dual route, suggesting that IP/IV chemotherapy could benefit a greater number of patients.

The researchers report their findings online ahead of print Aug. 4, 2015, in the *Journal of Clinical Oncology*. David O'Malley, MD, of the OSUCCC – James served as senior author of the study. Alexi Wright, MD, of Dana Farber/Brigham and Women's Cancer Center in Boston, Massachusetts, served as first author of the study.

"Our findings suggest IP/IV therapy is important and underutilized evidence-based treatment strategy for improving outcomes in ovarian cancer and the oncology community should begin considering this approach more frequently," says O'Malley, a gynecologic oncologist with the OSUCCC – James.
"Although use of IP/IV therapy increased between the years of this study, researchers found that less than 50 percent of eligible patients received this combined chemotherapy, despite clear survival benefit," says O'Malley. "What is exciting, however, is that those who received the intraperitoneal therapy had an improvement in their overall survival."

More than half of the nearly 23,000 American women diagnosed with ovarian cancer annually have advanced disease, leaving them with few treatment options for long-term cancer control.

In 2006, a National Cancer Institute-funded, multi-center trial (GOG 172) reported that ovarian cancer patients who received IP/IV chemotherapy had a 16 month survival benefit. Based on these 2006 findings, the NCI issued a rare clinical announcement encouraging use of the IP/IV approach in ovarian cancer. With the IP/IV therapy approach, in

addition to giving the chemotherapy drug paclitaxel IV through a vein in the arm, the drugs cisplatin and paclitaxel are injected into the abdominal cavity through a catheter (thin tube).

Study Design and Methods
The current study examined the use and effectiveness of IP/IV chemotherapy in clinical practice (i.e., outside of a clinical trial). It involved 823 women treated for stage-III ovarian cancer between 2003-2012 who were eligible for IP/IV chemotherapy. The women received therapy at one of six National Comprehensive Cancer Network (NCCN) institutions, including The OSUCCC – James, Dana Farber/Brigham and Women's Cancer Center, University of Arizona Cancer Center, University of Pennsylvania, City of Hope Comprehensive Cancer Center, University of Michigan Comprehensive Cancer Center, University of Texas MD Anderson Cancer Center and Fox Chase Cancer Center.

Patients were split into two groups. The first included 823 patients who had received adjuvant chemotherapy less than 90 days of surgery. The second group was a subset of 498 patients from the first group who were diagnosed after the NCI's clinical statement encouraging IP/IV therapy (January 2006 or later) and treated outside clinical trials.

Researchers note several barriers to integration of IP/IV chemotherapy into oncology practice, including treatment-related toxicities, absence of a "standard" regimen, patients' preferences and the inconvenience of an inpatient regimen.

"The magnitude of the survival benefit associated with IP/IV chemotherapy we detected is similar to results from randomized clinical trials," adds O'Malley. "Despite frequent modifications to the GOG-172 regimen, we found that the use of IP/IV chemotherapy in clinical practice is feasible and associated with improved survival compared to IV chemotherapy. Together, these findings suggest that IP/IV is an important and perhaps underutilized, evidence-based treatment strategy for improving outcomes in ovarian cancer."

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About the OSUCCC – James
The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute strives to create a cancer-free world by integrating scientific research with excellence in education and patient-centered care, a strategy that leads to better methods of prevention, detection and treatment. Ohio State is one of only 44 National Cancer Institute-designated Comprehensive Cancer Centers and one of only four centers funded by the NCI to conduct both phase I and phase II clinical trials on novel anticancer drugs. As the cancer program's 306-bed adult patient-care component, The James is one of the top cancer hospitals in the nation as ranked by *U.S. News & World Report* and has achieved Magnet designation, the highest honor an organization can receive for quality patient care and professional nursing practice. At 21 floors with more than 1.1 million square feet, The James is a transformational facility that fosters collaboration and integration of cancer research and clinical cancer care. For more information, visit cancer.osu.edu.