4254 POSTER Efficacy and patient preference for intranasal fentanyl spray (INFS)

Efficacy and patient preference for intranasal fentanyl spray (INFS) versus oral transmucosal fentanyl citrate (OTFC) for breakthrough cancer pain – an open-label crossover trial

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**Background:** The efficacy of intranasal fentanyl spray (INFS) was compared to oral transmucosal fentanyl citrate (OTFC) for relief of breakthrough pain (BTP) among in-/outpatients with cancer.

**Methods:** This crossover, open-label trial compared the efficacy of INFS with OTFC titrated to doses of 50, 100, or 200  $\mu g$  and 200, 400, 600, 800, 1200, or 1600  $\mu g$  fentanyl, respectively, in patients receiving chronic opioid treatment but experiencing BTP. The effective dose of each agent was used to treat six BTP episodes. The primary efficacy parameter was patients' recorded time by stopwatch to onset of meaningful pain relief. Pain intensity difference scores (PID), response rates, adverse events were also analysed.

**Results:** Among 196 patients enrolled, 139 were randomised. INFS provided shorter median time to meaningful pain relief: 11 mins (n = 101) versus OTFC: 16 mins (n = 100). In the primary analysis, the majority experienced the fastest onset (66%) with INFS, p < 0.001. The adjusted mean PID at 5, 10, 15, 20, 30, and 60 mins for INFS was significantly greater (1.14, 2.27, 3.18, 3.73, 4.15, 4.52) versus OTFC (0.54, 1.08, 1.83, 2.54, 3.39, 4.36), p < 0.001 throughout, except 60 mins p = 0.008, for 577 episodes in each case. Response rates (>33% PI reduction) for INFS and OTFC were 25.3% versus 6.8% (p < 0.001) and 51.0% and 23.6% (p < 0.001) at 5 and 10 min respectively. A significantly better median ease of administration score was recorded for INFS with 90% reporting 'Easy' or 'Very easy', versus only 40% for OTFC (p < 0.001). Among 86 patients, 76% preferred INFS, versus 22% for OTFC (2% unknown). Treatments were well tolerated.

**Conclusion:** INFS provided meaningful pain relief of BTP faster and in a greater proportion of episodes than OTFC, and was well tolerated.

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## Pain care of dying cancer patients in Finland

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Background: The most part of cancer patients near the end of life get medical and nursing care in public hospitals (central or regional) or in the wards of health care centres in Finland. It has been a national problem for at least for twenty years time that the pain care of cancer patients differs a lot in different care places and pain medicine is used too little and too late time for patients. The purpose of this study was to find out how the pain management of the dying cancer patients is implemented today in these organisations.

Material and Methods: The data were collected in the year 2008 by online questionnaire including both open and closed questions. The data was analysed by SPSS – statistical program. There were participants (n = 191) from 124 health centres, from 50 central hospitals and from 13 regional hospitals. Participants were mostly women (87%) and they had mostly (77%) nurse education and 23% had medical doctor education. Half (50%) was age of 46–55 and 28% was over age of 55. The participants had a strong working experience; most (68%) of them had been working over 20 years

Results: The majority (71%) of participant found that there was no medical doctor named to be responsible for coordination of pain management strategies in the area of their responsibility. On the contrary most participants (59%) said that there was a nurse named to be as a contact person in pain management. Shortages in pain education available was noticed. The implementation strategy of pain management was more clear in special health care than in health centres. The doctors estimated the quality of pain care higher than nurses. The most often used pain medicines and palliative care alternatives was identified and differences between organisation were noticed. The shortages was found in evaluation of pain and the results were related to organisation and professional education. The majority (97%) of participants had an opinion that there is a need for national network for professionals in responsible for pain management for cancer patients. The external quality evaluation group visiting in organisations was also found important by most (88%) participants.

Conclusions: There are still shortages and differences between organisations in pain care of dying cancer patients in Finland. Registered nurses and medical doctors are not aware of each others' work. The need for national network and external quality audit practices was identified and needs to be organised in the future. 4256 POSTER

Qol in correlation with access to chemotherapy: phase III NGO project on supportive care efforts by an Indian NGO

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**Issues:** Access to Anti-cancer-therapies [ACT] high priority issue in resouirce-poor-nations. Targeted anti-cancer therapies very-expensive, no state-Government planned program to subsidize cost of therapy. Additionally Social stigma, Fatigue, sexual-dysfunction, depression, pain reduce QOL in cancer-sufferers. from April 2007 our NGO started this Phase-III-project to alleviate suffering by supportive-care-initiatives.

Objective: ACT available to only 16% cancer-sufferers in India. Poordrugs-availability, lack of trained-personal increase mortality. statistically >92% suffered sexual-dysfunction, 72% experience unbearable-pain; >84% suffered social neglect/humiliation, >47% fatigue, >78% depression. phase-III-project evaluated needs/responses to alternative-system of medicines [CAM].

Methods: Our India Cancer Non-Govt-Organization [NGO] surveyed 192 cancer sufferers through QOL-questionnaires. None of them had access to Targeted anti-cancer therapies or newer anti-cancer compounds. After 14 weeks with psychosocial support. Counseling & palliative support with anti-depressants/pain-killers/nutrition QOL improved to statistically significant level. Need in cancer palliative care has been evaluated using the methodology suggested by Oncologists. Besides symptom assessment was performed on weekly basis. Traditional faith-healers involved for more psychological impact on patients community. Patients/family members attitudes towards CAM-therapy evaluated.

Results: CAM acceptable to >81% compared to chemotherapy. Advantages of CAM: No-ADR's, low-cost, high-acceptance, locally-available. >65% women expressed that spirituality/CAM was most important factor that helped them to cope with cancer. significant correlations between higher scores of spirituality with absence of depression. & sexual dysfunction. CAM administered in rural/tribal/India includes, hydrotherapy/hypno-therapy for pain, Acupressure/acupuncture stress-busting, Tulsi/Shatavari/Ashwagandha-plant-extract to increase immunity etc. >68% enquired for CAM-therapy in home-based-care-unit.

Conclusions: Resource-poor-communities may not get access to ACT before 2020. Life-span/QOL of cancer-sufferers depends on psycho-social care & appropriate-palliative-care/CAM. NGO-nurses should be trained in supportive-care-services. larger trials of CAM can bring hope for thousands in future Field of Spiritual/psycho-social/community support is fertile ground for further investigations by like minded NGO's. We NGO-representatives shall present our patients concerns/difficulties in access to Ca-chemotherapy at ECCO-ESMO 2009-conference. We NGO-oncologists need interactions with seniors from USA/Europe for developing our supportive treatment-advocacy-policy for recommendations to concerned authorities like ECCO/ESMO/WHO.

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Correlation of the nutritional status as measured by the Scored Patient-generated Subjective Global Assessment (PG-SGA) and Karnofsky Performance Score (KPS) in patients with advanced lung cancer

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Background: Malnutrition and weight loss are common in patients with advanced lung cancer and are independent survival prognostic factors. Prompt detection of nutritional compromise is thus a critical component of global care of these patients. PG-SGA is a simple, reliable and inexpensive screening tool that uses clinical data to detect mild or moderate malnutrition before the patient become severely wasted. The objective of this study was to characterize the nutritional status of patients with advanced lung cancer (stages IIIB and IV), as measured by the PG-SGA and correlate its results with the Karnofsky performance score.

Material and Methods: We evaluated the nutritional status and performance status of 49 patients (32 men), with advanced lung cancer (stages IIIB and IV), as measured by the PG-SGA and Karnofsky performance scores.

Results: Our cohort of patients had a mean age 60 years (40-81), with lung cancer stages IV (36 patients) and IIIB (13 patients). The mean PG-SGA score was 15. Eleven (22%) patients were well nourished (PG-SGA rating A), 23 (47%) patients were at risk of malnutrition (B), and 15 (31%) patients were malnourished (C). There was a statistically significant difference in the median PG-SGA scores (P<0.001) for each of the SGA classifications (4.6 vs 14.5 vs 23.3, respectivelly), with the malnourished patients having the highest scores. The mean KPS of the patients was 57 (20-90). We found a strong statistically significant