ABSTRACT: LBA3

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ANZGOG'S OUTBACK TRIAL AMONG THE MOST IMPORTANT CLINICAL RESEARCH ADVANCES FOR CERVICAL CANCER IN THE PAST YEAR

A significant international study in cervical cancer treatment, the OUTBACK trial, will be presented at the 2021 ASCO Annual Meeting Plenary Session. OUTBACK is an academic collaboration of the Australia New Zealand Gynaecological Oncology Group (ANZGOG), NHMRC Clinical Trials Centre at the University of Sydney, and NRG Oncology under the auspices of the international Gynecologic Cancer Intergroup (GCIG). OUTBACK is a phase 3, randomised trial of adjuvant chemotherapy after chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone. OUTBACK included 926 women recruited from seven countries. The trial was sponsored by the University of Sydney and is registered on the Australian & New Zealand Clinical Trial Registry (ACTRN12610000732088).

Principal Investigator of the trial, Professor Linda Mileshkin, said, *"The OUTBACK results confirm that chemoradiation alone is currently our best standard treatment for women with locally advanced cervical cancer. The addition of adjuvant chemotherapy did not improve 5-year survival rates, but it did add significant side effects. Although some oncologists have been giving adjuvant chemotherapy outside of trials while awaiting the results of OUTBACK, this practice should now stop."*

Professor Mileshkin is Deputy Director of Medical Oncology at Peter MacCallum Cancer Centre.

"We need to find ways to improve the tolerability and completion of standard chemoradiation, as well as investigate other ways to improve survival rates for this group of women."

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. Great credit is due to Principal Investigator Professor Linda Mileshkin for her pivotal role together with ANZGOG and our collaborators in generating these important results. Our heartfelt thanks go to the women, and their families, who participated in this trial, enabling us to move forward and test new ideas to improve the outcomes of women affected by cervical cancer".*

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ABOUT OUTBACK

OUTBACK is a phase 3 trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared with chemoradiation alone (ANZGOG 0902/ GOG 274).

OUTBACK originated from observations that while standard chemoradiation for women with cervical cancer was working well to cure many, 1 in 3 women were dying due to later developing distant metastatic disease. The trial aimed to show whether the addition of adjuvant chemotherapy after chemoradiation could improve survival.

OUTBACK is an international trial led by ANZGOG and the NHMRC Clinical Trials Centre at the University of Sydney. OUTBACK included 926 women from the USA (711), Australia and New Zealand (165), Canada (28), China, Singapore, and Saudi Arabia. The trial had financial support in Australia and New Zealand from the NHMRC Project Grant (APP1044349) and through the National Cancer Institute for the US sites. Hospira provided paclitaxel in Australia and New Zealand.

Key findings

The phase 3 OUTBACK trial showed that the addition of adjuvant chemotherapy following chemoradiation did not improve survival compared to standard chemoradiation alone in women with locally advanced cervical cancer.

At 5 years, overall survival was similar in the two treatment groups — 72% among those assigned adjuvant chemotherapy versus 71% among those assigned standard chemoradiation alone. Rates of progression-free survival at 5 years were also similar (63% versus 61%, respectively). Patterns of disease recurrence were also similar in the two treatment groups.

Severe side effects (grades 3-4) within a year of randomisation were experienced by more women assigned adjuvant chemotherapy than standard chemoradiation alone (81% versus 62%).

The trial also found that only 77% of women in each arm successfully completed all components of standard chemoradiation (including external beam radiotherapy, brachytherapy, and concurrent weekly chemotherapy with cisplatin).

Full results of OUTBACK will be presented in the Plenary Session at the American Society of Clinical Oncology (ASCO) Annual Meeting on Sunday 6 June, 1:00PM ET (Monday 7 June 2021, 3:00AM AEST).

View the full abstract online

ABOUT CERVICAL CANCER AND WHY THE TRIAL WAS DONE

Cervical cancer refers to the growth of abnormal cells in the lining of the cervix that develop into a malignant tumour. The cervix connects the uterus to the vagina in the female reproductive system. More than half a million women are diagnosed with cervical cancer worldwide each year, and many women die from this disease, particularly in areas of the world without cervical screening programs. Cervical cancer is the fourth-leading cause of cancer-related death in women worldwide.

The standard treatment for locally advanced cervical cancer is chemoradiation which involves giving external beam radiation and brachytherapy to the pelvis plus weekly chemotherapy with cisplatin,

given over 6 to 8 weeks. However, a significant percentage of women with locally advanced cervix cancer will relapse and die as a result of distant metastatic disease despite this treatment. Because carboplatin and paclitaxel chemotherapy are active treatments for women with metastatic or relapsed cervical cancer, and are successfully used as adjuvant therapy for other cancers, OUTBACK was designed to determine if this might also be helpful for women with locally advanced cervical cancer.

ABOUT ANZGOG

ANZGOG is the peak national gynaecological cancer research organisation for Australia and New Zealand. The Group's purpose is to improve the outcomes and quality of life for women with gynaecological cancers through conducting and promoting cooperative clinical trials and undertaking multidisciplinary research into causes, prevention and treatments of gynaecological cancer.

Professor Linda Mileshkin is an ANZGOG Director, Chair of the ANZGOG EDEN Initiative in endometrial cancer research, and a member of ANZGOG's Research Advisory Committee, Uterine Tumour Type Working Group and OASIS Initiative Steering Committee.

ABOUT THE NHMRC CLINICAL TRIALS CENTRE

The NHMRC Clinical Trials Centre (CTC) at the University of Sydney is an academic research organisation that develops and implements studies designed to improve global health outcomes. We work closely with key leaders and partners to bring together world leading experts in healthcare, clinical trials, and related research methods on studies to maximise impact.

ABOUT ASCO

Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO) is committed to making a world of difference in cancer care. As the world's leading organisation of its kind, ASCO represents more than 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured and every survivor is healthy.

ABOUT PETER MAC

Peter MacCallum Cancer Centre is a world-leading cancer research, education and treatment centre and Australia's only public health service solely dedicated to caring for people affected by cancer.

ABOUT NRG ONCOLOGY

NRG Oncology conducts practice-changing, multi-institutional clinical and translational research to improve the lives of patients with cancer. Founded in 2012, NRG Oncology is a Pennsylvania-based nonprofit corporation that integrates the research of the legacy National Surgical Adjuvant Breast and Bowel Project (NSABP), Radiation Therapy Oncology Group (RTOG), and Gynecologic Oncology

Group (GOG) programs. The research network seeks to carry out clinical trials with emphases on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization comprises multidisciplinary investigators, including medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians, and encompasses more than 1,300 research sites located world-wide with predominance in the United States and Canada. NRG Oncology is supported primarily through grants from the National Cancer Institute (NCI) and is one of five research groups in the NCI's National Clinical Trials Network.

ABOUT GCIG

The GCIG, an international consortium of clinical trial cooperative groups, has facilitated the conduct of definitive research for women with gynecological cancers for 28 years. The organization has grown from 3 member groups to 33 member groups during this time and has representation from North, Central and South America, the UK, Europe, Asia and Australia.

The GCIG promotes and facilitates international cooperation in clinical research which allows for rapid and large patient accrual to large RCT's, involvement in Phase II trials, translational studies in all gynecological cancers, including rare tumours. The results of the clinical trial research has contributed to evidence-based medicine in gynecological cancer and changes to standard of care.

GCIG continues to strive to improve outcomes for women with gynecological cancer through a focused common purpose, shared expertise and mutual respect among members and with recognition and accommodation of cultural, geographic and clinical diversities amongst and between members and patients.