3012 POSTER

Review of the Pharmacokinetic Profile of Fentanyl Transmucosal Formulations

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Background: Breakthrough pain (BTP) is a transitory flare of moderate-to-severe pain that occurs in patients with otherwise stable, controlled persistent pain. There are intra and inter-individual variations with BTP, including time to peak intensity from one second to 30 minutes and duration of pain from one minute up to several hours. Drug delivery technologies allowed the development of new fentanyl formulations: rapid-onset opioids with pharmacokinetic profiles more consistent with BTP episodes with faster onset of analgesia than traditional short acting opioids. There are 2 routes of transmucosal administration: oral or nasal. Among the oral routes: Actiq® (oral transmucosal fentanyl citrate [OTFC]) is via swabbing, Effentora® (fentanyl buccal tablet [FBT]) used buccally or sublingually with an active OraVescent® technology to enhance local fentanyl absorption, Abstral® (sublingual fentanyl [SLF]) is administered sublingually with a rapid dissolution and a passive absorption and Breakyl® (fentanyl buccal soluble film [FBSF]) is administered buccally via a film. Among the nasal routes: Instanyl® (intranasal fentanyl spray [INFS]) that flushes in passively and PecFent® (fentanyl pectin nasal spray [FPNS]) utilizes a gel-based formulation. Pharmacokinetic features differentiate these formulations.
Material: For this review, 3 available formulations were evaluated as representatives: OTFC, FBT and INFS. For comparison purposes similar C_{max} ranges (0.7–0.95 ng/mL) were selected.
Results: Plasma concentration increases: up to 60′ for OTFC, rapidly up to 30′ and sustained through 60′ for FBT, up to 15′ and decrease rapidly thereafter for INFS. Compared to FBT and INFS, the early increase in plasma fentanyl concentration with OTFC is more gradual. The plasma fentanyl concentration is maintained through 60 minutes with FBT and OTFC but declines rapidly with INFS. The elimination phase of fentanyl depends solely on the molecule (i.e., it is the same regardless of the delivery system).
Conclusion: It is important to consider the pharmacokinetic profile of each formulation along with clinical data when physicians are selecting a rapid-onset opioid for a patient. Given the substantial variability of BTP experienced by patients, these pharmacokinetic differences may provide useful information for physicians.

3013 POSTER

A Pan-European Phase IV Open-label Multicentre Study in Patients With Breakthrough Cancer Pain (BTcP) Treated With Fentanyl Buccal Tablet (FBT) − Preliminary Data From Germany

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Background: FBT treats BTcP in adult patients receiving opioid maintenance therapy. This study (EudraCT number: 2008–001841−24) was designed to compare the percentage of patients reaching an effective FBT dose when starting titration at 100 μg vs 200 μg and secondary objectives were to measure the efficacy and safety of FBT.
Methods: After the screening period, patients were enrolled in an open-label randomized titration period (patients titrated FBT starting at 100 or 200 μg up to a successful dose [100, 200, 400, 600, 800 μg maximum]) followed by an open-label treatment period (treatment up to 8 BTcP episodes at the successful dose). The patient inclusion criteria followed the SmPC for FBT. The preliminary data of the patients enrolled in Germany (n = 90) are presented with BTcP characteristics as well as patients' assessment of FBT treatment.
Results: Breast cancer was the most frequent primary tumour (26.7%; 70% out-patients (63/90]). The patients had a mean overall pain intensity=5.4±2.4 on a 0−10 NS, 71.8% (56/78) of the patients reported 1−3 BTcP episodes per day, at enrolment. The average time from onset to peak intensity was within 10 minutes for 48.7% of the patients (38/78), from 10 to 30 minutes for 38.5% (30/78) and more than 30 minutes for 12.8% (10/78). After titration, the percentage of patients achieving a successful dose of FBT at 100, 200, 400, 600 and 800 μg was 25%, 42%, 23%, 8% and 2% respectively. Patients' quality of life and functional status improved after treatment with FBT (Brief Pain Inventory-7 item subscale). FBT was assessed as very easy-easy/convenient for treating BTcP by 72.7% (32/44) of the patients. The patient satisfaction was in favour of FBT.
Conclusions: These preliminary data from Germany on BTcP episodes characterization are consistent with previous published studies. The majority of the patients found FBT convenient to use. Final results from the study will provide information on the optimal starting dose, the safety, and the efficacy of FBT; it will also offer information on BTcP characterizations & treatments in real clinical practice.

3014 POSTER

Medical and Nursing Interventions in Hospitals in the Last Days of Life of Cancer Patients in Italy and the Netherlands

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Background: International variation in end-of-life care is known to be present. More insight in current practices in different countries makes it possible to discuss this variation in order to improve end-of-life care in general. This study aims to describe medical and nursing interventions in hospitals for dying cancer patients in Italy and the Netherlands.
Method: Medical records were scrutinized using a checklist of medical and nursing interventions, such as anti-cancer treatments, invasive interventions, non-invasive interventions, diagnostics and nutrition and hydration. In Italy consecutive deceased cancer patients of three general medicine wards of a general hospital (n = 59) were included. In the Netherlands 38 cancer patients who consecutively deceased at one of 9 different wards of a university hospital were included. All patients had to have been admitted in the hospital for at least 3 days.
Results: In the last days of life only 2 Italian patients received anti cancer treatments and in both countries no patients received invasive interventions like dialyses, invasive inhalation or resuscitation.

Patient characteristics and most often applied interventions

	Number of patients (%)			
	Italy (n = 59)		Netherlands (n = 38)	
	Day 3 before death	Day of death	48−72 h before death	0−24 h before death
Age, mean	74		61	
Admission duration, mean (median)	20 (15)		19 (9)	
Interventions				
Therapeutic drainage	0 (0)	0 (0)	10 (26)	7 (18)
Central venous access	9 (15)	9 (15)	n/k	n/k
Urinary catheter	36 (61)	41 (70)	14 (37)	19 (50)
Oxygen inhalation	18 (31)	23 (39)	18 (51)	22 (58)
Diagnostics				
Blood test	19 (32)	6 (10)	21 (55)	13 (34)*
Oxygen saturation	n/k	n/k	30 (79)	20 (53)*
ECG	2 (3)	2 (3)	9 (24)	5 (13)
Diagnostic radiology	1 (2)	0 (0)	17 (45)	5 (13)*
Nutrition and hydration				
TPN	14 (24)	10 (17)	1 (3)	0 (0)
Nasogastic tube	0 (0)	0 (0)	7 (18)	2 (5)*
Liquids (hydration)	43 (73)	29 (49)*	18 (51)	15 (40)*

n/k, not known.
*Significant difference between day 3 and day of death, p-value <0.05.

Conclusion: In Italy and the Netherlands diagnostics are rather common in the last days of life, especially in the Netherlands. We found few changes in interventions during the last three days of life, except a decrease of artificial hydration in both countries and a decrease in diagnostics and artificial nutrition in the Netherlands.

3015 POSTER

The Associates of the Risk of Febrile Neutropenia After Conventional Dose Chemotherapy in Patients With Common Cancers − a Prospective Study From Two Tertiary Centers

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Aim: Febrile neutropenia (FN) is a life threatening complication of cancer chemotherapy. However, homogenous risk models for FN solely in solid tumours, is still not frequently reported and validated. In this prospective