4273 POSTER

Questionnaire development to explore sleep disturbances in oncology patients

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Background: Around 45% of oncology patients suffer sleep disturbances. Nurses involvement in the assessment of the patient's sleep pattern is key to develop strategies to help the patient to improve quality of sleep.
The aim of this study is to develop and validate a questionnaire to explore patients' perception of their sleep and influencing factors.
Method: The structure of the questionnaire is based on environment characteristics and parameters defined by the Oncology Nursing Society to measure characteristics of sleep-wake disturbances. Principal items were drawn based on an overview of the existing literature and discussed with 5 hospital's experts on oncology care. The questionnaire was distributed to 35 patients in our cancer outpatient unit. Patients completed the questionnaire and the Edmonton System Assessment Symptom (ESAS). Data were codified and analysed with SPSS 15.0.
Cronbach's alpha coefficient was used to determine internal consistency and correlations with sleep items on ESAS for convergent validity.
Results: 44% of the patients reported sleep problems. Sleep efficiency in these patients with sleep problems showed a mean value of 77% (SD 16.6) and those with no problems of 83% (SD 12.6). Quality of sleep showed a mean = 2.43 (SD 0.58) in a Likert scale from 1 (very good) – 5 (very bad). Cronbach's alpha for all the items included in the different scales was significant.
There is a significant positive correlation between sleep items of ESAS and the different items used in the questionnaire to measure quality of sleep: overall satisfaction (0.424**) and scale for quality of sleep (0.461**).
In total, 2.4% questions were not answered, mainly regarding the open questions.
Conclusions: The study provides a valid and reliable instrument to evaluate patients' perceptions of the quality of sleep that could be used in other studies and larger samples. Patients' accounts of their experience completing the questionnaire have helped to clarify and rewrite some of the questions included. Development of instruments with description and analysis of psychometric properties helps to interpret results in a meaningful way and to advance this field in a consistent and comparable way.

4274 POSTER

Influence of malignant diseases on the sexual and reproductive functions

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According to WHO definition, sexuality includes the integrity of physical, psychological and social human functions. Malignant disease, as well as its treatment may influence all aspects of sexuality, in a different ways and different extent. Sexual and reproductive disorders could be divided in two main categories: psychological and organic or iatrogenic (artificial) dysfunctions. Psychological disorders are manifested in the loss of libido, mood alterations, preoccupation with body functioning and disease progression etc, while organic and iatrogenic dysfunctions are mostly caused by the influence of anti-cancer treatments on gonadal endocrine and reproductive role, temporary or definitive infertility, early menopause, with its symptoms and disabilities etc. Both psychological and organic disorders depends in their manifestation, duration and seriousness on various factors, such as age, gender, sexual functioning and fertility prior to diagnosis, as well as the type and stage of malignancy, overall treatment procedures, anti-cancer drugs used, and specific manipulation on endocrine or reproductive organs, in particular. Although sexuality and fertility are very important to patients, most drug-oriented clinical trials do not follow specifically the sexual disorders caused by the treatment. This is why we do not know exactly the rate of psychological disorders or gonadal dysfunctions of most anti-cancer drugs, or their influence on fertile capacity. In addition, very important is the research of fertility preservation, both in males and females, especially in those young patients who are potential survivors, and who do not finish their reproductive life before diagnosis of malignancy. In our Institution, in a group of female patients, being treated for early breast cancer, around 80% declared a satisfactory sexual functioning prior to diagnosis, while it became worsened in 40% patients after the treatment.

Breast cancer

Oral presentations (Mon, 21 Sep, 11:00–13:00)

Breast cancer I – Advanced disease

5000 ORAL

A 3-arm randomised phase II study of oral vinorelbine (NVBo) plus capecitabine (X) versus NVBo and X in sequential versus docetaxel (D) plus X in patients with metastatic breast cancer (MBC) previously treated with anthracyclines

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Background: The widespread use of anthracyclines in the adjuvant setting limit their administration as first-line therapy in metastatic disease. Active agents in sequence or in combination which might improve outcomes with acceptable toxicity are still sorely needed for patients (pts) with prior anthracycline exposure.
Materials and Methods: Pts with HER2-negative MBC previously treated with anthracyclines in (neo)adjuvant setting and with a disease-free interval of at least 12 months were eligible. Pts were randomized to fully oral 3-weekly cycles of either arm A [NVBo d1, d8 at a dose of 80 mg/m^2 (after the first cycle at 60 mg/m^2), X at 1000 mg/m^2 bid d1-d14], arm B (NVBo d1, d8, d15 alternating with X every 3 cycles at the same doses as arm A) and arm C (D d1 at a dose of 75 mg/m^2, X at 1000 mg/m^2 bid d1-d14). The primary endpoint was disease control rate. Pts were stratified according to prior fluoropyrimidine or taxane therapy, age, and centre.
Results: 139 pts were randomised to treatment (A, 44; B, 47; C, 48). Baseline characteristics were as follows (A/B/C): median age (55/56/52 years), visceral disease (66/91/65%), median disease-free interval (2.9/2.6/2.8 years), measurable disease (91/100/88%). Median number of cycles (range) received were (A/B/C): 6 (1–25)/4 (1–15)/6 (1–18). Incidence of febrile neutropenia and neutropenic infections were as follows (A/B/C): 2/0/6% and 0/0/12%, respectively. Incidence of grade 3 non-haematological toxicities ($\geqslant$5%) were: 9% of diarrhoea in arm A, 0% in arm B, 8% of fatigue and 19% of hand-foot syndrome in arm C (no grade 4 toxicity). Disease control rate (CR+PR+ SD $\geqslant$3 months) in the intent-to-treat population according to the investigator and after an independent review was (A/B/C): 73%, 48%, 79% and 71%, 37% and 69%, respectively. Lower disease control rate in Arm B could be due to higher prevalence of patients with visceral disease in this arm. Due to short follow-up, the progression-free survival and overall survival have not been reached.
Conclusions: The combination arms seem to offer higher disease control rate than sequential schedule in this population of pts. The first line all-oral combination of NVBo with X induced acceptable clinical toxicity and allowed prolonging the infusion-free survival.