1495 PUBLICATION

Transdermal Fentanyl for the treatment of chronic cancer pain in patients under home palliative care

A. Gamallo[1], M.A. Monescillo[1], M.A. Pereira[1], J.L. Nuñez[1], S. Hernansanz[1], J. López-Escudero[1], F. Sánchez-Domínguez[1], R. De Pablo[1], P. Satre[1], M. Feyjoo[2]. [1]*Asociación Española Contra el Cancer, Spain;* [2]*The R.W. Pharmaceutical Research Institute*

We report preliminary results of a study aimed to determine patients (pts) and caregivers satisfaction with TTS-fentanyl treatment.

Methods: Pts who were under home palliative care on weak or strong opioids treatment were included. The lowest TTS-fentanyl delivery rate, 25 micrograms/hour was used as the initial dose for strong opioids naive pts. We used the recommended conversion table for non-naive strong opioids pts. Short-acting oral or subcutaneous morphine were supplied as rescue medication. The TTS patch was replaced as a rule every 72 hours. Pain intensity (baseline, days 4, 15, 30 and 45) and satisfaction (baseline, days 15, 30 and 45) were determined by a visual analogue scale going from 0–10 (0: no pain or no satisfied; 10: worst pain ever or very satisfied).

Results: eighty pts were evaluated in this analysis: 36 strong opioid naive and 44 on strong opioids. Fifty-two pts stopped the treatment, 46 because of death, and 6 because other reasons. Number of pts under treatment were 80 at day 4, 58 at day 15, 37 at day 30 and 28 at day 45. Fourteen pts required a dose increase at day 4. Median initial TTS-fentanyl delivery was 25 micrograms/hour (25 micrograms/hour-150 micrograms/hour) and median final delivery was 50 micrograms/hour (25 micrograms/hour-150 micrograms/hour). The mean treatment duration for the 52 pts who stopped the medication was 19 days (4–43). No respiratory depression was observed. The reported side effects were nausea and vomiting (2 pts), diarrhoea (1 pts), anxiety (1 pts) and confusion (2 pts). Comparison of satisfaction at days 15, 30, 45 were statically significant higher ($p < 0.001$) vs. baseline. Comparisons of pain assessments at days 4, 15, 30 and 45 were statically significant ($p < 0.001$) vs. baseline, indicating better pain relief. Mean score in patient's satisfaction changed from 5.2 at baseline to 7.5 at day 45. Caregiver's satisfaction increased in 2.8 points at the end of treatment (5.0 at baseline, 7.8 at day 45). Pain decreased significantly during the 45 days period, mean scores were 5.9, 3.1, 3.0, 2.3, 1.7 and at baseline and days 4, 15, 30 and 45 respectively.

Conclusions: TTS-fentanyl for the treatment of cancer pain in patients under home palliative care is well tolerated and extremely appreciated by patients and caregivers with excellent pain relief.

1496 PUBLICATION

Evidence-based approach to cancer of unknown primary

F. Porzsolt[1], C. Sellenthin[1], H.-J. Schmoll[2], H.-J. Illiger[3]. [1]*University Hospital Ulm, Clinical Economics Group, Ulm;* [2]*University Hospital Halle, Hematology and Oncology, Halle;* [3]*Town Hospital Oldenburg, Wilsede School of Oncology, Oldenburg, Germany*

Purpose: Planning a randomized trial we describe the homogeneity of assumptions in the diagnosis and treatment of cancer of unknown primary (CUP).

Methods: We asked 56 participants (23 m, 31 f, 1 na; 19 with <3 yrs of experience, 29 with 3–10 yrs, 7 with >10 yrs and 1 na) of an educational course on CUP organized by the Wilsede School of Oncology to answer 33 questions (yes/no). These were derived from a review by M. Markman, Clev Clin J Med 1997, 64 (2): 73–75.

Results: In 26/33 statements the responses were homogenous (>80% agreement). In 23/33 there was agreement with the review article. Disagreement (>80%) was found in 3 statements: 1. the most likely primary site found in autopsies is pankreas if the manifestations occurred below the diaphragm, 2. the most likely site is the lung if the manifestation occurred above the diaphragm, 3. Electron Microscopy should be included in the diagnostic evaluation. The responses were heterogenous in 7/33 statements: 1. In 30% of patients the primary is not found in autopsies, 2. The goal of diagnosis in CUP is histologic documentation of cancer, 3. The goal of diagnosis is prevention of immediate harm to the patient (bleeding, obstruction), 4. 1-year survival is 25%, 5. Survival from diagnosis is <6 months, 6. Overall survival rate has changed little over the past 20 yrs, 7. Watchful waiting may be reasonable if the goal is palliation and the tumor is not causing symptoms. There was no correlation with clinical experience, but clinicians with >10 yrs of experience were more likely to accept the statement that survival has changed little in the past 20 yrs.

Conclusion: There is some heterogeneity in the assumptions which could be adressed in randomized trials. We will use these results to design clinical trials and hope that interested physicians will be convinced to participate.

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Patient selection in perfusional heated chemotherapy in advanced abdominal tumors

M. Pace[1], L. Bandettini[1], D. Brugnola[1], A. Galli[1], R. Gattai[1]. [1]*Clinica Chirurgica I Università di Firenze Florence, Italy*

Introduction: The correct pt. selection is essential for evaluating the efficacy of a therapeutic approach in relation to morbidity, mortality and disease-free and overall survival.

Purpose of the Study: To identify valuable parameters for an exact pt. selection by the analysis of 17 pts. suffering from peritoneal carcinomatosis treated by cytoreductive surgery followed by heated perfusional chemotherapy.

Patients and Methods: Out of 36 pts. evaluated for heated chemotherapy (6/96–12/98), in 15 pts. the procedure was not performed due to age > 70 yy, associated diseases or impossibility to obtain minimal residual disease. The procedure was carried out in 21 pts.: for adiuvant purpose in 4 pts. (group A), with serosal invading gastric and colo-rectal cancer, but without carcinomatosis. The residual 17 pts. (group B) suffered from carcinomatosis; the pts. are 6 men and 15 women with mean age 60 yy (range 35–70). At laparotomy, peritoneal cancer index (PCI) according to Sugarbaker was evaluated; the cytoreduction was classified as low, middle and high grade. After radical (group A) or cytoreductive surgery (group B), heated chemotherapy was performed with "closed abdomen" technique, typically with Cisplatinum (25 mg/sm/lt) and Mitomycin C (3 mg/sm/lt) and at a peritoneal temperature ranging 42–43°C.

Results: In group A no morbidity or mortality were observed, and pts. discharge was not delayed. In group B 7 pts. experienced major morbidity requiring relaparotomy for haemorrhage, perforation or anastomosis leakage, with 3 pts. dead because of MOF. The mean PCI was 10.5 (range 3–22) in pts. without complications whilst was 17.1 (12–20) in the 7 above pts.: moreover, cytoreduction was of high grade in all these pts.

Quality of life in follow-up was satisfactory, especially in pts. with preoperative ascites.

Conclusions: The procedure is able to supply encouraging results also in advanced carcinomatosis pts.; relevant morbidity and mortality were observed, possibly related to PCI and consequently to cytoreduction; furthermore, all the pts. with complications had been previously submitted to surgery and/or radio-chemotherapy.

1498 PUBLICATION

Endoscopic palliative laser disobstruction (LD) for endobronchial non resectable or recurrent lung cancer: An evaluation of its impact on the quality of life

G. Mantovani, G. Astara, G. Manca, R. Versace, P. Contu, A. Carai, M. Pisano. *Department of Medical Oncology and Internal Medical Sciences, University of Cagliari, 09124 Cagliari, Italy*

Study Objectives: The objective of this study was that of assessing the impact of LD on the quality of life (QL) of patients with endobronchial obstructions due to non-resectable or recurrent lung cancer.

Design: Evaluation was based on 1) Performance Status (PS) (ECOG Scale), for the "objective" assessment of QL and 2) the EORTC QLQ-C30 version 1.0 ($QLQ\text{-}C30_{(v1)}$) questionnaire for the "subjective" assessment of QL.

Patients: From May 1994 to June 1997, 133 LDs were performed on 89 evaluable patients (M/F 78/11, mean age 62.7/63.7 years, range 42–82/47–73). The QL was evaluated by ECOG PS and $QLQ\text{-}C30_{(v1)}$ at baseline (3 days before LD), t1 (7 days after LD) and t2 (1 month after LD). The objective tumor response was evaluated at t2.

Results: The objective tumor response to LD intervention was: CR in 33 (24.8%) patients, PR in 97 (72.9%) patients, with an ORR of 97.7%. A highly significant decrease in high score (3–4) ECOG PS was registered from baseline to t1 and from t1 to t2. The functioning scales, the global QL scale and the symptom scales/items of $QLQ\text{-}C30_{(v1)}$ showed a highly significant improvement at t1 compared to baseline ($p < 0.001$), whereas only emotional functioning, global QL and the single symptom "fatigue" improved at t2 compared to t1. The results were not related to age, gender, tumor histology, first LD intervention.

A comparison of baseline ECOG PS scale with $QLQ\text{-}C30_{(v1)}$ scale revealed a strong relationship of PS with the symptom "fatigue".

An higher patient clinical response to tumor (CR vs PR) after LD was not consistent with an higher degree of QL improvement during the study.

Conclusions: Our study demonstrates that clinical improvement obtained by an highly effective, although palliative, treatment, such as LD intervention,