Editorial
Volume 7:1, 2022

Journal of Cancer Clinical Trials

ISSN: 2577-0535 Open Access

Disease-specific Mortality as a Primary Outcome

Ven Elger*

Department of Medical Oncology, Royal Brisbane and Women's Hospital, Herston, Australia

Editorial

The exclusion of elderly patients from randomised controlled trials evaluating the treatment of breast and other forms of cancer has been acknowledged for several years. However, new trials specifically addressing this issue have been slow to appear. The reasons for the failure to include elderly women in clinical trials are well documented. They predominantly relate to protocol restrictions and the reservations of clinicians in relation to the efficacy of treatment compared with the burden of side-effects in a population with a greater incidence of comorbidity and end-organ physiological decline when compared with younger patients. In addition, the high incidence of co-morbid diseases means that the cause of death is less likely to be related to the target cancer, which reduces the power of a trial where the primary outcome is overall mortality. Disease-specific mortality as a primary outcome may be less accurate as few causes of death are verified by post mortem. The fact that older women with breast cancer have largely failed to benefit in the improved prognosis experienced by younger women may be due to a lack of screening and a failure to benefit from systemic therapies other than tamoxifen.

However, these concerns are not necessarily shared by patients who may be as willing as younger patients to participate in clinical trials if approached. The lack of a robust evidence base has resulted in failure to develop specific evidence-based guidelines for older women with breast cancer and a tendency to extrapolate from studies in younger women. In some health care systems, commissioners will not fund expensive systemic therapies in the absence of specific evidence of benefit from randomised controlled trials, further limiting the access of older women to effective treatment. The Early Breast Cancer Trialist's Collaborative Group data assessing the benefits of tamoxifen and/or chemotherapy concluded that the trials of chemotherapy included 'too few women aged over 70 to be reliably informative' despite evidence that the magnitude of benefit was possibly similar to the 60-69 years of age group. Furthermore, none of these studies was primarily aimed at addressing the treatment of older women.

Recently published audits from different national settings continue to show the wide variations in practice in all aspects of the treatment of older women with breast cancer, particularly in the use of systemic therapy as an adjuvant to or an alternative to primary surgery. Therefore, the development of new randomised controlled trials addressing these issues is essential. Adjuvant or Primary Endocrine Therapy for Older Women with Breast Cancer After the publication of several small studies showing the efficacy of tamoxifen as an alternative to surgery in the early 1980s this strategy gained widespread acceptance, particularly in the UK. A small number of randomised controlled trials were carried out and these have recently been the subject of a Cochrane Review. This analysis showed no significant survival benefit when primary endocrine therapy with tamoxifen was compared with surgery and adjuvant tamoxifen. However, there was a significant advantage in favour of surgery in terms of local disease control. However, subgroup analysis showed that in the age group 70-75 years, surgery seemed to have a significant benefit in terms of survival and local control, whereas in the over 75 years age group surgery had no effect on survival due to the increasing frequency of mortality from other causes. Most of the previous studies did not assess oestrogen receptor status and recruited patients who were deemed fit for surgical treatment. Hence, very few of the frail older population with breast cancer were included in these studies. With increasing age there is an increase in the proportion of patients with oestrogen receptor- and progesterone receptor-positive tumours and a reduction in the number of tumours demonstrating HER-2 positivity. Furthermore, patients over the age of 75 years have a reduced overall life expectancy, increased frequency of co-morbid illness and reduced physiological function. Recently, the aromatase inhibitors have shown increased efficacy in comparison [1-5].

References

1. Seyi-Olajide, Justina O, Jamie E. Anderson, Omolara M. Williams and Omolara Faboya, et al. "National surgical, obstetric, anaesthesia and nursing plan, Nigeria." Bull World Health Orga 99 (2021): 883.
2. Pandya, Sunil T, Kousalya Chakravarthy, Pratibha Jain Shah and Anjan Trikha. "Obstetric anaesthesia as a career." *Indian J Anaesth* 65 (2021): 43.
3. Maronge, L, and D. Bogod. "Complications in obstetric anaesthesia." *Anaesth* 73 (2018): 61-66.
4. Landau, Ruth. "COVID-19 pandemic and obstetric anaesthesia." *Anaesth Crit Care Pain Med* 39 (2020): 327.
5. Lee, J. S. E, J. J. I. Chan, F. Ithnin, and R. W. L. Goy, et al. "Resilience of the restructured obstetric anaesthesia training programme during the COVID-19 outbreak in Singapore." *Int J Obst anesth* 43 (2020): 89.

How to cite this article: Elger, Ven. "Disease-specific Mortality as a Primary Outcome." J Cancer Clin Trials 7 (2022): 145.

***Address for Correspondence:** Ven Elger, Department of Medical Oncology, Royal Brisbane and Women's Hospital, Herston, Australia, E-mail: Elger.ven@gmail.com*

***Copyright:** © 2022 Elger V. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.*

Received 04 January, 2022, Manuscript No. jcct-22-54844; **Editor assigned:** 05 January, 2022, PreQC No. P-54844; **Reviewed:** 10 January, 2022, QC No. Q-54844; **Revised:** 15 January, 2022, Manuscript No. R-54844; **Published:** 21 January, 2022, DOI: 10.37421/jcct.2022.7.145