8 INVITED

Evolving paradigms in the management of radiation side-effects

L. Sharp[1]. [1]*Karolinska Universitetssjukhuset, Department of Oncology/Radiotherapy, Stockholm, Sweden*

Cancer patients and their families are more involved in decision making regarding their cancer care today and need to take a more active role in reducing the risk for and treating side effects from the radiotherapy. Nurses and other members of the multi professional teams need better recognise this and follow evidence based guidelines for different type of radiation induced side effects. The guidelines should include self care strategies and patient (and family) education.
During this session, the author will discuss how evidence based guidelines for; A. Oral care, B. Skin care, C. Smoking cessation and D. Issues concerning sexuality and intimacy in relation to radiotherapy was developed, implemented and evaluated a the radiotherapy unit at Karolinska University Hospital in Stockholm.
Possibilities, experiences and hinders will be discussed.

9 INVITED

The balance of endocrine therapy, symptom burden and outcomes for cancer survivors

L. Fallowfield[1]. [1]*University of Sussex, CRUK Psychosocial Group, Brighton East Sussex, United Kingdom*

The primary aim of treatment is to improve the quality of individuals' lives hopefully by curing them of disease and ameliorating any cancer related or treatment related symptoms. Having accurate methods for the monitoring of symptom control and the wider impact symptoms may have upon quality of life (QoL) is of course an imperative; unfortunately outside of a clinical trial setting, formal assessment of QoL is rare. Even within trials, reporting of Patient Reported Outcomes (PROs) is given less prominence than safety data from Case Report Forms (CRFs). This situation is curious given that traditional outcomes such as partial response or stable disease (always assuming that they are evaluable) that might excite the clinical scientist, may be of little benefit to a patient experiencing unremitting symptoms. Clinicians willing to alter patient management on the basis of a tumour marker result maybe unlikely to do the same on the basis of a changed QoL score.
Many still do not 'trust' PROs, feel uncomfortable discussing issues in questionnaires, have difficulty interpreting the scores, are over-confident in their ability to elicit symptoms through face-to-face communication, and worry that they will unleash emotional or psychosexual problems for which they have no referral services. All these things need challenging if both doctors and nurses are to communicate more effectively about treatment burdensas well as benefits. The past decade has seen the successful development of many interesting new diagnostic procedures, drugs and surgical techniques for breast cancer patients. Together these have contributed to fewer recurrences, less contralateral breast cancer and improved survival. However novel treatments do not come without cost and although there are many publications reporting efficacy and safety data, less attention has been given to PROs. For example there is a common perception that endocrine treatments are well-tolerated, especially when compared with cytotoxic chemotherapy regimens but several studies have shown that many side-effects are under-recognised, under-reported and consequently remain under-treated. The litany of side effects associated with cytotoxic treatment e.g nausea, vomiting and alopecia, are fairly immediate and obvious, and many will abate at the end of treatment. The development of side effects from adjuvant hormonal therapy are more insidious and last for a longer time, as current treatment recommendations are for 5–10 years. Trials of novel endocrine therapy almost always report primary clinical outcomes and other safety data a long way ahead of PROs. However several authors have shown that comparison of AEs recorded on the CRFs by physicians compared with those reported by patients in QoL questionnaires show extremely poor congruence. In some cases the differences may be large enough to have altered conclusions about a trial. Correlations are especially poor for non-life threatening events but the burden imposed on women who experience untreated, non life-threatening but QoL-threatening side-effects can lead to poor adherence in adjuvant settings and in advanced disease. Ways to help alter healthcare professionals beliefs about the value of measuring PROs will be discussed together with the skills needed to promote more patient centred PRO focussed communication. Unless this happens too many patients will continue to experience unwanted, unnecessary iatrogenic harms of otherwise effective anti-cancer treatment delaying research into ameliorative interventions.

10 INVITED

Complex symptoms in advanced cancer: understanding multidisciplinary approaches

E. Ream[1]. [1]*King's College London, The Florence Nightingale School of Nursing and Midwifery, London, United Kingdom*

Cancer and its treatment give rise to troublesome symptoms which typically become more complex and numerous as disease progresses. Symptoms directly influence quality of life and their ineffective management can result in unplanned admissions, and risk people not being cared for in a place of their choice. This session will review symptoms that commonly cluster together in advanced cancer. It will appraise evidence regarding effective interventions for their relief and review how such interventions are applied in practice through different service configurations. Features of effective multidisciplinary team approaches will be identified.

Scientific Symposium (Mon, 21 Sep, 11:00−13:00)
Methodology and regulatory aspects of biotherapeutics and chemotherapeutics

11 INVITED

New response evaluation criteria in solid tumors: RECIST GUIDELINE VERSION 1.1

E.A. Eisenhauer[1], J. Verweij[2]. [1]*Queen's University, Cancer Research Institute, Kingston – Ontario, Canada;* [2]*Erasmus University, Medical Center, Rotterdam, The Netherlands*

Background: Assessment of the change in tumor burden is an important feature of the clinical evaluation of cancer therapeutics: both tumor shrinkage (objective response) and disease progression are useful endpoints in clinical trials. Since RECIST was published in 2000, many investigators, cooperative groups, industry and government authorities have adopted these in criteria in the assessment of treatment outcomes. However, a number of questions and issues have arisen which have led to the development of a revised RECIST guideline (RECIST 1.1), which was released in a special issue of the European Journal of Cancer in January 2009.
Highlights of Revised RECIST 1.1: Changes include: *Number of lesions to be assessed:* based on evidence from numerous trial databases merged into a data warehouse for analysis purposes, the number of lesions required to assess tumor burden has been reduced from a maximum of 10 to a maximum of 5 total (and from 5 to 2 per organ, maximum). *Assessment of pathological lymph* nodes is now incorporated: nodes with a short axis of >15 mm are considered measurable. The short axis measurement should be included in the sum of lesions in calculation of tumor response. Nodes that shrink to <10 mm short axis are considered normal. *Confirmation of response* is required only for trials where this is the primary endpoint, since in phase III trials, where response is secondary endpoint, the control arm provides the best means of assessing relative effect of a new treatment on response rate. This will make it easier to deploy RECIST criteria in phase III settings. *Disease progression* is clarified in several aspects: in addition to the previous definition of progression in target disease of 20% increase in sum, a 5 mm absolute increase is now required as well to guard against over calling PD when the total sum is very small. Furthermore, there is guidance offered on what constitutes "unequivocal progression" of non-measurable/non target disease, a source of confusion in the original RECIST guideline. Finally a section on detection of new lesions, including the interpretation of PET scan assessment is included. *Imaging Guidance:* the revised RECIST includes a new imaging appendix with updated recommendations on the optimal anatomical assessment of lesions
Future Work: A key question considered by the working group in developing the revision to RECIST was whether it was "time" to move from anatomic unidimensional assessment of tumor burden to either volumetric anatomical assessment or to functional/molecular imaging with PET or MRI. The Working Group did not believe there was sufficient standardization and wide-spread availability to integrate these alternative assessment methods into all aspects of RECIST, thus a key aspect of future RECIST working group activity will be to stimulate international standardization and assessment of these modalities in rigorous clinical validation studies in the next years to determine where and how they add value to standard anatomical imaging.