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Epoetin Alfa and Darbepoetin Alfa in Clinical Practice in Patients With Chemotherapy Induced Anemia in the Netherlands (EVALUATE)

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Background: Non-randomized clinical practice of epoetin alfa (Eprex®) treatment (E) or darbepoetin alfa (Aranesp®) treatment (D) for chemotherapy (CT) induced anemia (CIA) in the Netherlands between 2005 and 2010 was evaluated in 491 patients (pts).
Materials and Methods: Eligible pts (solid tumours, multiple myeloma and lymphoma, age $\geqslant$18 years), received or started CT within a week (wk), and E or D. Data on hemoglobin levels (Hb), blood transfusions (BTx), CT, E, D and treatment-emergent adverse events (TEAE) were collected. Effectiveness was assessed by Hb rise and BTx.
Results: 491 pts were enrolled (248 E, 243 D, 48% male). Mean age was 64 years. Body Mass Index was slightly lower for E (24.7 E, 25.3 D; $p = 0.049$). Other baseline as well as effectiveness parameters and % pts with TEAE were all not statistically significantly different between E and D ($p > 0.05$). Most pts had lung cancer (42% E, 42% D), breast cancer (12% E, 14% D) or colorectal cancer (12% E, 10% D), metastatic disease (70% E, 72% D) and had no BTx during 28 days before start (83% E, 88% D). WHO performance score was 0 or 1 in 52% (E) or 58% (D) and not recorded for 33% (E) or 31% (D) of pts. Initially, dosing was for E 98% 40,000 IU /wk, and for D 67% 500 μg/3wks, 23% 150 μg/wk. 95% Of pts had no dose modifications during study. Mean duration of treatment was 11.7 wks (E) or 11.9 wks (D). Most pts received platinum-based CT (64% E, 59% D) in cycles of 3 wks (85% E, 81% D). Effectiveness analysis was possible in 452 pts (229 E, 223 D). Mean Hb before treatment start was 10.03±1.03 (E) or 10.03±1.04 (D) g/dl. During E or D 38% (E) or 36% (D) received BTx. BTx independent Hb rise after 4 wks (21−35 days), 8 wks (49−63 days) and end of treatment (43–473 days) were statistically significant within E and D with 0.26±1.61, 1.24±1.91, 0.97±2.41 g/dl (E) or 0.54±1.66, 0.98±2.04, 0.94±2.33 g/dl (D). A BTx independent response defined by Hb $\geqslant$11 g/dl was reported in 65% (E) or 66% (D) of pts. TEAEs were seen in 81% (E) or 73% (D), serious TEAEs in 36% (E) or 29% (D) of pts. TEAEs assessed as having a causal relation to E were 1% and D 2%, amongst which 4 pts with thrombosis (3 E, 1 D) and 2 pts with embolism (1 E, 1 D). Thrombovascular TEAEs occurred in 21 pts (10 E, 11 D) and resulted in 4 pts stopping treatment. 57 pts died during study, in 65% of pts due to disease progression.
Conclusions: E and D were used according to label in pts with CIA. Both show increase of Hb and TEAEs were as expected.

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Scalp Cooling as Cost-effective as Purchasing a Wig or Head Cover

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Background: Chemotherapy-induced alopecia (CIA) is a frequent occurring side effect that has high impact on cancer patients. CIA may be prevented by scalp cooling. This study compared costs and effects of scalp cooling with usual care, i.e. purchasing a wig or head cover.
Methods: Scalp cooled patients (n = 160) were compared to non scalp cooled patients (n = 86) in 15 Dutch hospitals. Cost-effectiveness was determined by the ratio between costs and quality adjusted life years (QALYs) at a time horizon of 1 year. Costs for scalp cooling (as machines and nursing time), hair dressers, wigs and head covers were estimated from the societal perspective (hospitals, patients, insurance companies). QALYs were calculated using Short Form (SF-6D) health survey outcomes and visual analogue scales for quality of life. CIA was measured by the WHO score for alopecia.
Results: Average societal costs decreased €252 per patient due to scalp cooling ($p = 0.03$), but there was no difference in QALYs between patients with or without scalp cooling. Therefore cost-effectiveness depended on the willingness to pay (WTP) for a QALY. The break even point for scalp cooling being cost-effective was within the range of WTP for a QALY in the Netherlands (€20,000-€40,000 per QALY). As a result scalp cooling as well as purchasing a wig or head cover are acceptable from the societal perspective.
Scalp cooling was effective, it significantly reduced the severity of CIA ($p < 0.001$) in scalp cooled patients compared to non scalp cooled patients. Furthermore, it significantly reduced the purchase (73% vs 97%) and use (69% vs 94%) of wigs and head covers. Wigs were unnecessarily purchased in 38% of the scalp cooled patients.
Discussion/Conclusion: On the basis of the current Dutch economic threshold for the WTP for a QALY, both scalp cooling and usual care are acceptable from a societal point of view. The advantage in costs when comparing scalp cooled to non scalp cooled patients may be increased by postponing purchasing wigs and head covers, offering scalp cooling to all eligible patients and therefore using the machine more intensively, and improving the overall scalp cooling efficacy.

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Effect of Denosumab Treatment on Prevention of Hypercalcemia of Malignancy in Cancer Patients With Metastatic Bone Disease

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Background: Hypercalcemia of malignancy (HCM) is a potentially life-threatening, systemic, skeletal-related complication that results from cancer-induced bone destruction or paraneoplastic disorders. Osteolytic metastases are present in the majority of cases. HCM most often occurs in patients with squamous cell lung cancer, breast cancer, kidney cancer, myeloma, or lymphoma (Body JJ 2010, Coleman RE 2006, and Berenson JR, et al 2006). IV bisphosphonates are used to treat HCM. Preclinical data showed that inhibition of RANKL prevents and effectively treats HCM (Morony S, et al 2005 and Capparelli C, et al 2000). In phase 3 double-blind, double-dummy trials in patients with metastatic bone disease, denosumab was superior to ZA in preventing skeletal-related events. In a post-hoc analysis of these trials, we evaluated the effect of treatment with denosumab or zoledronic acid (ZA) on prevention of HCM.
Materials and Methods: Patients with breast or other solid tumours or multiple myeloma and $\geqslant$ 1 bone metastasis were included in this analysis (Clinicaltrials.gov id: NCT00321464 and NCT00330759; sponsor Amgen). Patients with prostate cancer were not included as HCM occurs rarely in this disease. Enrolled patients were randomized to receive denosumab (120 mg) or ZA (4 mg, adjusted for renal function) every 4 weeks. Calcium and vitamin D supplementation was advised unless HCM developed. HCM was defined as a serum calcium value (albumin-adjusted if necessary) of CTCAE v. 3.0 grade $\geqslant$2 (ie, >11.5 mg/dL; >2.9 mmol/L; ionized calcium >1.5 mmol/L) measured by a central laboratory. These trials are completed.
Results: Of 3822 patients enrolled, 1912 were randomized to denosumab and 1910 were randomized to ZA. HCM was reported for 32 (1.7%) and 52 (2.7%) patients in the denosumab and ZA groups, respectively. A total of 150 events of HCM occurred on study: 48 in the denosumab group and 102 in the ZA group. Denosumab prolonged the time to first HCM by 37% compared with ZA (HR 0.63 [0.41, 0.98]; $p = 0.04$). Similarly, treatment with denosumab delayed the time to first and subsequent HCM by 52% vs ZA (RR 0.48 [0.29, 0.81]; $p = 0.006$). Most patients experienced a single event of HCM (22 [69%] patients in the denosumab group and 31 [60%] patients in the ZA group). Fewer patients in the denosumab group (n = 10) than the ZA group (n = 21) experienced multiple HCM events.
Conclusion: In patients with metastatic bone disease due to breast or other solid tumours (except prostate) or multiple myeloma, denosumab prevented HCM more effectively than ZA. Denosumab is currently being evaluated for treatment of HCM in patients who do not respond to IV bisphosphonate therapy.