

and nurse, continuity of care, length of medical visit, communication and expectations. Finally, patients are asked for suggestions for improvements at the clinic in an open-ended question. The first measurement was conducted in the winter 2000/2001, and the last in the spring 2004 and during that time period, efforts to improve care were implemented.

Results: A total of 316 patients completed the questionnaire in 2000/2001 and 287 in 2004. Statistically significant improvements were found for 8 of the 12 items: waiting time (2), length of medical visit (2), information (1), expectations (1) and continuity of care (1). Regarding continuity of care, a higher proportion of patients reported having met the same doctor at the previous visit in 2004 compared to in 2000. No differences were found regarding the importance of meeting the same doctor, the evaluation of physicians' and nurses' interpersonal skills, feeling cared for at the clinic. Further results will be presented and the changes in the clinical practice will be discussed.

Conclusions: The questionnaire captured positive changes in patient satisfaction between the two measurements. One of the improvements concerned the continuity of care. However, further improvements are still requested.

1302

PUBLICATION

Cancer pain: Multicentre epidemiological and longitudinal study on opioid instauration/rotation (OR) in advanced cancer patients

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Aim: To know the natural history of the use of opioids in far advanced cancer, the effectiveness of OR and the causes to do it.

Method: We designed a descriptive, longitudinal and multicenter study, enrolling advanced cancer patients from their first visit in a Palliative Care, Medical Oncology or Radio-Oncology Services and followed up till 3 months. The study was approved by a Ethical Committee and was carry on in 7 Spanish communities. We record any switch of opioid, considering or change of route, cause of OR, and its effectiveness using verbal rating scale (VRS) (0-10) at day 0 and 7. Evaluation was done even by phone or visit in the clinic.

Results: 257 patients have been enrolled from May 2004 to March 2005, 68.9% were men. Lung cancer (23.7%) and head-neck cancer (20.6%) were the most frequent tumours and the pain was somatic in 40.9% of patients and constant (72.4%). We recorded 155 instaurations and 225 OR. The main cause of instauration was pain unrelieved. Most used starting opioid in naïve patients were fentanyl (45.8%) and buprenorphine (25.2%). In OR the most frequent opioid used to switch was morphine (45.8%). Principal cause of OR was pain unrelieved (50.4%). The mean VRS reduction after instauration was 2.77 (SD 2.31) and mean VRS reduction after rotation was 2.27 (SD 2.54). The rotations made because of uncontrolled pain were the most effectiveness. 72.5% of instaurations and 59.4% of rotations were efficacy. Regarding the drug used the proportion of effectiveness was: buprenorphine (67.9%), morphine (58.7%), fentanyl (55.6%)

Conclusions: We describe clinical practice in our country regarding starting and switch opioids and we have found that both practices are effectiveness although there are differences between opioids. Comparative studies are necessary to confirm these results.

1303

PUBLICATION

Efficacy of once weekly 30,000 IU Epoetin beta in daily practice: results from a post marketing surveillance study

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Background: Anaemia commonly occurs in malignant disease and is aggravated by most antitumoral therapies. Erythropoiesis stimulating factors have been available since more than 12 years, and a once weekly dosing regimen is now the standard practice, also supported by the recently published guidelines from the EORTC. To monitor routine use of Epoetin beta (NeoRecormon®), we have conducted a post marketing surveillance study with Epoetin beta in Germany. In the present analysis we compare the efficacy of once weekly (qw) versus three times per week (tiw) administration of Epoetin beta in an unselected patient population in daily practice.

Methods: Recruitment started in February 2003, and patients documented until April 2005 were included in this analysis. The course of anaemic

cancer patients over 18 years old who gave their informed consent and who received Epoetin beta as standard therapy could be documented. Patients with both solid and haematological tumors were included. Of the 630 patients documented by 149 centres, the 362 pts. (57.5%) who received 30,000 IU Epoetin beta once weekly (qw) and the 180 pts. (28.6%) who received 3 x 10,000 IU Epoetin beta per week (tiw) were analysed.

Results: Patient characteristics in both treatment groups were comparable. Mean age was 60.7 (qw) and 62.9 (tiw) years. 42.8% (qw) and 40.6% (tiw) of patients were female. Mean weight at baseline was 70.6 kg (qw) and 68.4 kg (tiw). Mean hemoglobin values at baseline were 9.77 g/dl (qw) and 9.78 g/dl (tiw) and increased in both groups steadily to 10.3 g/dl at week 4 and to 11.3 g/dl at week 16. Median Epoetin beta dose was stable at 30,000 IU per week and identical in both arms.

Conclusion: The efficacy of anaemia treatment with Epoetin beta given once weekly at a dose of 30,000 IU or given 3 times weekly at single doses of 10,000 IU is comparable in this unselected patient population. Both administration schedules led to a significant and steady increase in hemoglobin values at comparable average doses.

1304

PUBLICATION

Assessment of bone turnover markers in breast cancer or multiple myeloma patients with bone metastases treated with intravenous ibandronate infused over 15 minutes followed by daily oral ibandronate

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Background: Bisphosphonates are the standard of care for metastatic bone disease. Ibandronate is a single-nitrogen, non-cyclic bisphosphonate available in intravenous and oral formulations. In phase III trials of metastatic breast cancer, both formulations decreased the incidence of skeletal-related events and reduced metastatic bone pain scores. Bone turnover markers are prognostic indicators of skeletal complications. This 12-week trial examined bone turnover marker responses following a single rapid infusion of intravenous ibandronate followed by daily oral ibandronate.

Materials and methods: Patients (n=39) with advanced multiple myeloma or breast cancer and ≥ 1 confirmed lytic or mixed bone lesion received a single 15-minute infusion of intravenous ibandronate 6mg followed by 12 weeks of oral ibandronate 50 mg once daily. Markers of bone resorption (cross-linked C-terminal telopeptide of type I collagen in serum [S-CTX]) and bone formation (bone specific alkaline phosphatase [S-bALP], amino-terminal procollagen propeptide of type I collagen [P1NP], osteocalcin [OC]) were measured at various timepoints. Safety assessments, including adverse event monitoring, serum chemistry, and urinalysis, were performed.

Results: Intravenous followed by oral ibandronate resulted in a rapid decrease in S-CTX by 77% from baseline within 2 weeks of treatment, and this was maintained throughout the 12-week trial. At study end, S-bALP, P1NP, and OC had decreased by 27%, 42%, and 24% from baseline, respectively. The treatment schedule was well tolerated with few adverse events.

Conclusions: Treatment with a single dose of intravenous ibandronate 6mg infused over 15 minutes followed by daily oral ibandronate 50 mg causes a marked decrease in bone turnover markers with no safety concerns. This treatment regimen is undergoing further assessment.

1305

PUBLICATION

Results of the ESOPE multicentre study on electrochemotherapy

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Background: The objective of the ESOPE project was to define and validate European Standard Operating Procedures for ElectroChemoTherapy (ECT). ECT is a combination of a physical effect, electroporation (EP) and drug administration. Cell exposure to sufficiently high intensity electrical pulses results in enhanced cell membrane permeability. This EP is exploited to deliver anticancer drugs directly into the cells otherwise, these large molecules cannot cross the cell membrane.

Materials and methods: Fifty-five patients were treated with ECT, and 37 met inclusion criteria. There were 163 nodules included in the analysis

in these 37 patients. The majority of lesions were melanoma (59%); 41% were other tumour types (carcinoma, adenocarcinoma and sarcoma). Two drugs were used, bleomycin (BLM) and cisplatin (CDDP). BLM was delivered intratumourally or intravenously, while CDDP was administered only intratumourally. ECT was performed under general or local anaesthesia. Electric pulses were delivered by CLINIPORATOR™. EP occurred following the delivery of 8 high voltage pulses (1kV/cm), 100 µs long. Three different types of electrodes (plate, linear needle and hexagonal needle) were available for treatment. Evaluation of anti-tumour efficacy was based on WHO criteria: Complete Response (CR), Partial Response (PR), No Change (NC) and Progressive Disease (PD).

Results: Among the 37 patients, the average age was 63. The average size of tumour nodules before treatment was 1.82 cm³ (SD 7.86 cm³). The Objective Response (OR) rate (CR+PR) was 78.5% with a 63.2% CR rate. Non-melanoma nodules had a significantly higher OR rate (83.5%) than melanomas (75%), $p = 0.009$.

There was no significant difference between drug delivery modes: OR rate was 75.3% for the intratumour versus 82.9% for the intravenous route. Intratumour CDDP was found to be slightly more efficient (OR 82.5%) than intravenous CDDP (69.2%), N.S.

When the current levels delivered were considered, the best results were observed when at least 1.5 amps and 2 amps were delivered via needle electrodes and plate electrodes respectively.

Conclusion: ECT is a safe and effective treatment capable of controlling tumour growth locally. Negative side effects were rare and were tractable. This multicentre study allowed us to develop Standard Operating Procedures to be used as guidelines in daily clinical practice.

1306

PUBLICATION

Amenorrhea in younger women treated with neoadjuvant/adjuvant chemotherapy for early breast cancer

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Chemotherapy (CT)-related amenorrhea can influence heavily the quality of life of younger women with early breast cancer (menopausal symptoms, loss of fertility, long-term side-effects). On the other hand the suppression of ovarian function has a major therapeutic role in hormonal receptors positive patients (pts). The risk of amenorrhea is related to the type and doses of CT and to patient age (less than 20% in pts younger than 35 years treated with standard-dose CT). We analyzed 45 consecutive pts aged ≤ 39 years with early or locally advanced breast cancer (Stage I to IIc) treated with primary and/or adjuvant CT: 21 and 24 pts were aged < 35 and 35–39 years, respectively.

Characteristics of the pts: Stage I: 8 (18%); Stage II a-b: 18 (40%); Stage III a-b-c: 19 (42%); hormonal receptors (ER and PgR) were both positive ($>10\%$ by IHC) in 17 pts (38%), both negative in 14 pts (31%), ER+/PgR- in 10 pts (22%) and ER-/PgR+ in 4 pts (9%); 67% of the pts treated with adjuvant CT were node positive and the median number of axillary lymphnodes involved was 4 (range 1–16).

CT regimens (all doses are in mg/m²): CMF d1–8 for 6 courses: 8 pts (18%); epirubicin 120 for 3–4 courses followed by CMF d1–8 for 3–4 courses: 12 (27%); epirubicin 90 or doxorubicin 60 plus paclitaxel 175–200 for 4–6 courses: 9 pts (20%); FEC 75–100 for 6 courses: 6 pts (13%); high-dose sequential CT with peripheral haematopoietic stem cells support (cyclophosphamide 7000; methotrexate 8000; thiotepa 600 or mitozantrone 60 followed by melphalan): 10 pts (22%); three pts were treated with primary CT with anthracyclines/paclitaxel before surgery and high-dose adjuvant CT. CT was followed by hormonal therapy if ER and/or PgR were positive.

Results: after a median follow up of 46 mo.s (range 2–90) 7 patients relapsed (16%) and 3 died for metastatic breast cancer (7%). Forty pts are evaluable for amenorrhea (5 pts are still on treatment). Permanent amenorrhea was observed in 14 pts: 4/17 (24%) in the group aged under 35 and 10/23 (43%) in the group aged over 35 yrs. These patients had received high-dose CT (4/4 in the former group and 6/10 in the latter), anthracyclines and paclitaxel ($n = 3$) or FEC ($n = 1$).

Conclusions: in this group of younger patients (aged ≤ 39 years) amenorrhea was universal after high-dose sequential CT and rare (13%) in pts treated with standard dose CT (anthra. \pm paclitaxel containing regimens). No permanent amenorrhea was observed in 20 pts treated with i.v. CMF or with epirubicin 120 mg/m² followed by CMF.

1307

PUBLICATION

Zoledronic acid provides early reduction in the occurrence of skeletal complications in patients with bone metastases from a broad range of solid tumors

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Background: Bone metastases are associated with significant skeletal morbidity in patients with advanced cancer. Patients with skeletal metastases are at risk for developing painful skeletal-related events (SREs), including pathologic fractures, spinal cord compression, and radiation or surgery to bone. Zoledronic acid is the only bisphosphonate that has demonstrated efficacy in preventing SREs in patients with bone metastases from any solid tumor.

Material and methods: In this retrospective analysis, the occurrence of SREs was evaluated at 1, 2, and 3 months after treatment initiation (zoledronic acid 4 mg or placebo every 3 or 4 weeks) in patients with bone metastases from prostate cancer ($n = 422$) or lung cancer and other solid tumors ($n = 507$).

Results: The numbers of SREs experienced at months 1, 2, and 3 are shown in the table below. Compared with placebo, zoledronic acid 4 mg substantially reduced the total number of SREs within the first 3 months of treatment in patients with prostate cancer or lung cancer and other solid tumors. While the number of patients was similar between the zoledronic acid and placebo groups, the total number of SREs was higher in the placebo group and the effect was observed as early as the first month of treatment.

Total Number of Skeletal-Related Events in the First 3 Months of Treatment.

Month	Number of events (number of patients at risk)			
	Prostate cancer		Lung cancer and OST	
	Zoledronic acid	Placebo	Zoledronic acid	Placebo
1	12 (214)	21 (208)	43 (257)	64 (250)
2	27 (203)	50 (199)	75 (229)	120 (215)
(186)	88 (190)	133 (185)	179 (174)	

OST = Other solid tumors

Conclusions: Zoledronic acid has a fast onset of action in the prevention of SREs in patients with bone metastases from any solid tumor with the effect observed within the first 3 months of treatment.

1308

PUBLICATION

Care during the last 3 days of life of patients in hospital

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Background: of all deaths in the Netherlands, about 40% occurs in the hospital. Whereas patients are usually admitted to a hospital to temporarily receive intensive treatment, care in the hospital may not be tailored to dying patients. Therefore it is worthwhile to investigate the characteristics of terminal care in the hospital.

Patients and methods: Between December 2003 and February 2005 data were collected concerning patients who died at the department of medical oncology of a general hospital and at the departments of medical oncology, radiotherapy, pulmonary diseases and gynaecological diseases of a university hospital in the Netherlands. Nurses who had been closely involved with the care for these patients were asked to fill in a written questionnaire on the care that was provided during the last 3 days of life. Medical information was gathered from the medical record.

Results: Hundred thirteen deceased patients were included in the study. For 99% of them the nurses filled in a questionnaire. The median age of the deceased patients was 66 years (range 19–90) and 50% of the patients were male. The cause of death was a malignancy in 89% of all patients. The median number of symptoms during the last 3 days of life was 15 (range 0–24). The most troublesome symptoms were fatigue, lack of appetite, shortness of breath and pain. Patients received a median of 2 medical interventions during the last 3 days of life, such as the set