



Stop excluding male patients

→ Fatima Cardoso ■ GUEST EDITOR

Male breast cancer is a rare disease, accounting for less than 1% of all breast cancers worldwide. According to the American Cancer Society, last year it was expected that around 1910 men would be diagnosed with breast cancer in the US with around 440 deaths, compared with around 192,370 expected new cases and 40,170 deaths among women.

Male breast cancer patients go through their difficult fight with very little support, while having to cope with the additional stigma of having a 'female disease'. They also suffer from a lack of evidence on how best to manage their disease. Not a single randomised phase III trial has ever been concluded on male breast cancer. As a consequence, management of male breast cancer is mainly done by extrapolation from its female counterpart.

The Breast International Group and the North American Breast Cancer Groups have now joined forces to launch a three-part international research programme for male breast cancer, coordinated by the EORTC. It has kicked off with a meta-analysis of clinical data and a central pathology review of tumour specimens from about 1700 male breast cancer cases diagnosed in participating institutions over the last 20 years. Part 2 of the programme will involve building a prospective international registry of all male breast cancer cases diagnosed at participating institutions over a two-year period, to collect data on demographics, risk fac-

tors, treatment and outcomes. Funding is being sought to finance a central analysis of the biological material collected, with a virtual tumour bank being used in the meantime.

The intention is to proceed to a randomised clinical trial of endocrine therapy, which could be launched as part 3 of this programme. In view of the failure of all previous attempts to run a clinical trial in this setting, a fully committed international effort will be indispensable.

Securing funding for such a non-drug related, purely academic effort has been a daunting process, demonstrating once again the need for a central funding body in Europe. While continuing to look for additional sources of funding, work on the retrospective analysis has already begun thanks to support from the US Breast Cancer Research Foundation.

This research programme could greatly enhance our knowledge of the biology of male breast cancer – an essential first step to guide the development of future therapies. While waiting for the results, a plea is made to all those involved in the design and implementation of breast cancer trials to stop excluding male patients without a good reason. If excluding male patients from endocrine therapy trials may be understandable, excluding them from trials of cytotoxic and biological agents is not. Cancer societies and organisations also need to play their part, by increasing efforts to raise awareness and establish support groups for these patients.

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