



GOG PARTNERS CONNECTION

FEATURED SPECIAL EDITION

A Quarterly Newsletter

From GOG Partners, A GOG Foundation Program

The GOG Foundation, Inc. has one mission that is dedicated to transforming the standard of care in gynecologic oncology.

THE OUTBACK TRIAL (GOG-0274/RTOG 1174/ANZGOG 0902)

A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: THE OUTBACK TRIAL (GOG-0274/RTOG 1174/ANZGOG 0902) will be presented as a Late Breaking Abstract (LBA3) at the 2021 ASCO Annual Meeting plenary session on Sunday, June 6, 2021, between 1:00 pm – 4:00 pm EST. Professor Mileskin, Deputy Director of Medical Oncology at Peter MacCallum Cancer Center will be the presenting author.



About the OUTBACK TRIAL

The OUTBACK trial, a cervical cancer trial, included 926 patients from seven countries and was sponsored by the University of Sydney. The primary objective of this study was to determine if the addition of adjuvant chemotherapy to standard cisplatin-based chemo-radiation improves overall survival. This randomized phase III trial studied how well giving cisplatin and radiation therapy together with or without carboplatin and paclitaxel works in treating patients with cervical cancer has spread from where it started to nearby tissue or lymph nodes. Drugs used in chemotherapy, such as cisplatin,

carboplatin, and paclitaxel, work in different ways to stop the growth of [cancer/tumor] cells, either by killing the cells, by stopping them from dividing, or by stopping them from spreading. External radiation therapy uses high-energy x-rays to kill tumor cells. Internal radiation uses radioactive material placed directly into or near a tumor to kill tumor cells. It is not yet known whether giving cisplatin and external and internal radiation therapy together with carboplatin and paclitaxel kills more tumor cells. [1]

The primary objectives of this study were to determine if the addition of adjuvant chemotherapy to standard cisplatin-based chemoradiation improves overall survival.

Secondary and Tertiary objectives included to determine the progression-free survival rates, acute and long-term toxicities, patterns of disease recurrence, the association between radiation protocol compliance and outcomes and to determine patient quality of life, including psycho-sexual health.

Finally, the tertiary objective was to determine the association between the results of a follow-up positron emission tomography (PET) scan performed 4-6 months post completion of chemoradiation and outcomes for all patients in the trial and determine the biological predictors of patients' outcomes based on translational laboratory studies of blood and tissue specimens.

This large study enrolled 919 women from April 2011 to June 2017. 463 were assigned adjuvant chemotherapy (ACT), and 456 no ACT. ACT was started in only 361 (78%) women assigned to receive it. Median follow-up was 60 months (IQR 45-65). OS at 5 years was similar in those assigned ACT versus control (72% vs 71%, difference <1%, 95% CI -6 to +7; P = 0.91). The hazard ratio for OS was 0.91, (95% CI 0.70 to 1.18). PFS at 5 years was similar in those assigned ACT versus control (63% vs 61%, difference 2%, 95% CI -5 to +9; P = 0.61). The hazard ratio for PFS was 0.87, (95% CI 0.70 to 1.08). AE of grade 3-5 within a year of randomisation occurred in 81% who were assigned and received ACT versus 62% assigned control. There was no evidence of differences between treatment groups in AE beyond 1 year of randomisation. Patterns of disease recurrence were similar in the two treatment groups.

NRG/GOG 274 Principle Investigator, Dr. Kathleen Moore, Stevenson Cancer Center at the University of Oklahoma and GOG Partners Co- Associate Director shared, "The OUTBACK trial was built upon the belief that adjuvant chemotherapy following chemotherapy and radiation would lead to fewer recurrences and improved survival among women with local regionally advanced cervical cancer. The results of this study demonstrate no benefit, which in and of itself is important given the uptake of this practice based on

earlier data which now should be discontinued. The sheer number of women who volunteered to take part in this trial are the real heroes of the story and we owe it to them to continue to analyze this data and biospecimen collection to learn as much as possible about how to improve outcomes for women impacted by cervical cancer.”

A press release was shared by ANZGOG stating the importance of global efforts in clinical trials. Associate Professor Philip Beale, Chair of ANZGOG, said, “*OUTBACK has been a fantastic effort from investigators and trial units around the world. This global effort has culminated in a high-quality, rigorously-conducted clinical trial, producing robust results that answer an important question for women with cervical cancer*”. Larry J. Copeland, President of The GOG Foundation, Inc. agrees by noting: “By working collaboratively across the globe, we can help fulfill the GOG Foundation’s mission of transforming the standard of care for women with recurrent cervical cancer.”

About Cervical Cancers

Cervical cancer is the fourth leading cause of cancer death in women worldwide and is most frequently diagnosed in women between the ages of 35 and 44. Almost all cases are caused by the human papillomavirus (HPV) infection, with approximately 80% classified as squamous cell carcinoma (arising from cells lining the bottom of the cervix) and the remainder largely adenocarcinomas (arising from glandular cells in the upper cervix).

Cervical cancer is often curable when detected early and effectively managed, but treatment options are more limited in advanced stages. It is estimated that there are approximately 570,000 women diagnosed with cervical cancer worldwide each year. In the U.S. there are 14,500 new patients diagnosed annually and approximately 4,000 women die each year.

To see the full press release, [click here](#), June 2021

To view the abstract being presented at ASCO 2021, [click here](#)

[1] [Clinicaltrials.gov](https://clinicaltrials.gov)



How Can We Help?

The GOG Partners Connection Quarterly Newsletter is produced by the GOG Foundation Communications Committee.

Please contact us at info@gog.org with any questions or suggestions regarding future content.

