therefore the need to develop a critical thinking to assess their merit. The reasoning involved in this process is, from the statistical point of view, very similar to the steps one takes when designing and conducting a clinical trial to its end.
Whether you write or read a scientific paper, start by identifying the objectives, then read the methods and the results, and then make your own judgment about their value before reading/writing the discussion and conclusion. Make this with a fresh mind, free of prior beliefs and with logic and objectivity!
Be mindful that bias may be introduced at every step of a clinical experiment:
– By construction (if e.g. endpoints or follow-up assessments systematically favor one group, or by selection of a suboptimal comparator)
– In the conduct (selection bias, selective reporting of events, operational bias − this one comes when intermediate results are divulged that influence the further conduct of the experiment)
– In the data analysis (sub-grouping, data dredging, hindsight bias − a natural human tendency to try to confirm prior beliefs, disconfirmation bias − the opposite tendency to scrutinize more the results that go against prior beliefs)
– In the presentation of the results (when more focus is given to the significant findings, even if they are secondary/exploratory; when effect estimates are not reported thus clincal significance cannot be assessed)
– In the interpretation of the results (a tendency to confirm prior beliefs and to see causality)
– In the publication of the results (publication bias: a tendency to make more publicity for positive results than for negative results).

Modern clinical trials are becoming increasingly complex due to the increasing economical pressure and to the growing scientific knowledge. Trials that use adaptive designs, surrogate endpoints or sophisticated pharmaco-genomic classifications are at particularly high risk of bias. In reading articles, be mindful that intermediate endpoints may not always be surrogates for long term clinical benefit; that adaptive designs carry the risk of operational bias or require appropriate safeguards and that the risk of false positive findings must be controlled by appropriate measures whenever analyses in subgroups or interim analyses are conducted.
Find current reporting guidelines on www.equator-network.org

359 INVITED

How to Get Good Evidence Based Information

Abstract not received

Tuesday 27 September 2011

Scientific Symposium (Tue, 27 Sep, 09:00−11:00) Relieving Symptoms of Hormonal Therapies in Patients With Breast Cancer

360 INVITED

Endocrine Symptom Assessment in Women With Breast Cancer

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Background: Toxicity and tolerability profiles of endocrine treatments in breast cancer trials are usually derived from physician-recorded adverse events. However, there is some evidence that these proxy rating do not adequately reflect endocrine symptom burden experienced by women with breast cancer.
Objective and Methods: The objective is to give an overview of measures used to assess self-reported symptoms related to endocrine therapy in women with breast cancer, to summarise major findings of clinical trials including self-reports of endocrine symptoms and their impact on quality of life (QoL), and to discuss implications for clinical practice.
Results: Several valid tools are available to assess self-reported endocrine symptoms in breast cancer clinical trials. These tools encompass subscales of commonly used cancer-specific QoL measures (e.g. Functional Assessment of Cancer Therapy − Endocrine Subscale; FACT-ES) or checklists specific to endocrine or menopausal symptoms (e.g. Breast Cancer Prevention Trial (BCPT) Symptom Checklist). In contrast, the Checklist for Patients on Endocrine Therapy (C-PET) was developed for the individual assessment of patients' experience with endocrine treatment at clinical visits in order to facilitate communication between the patient and the treatment team. Prevalence rates for most endocrine symptoms are higher when self-reported compared to physician ratings published in pivotal clinical trials. Studies that assessed subjective endocrine symptoms focused on treatment comparisons rather than on the associations between endocrine symptoms and QoL measures. Regarding the impact of endocrine treatment on QoL, findings are not consistent.
Conclusion: The use of endocrine agents, particularly aromatase inhibitors like anastrozole, letrozole and exemestane will extend in earlier stages of disease and for longer periods of time. It's therefore important to collect data on patients' self-reported symptom burden from clinical trials. This information is relevant to inform women about the potential physical sequelae of different endocrine agents, to interpret the association between symptoms and QoL, and to symptom management.

361 INVITED

Evidence-based Management of Symptoms Related to Endocrine Treatment

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Endocrine treatment will be a major part of breast cancer therapy for postmenopausal women with hormone-sensitive early breast cancer for years to come, the safety and long-term tolerability of the treatment are therefore important considerations. Like all adjuvant therapies, endocrine treatment has symptoms and side effects associated with their use, many of which resemble symptoms common to menopause. There is a great need to support patients to tolerate and effectively manage and/or prevent these symptoms. Educating patients about anticipated symptoms and side effects may help them understand, accept, and cope with treatment long-term. This presentation reviews symptoms and side effects associated with different adjuvant endocrine treatments and highlight some strategies to manage them effectively. It also highlights the importance of patient education regarding endocrine therapy and involvement in treatment decisions, which may lead to better long-term adherence and ultimately to better outcomes.

362 INVITED

Identification and Management of Treatment-Related Symptoms for Breast Cancer Patients Receiving Adjuvant Endocrine Therapy

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Data from several multi-national clinical trials have demonstrated that adjuvant endocrine treatment significantly reduces the risk of recurrence and death in women with ER+ breast cancer. It is however difficult to determine which patients actually need treatment: many with early stage disease will be cured of their cancer by adequate surgical and radiation therapy. Consequently some women may receive adjuvant hormone therapy for 5−10 years and experience considerable iatrogenic harms without deriving any discernable benefit. Some of the rarer harms e.g. thromboembolic events and endometrial cancer maybe life-threatening. More commonly experienced harms that are quality of life threatening include: vaso-motor complaints, loss of libido, vaginal dryness and arthralgias. If these are left untreated they can compromise adherence to therapy. We need to minimise the impact of these troublesome side-effects by careful monitoring and prompt implementation of ameliorative interventions. Some of the methods for managing symptoms are reviewed and areas that demand more research to demonstrate efficacy will be outlined.

363 INVITED

Non-compliance in the Adjutant Endocrine Treatment of Women With Breast Cancer

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Enhanced therapeutics and treatment options have improved outcomes of patients with endocrine responsive early breast cancer. Contribution from both physicians and patients is necessary to translate this progress for the overall population into benefit for the individual patient. To ensure the latter one, potential and actual adverse events and respective management options as well as the importance of compliance need to be addressed and discussed openly with empathy and self confidence before and during the course of therapy.
Oral therapies are used increasingly in the treatment of all cancers, especially breast cancer accommodating most women's preferences for tablet therapies. For that reason, patient compliance with recommended treatment is crucial to successful outcomes. However, a 2003 study among 2,378 women with early stage breast cancer revealed that overall adherence to tamoxifen decreased to 50% by the fourth year of therapy. These results were confirmed by more recent studies for patients prescribed tamoxifen or anastrozole. Reasons for non-adherence