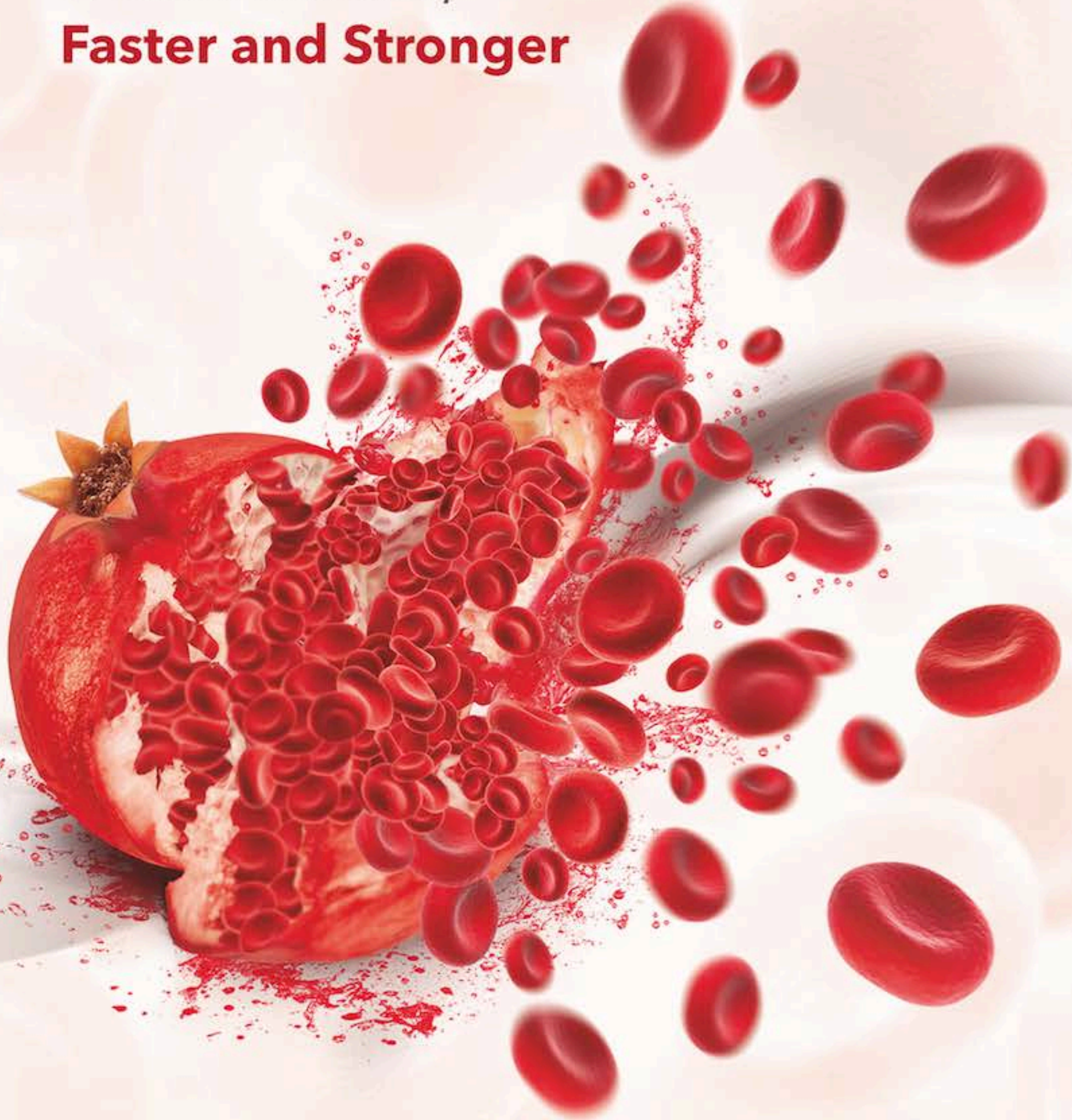
Cinnapoietin®

Erythropoietin ß

Protect Yourself,

Faster and Stronger



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CinnaGen

CinnaPoietin®

Erythropoietin beta

Indications

Indications:

- Anemic Patients with Chronic Kidney Disease (CKD)
- Autologous Pre-Donation
- Anemia of Prematurity
- Anemia due to Chemotherapy in Patients with Non-Myeloid Malignancies

Epoetin Beta:

- A short-acting erythropoiesis-stimulating agent (ESA)
- Directly stimulate erythrocyte production
- A hallmark of anemia therapy in patients with chronic kidney disease (CKD)
- Improve quality of life across many different malignancy types

PROVEN EFFICACY AND SAFETY

Clinical efficacy of epoetin beta in treatment of chemotherapy-induced anemia across a broad range of malignancy types

- Epoetin beta is effective in anemia due to chemotherapy in wide range of malignancies, both solid (e.g., breast, lung, ovarian and prostate) and hematologic (MM, NHL, CLL).
- Transfusion need is reduced with epoetin beta, with as many as 90% of patients reported to remain transfusion free.
- The approved 30,000 IU once-weekly dosing regimen (as opposed to the 10,000 IU three-time weekly regimen) provides greater convenience and can result in improved treatment compliance[1]

Overview of key epoetin beta studies in patients with various types of malignancies

Patient population	Study design and duration	Efficacy of epoetin beta		
		Hb efficacy parameter	Transfusion status	QoL benefit
Solid tumors[2] (n = 255)	Open-label, single-arm, mean 75 days	Hb response (increase > 1 g/dl): 62%	Patients transfused: 13%	Yes
Solid tumors[3] (n = 189)	Parallel-group, 12 weeks	Response after 12 weeks: 38% (epoetin) vs. 9%(control)	Patients transfused (week 1–12): 26% (epoetin) vs. 41% (control)	Not known
MM, NHL or CLL transfusion-dependent[4] (n = 343, ITT)	Double-blind, parallel-group, 16 weeks	Hb response: 67% (epoetin) vs 27% (control)	Transfusion-free patients: from wk 5–16: 67% (epoetin) vs. 48% (placebo)	Yes
Solid/hematologic malignancies (n = 262, ITT)[5]	Open-label, parallel-group, 12 weeks	Hb increase: 2.1 g/dl (epoetin) vs. 0.9 g/dl (control)	Pts transfused: 32% (epoetin) vs. 52% (control)	Yes

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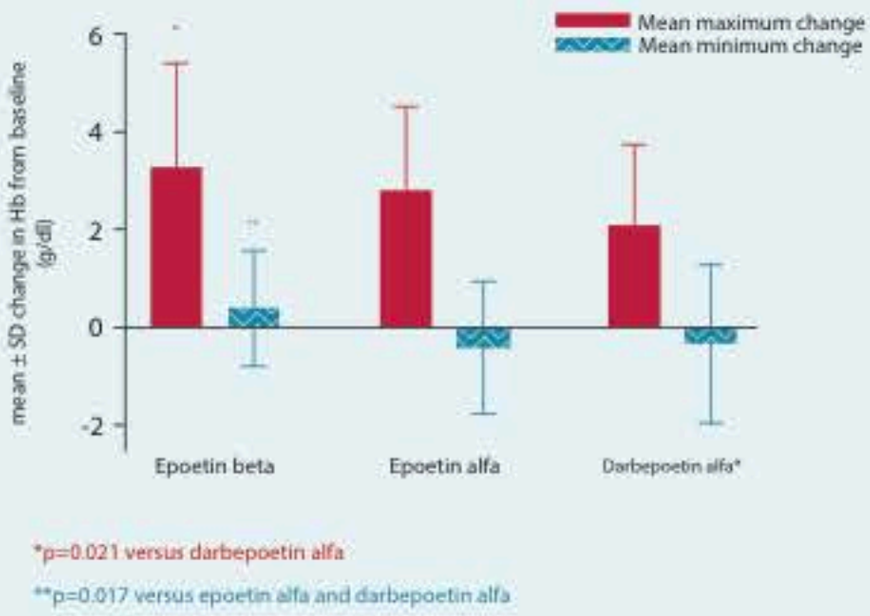
Comparison of the therapeutic efficacy of epoetin beta and epoetin alfa and darbepoetin alfa in anemic cancer patients

The results of a recent retrospective survey including 125 patients in 27 French oncology centers, have indicated that in daily clinical practice, all three commercially available erythropoietic proteins are effective in managing anemia in patients with cancer; however, this study has showed the percentage of patients, amongst whom the Hb level was never lower than its initial value was significant greater in epoetin beta treated patients compared with those treated with epoetin alfa or darbepoetin alfa[6].

FAST AND CONVENIENCE IN USE (PREFILLED SYRINGE)

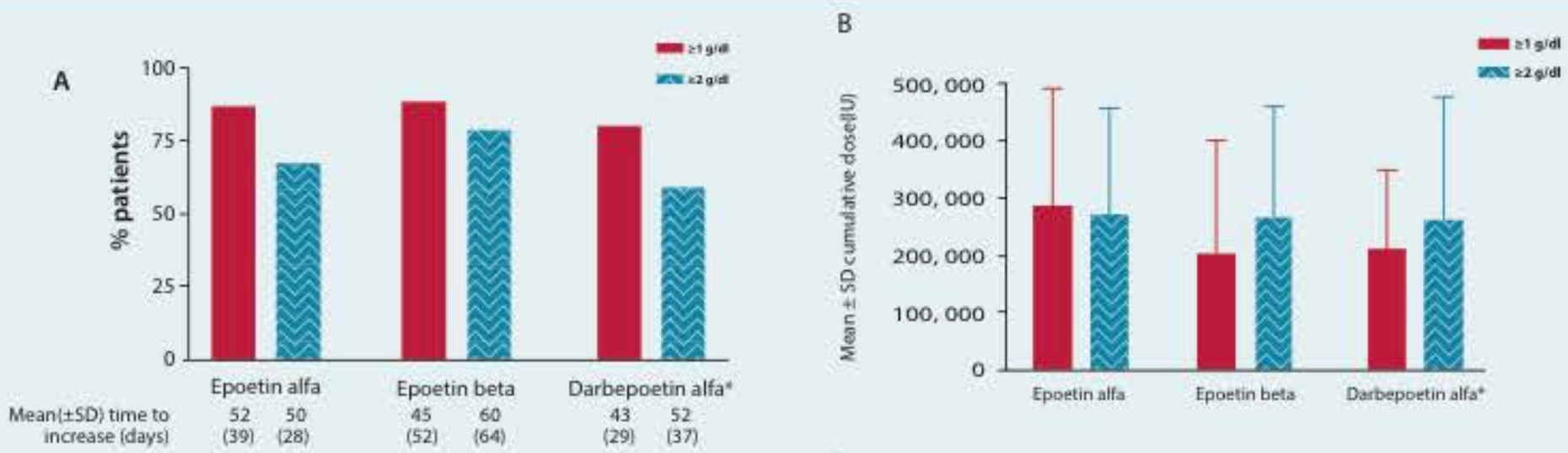


*p=0.021 versus darbepoetin alfa

**p=0.017 versus epoetin alfa and darbepoetin alfa

Comparison of mean maximum and minimum change in hemoglobin levels between erythropoietic proteins

Hemoglobin increase of ≥1 and ≥2g/dl (with mean time to increase, days) in patients over the duration of treatment (A)and associated mean cumulative dose (B).



*Converted from µg based on 1 µg:200 IU peptide mass ratio

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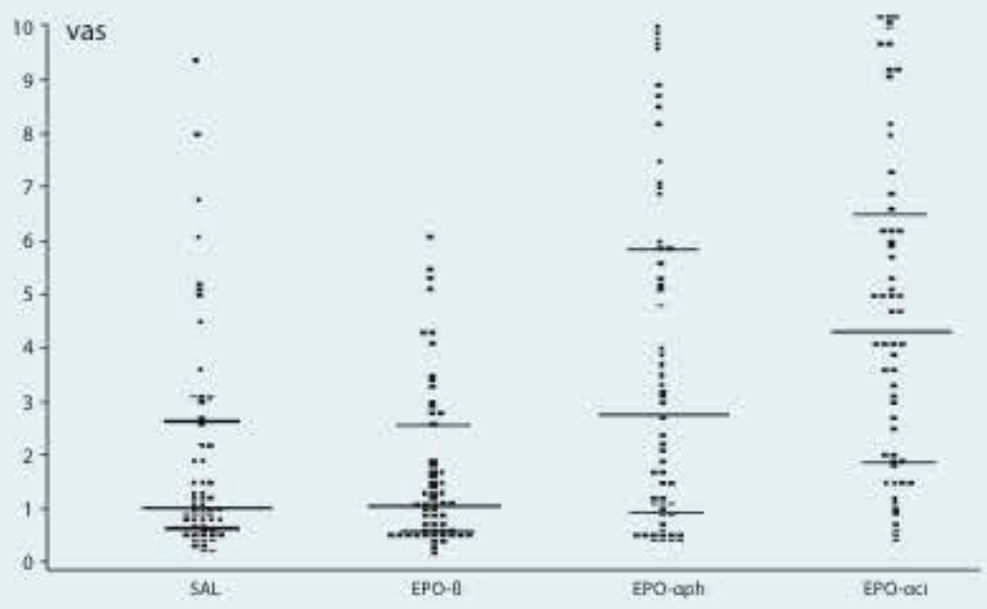
Comparison

Comparison of subcutaneous injection pain among equivalent doses epoetin beta and epoetin alfa and darbepoetin alfa

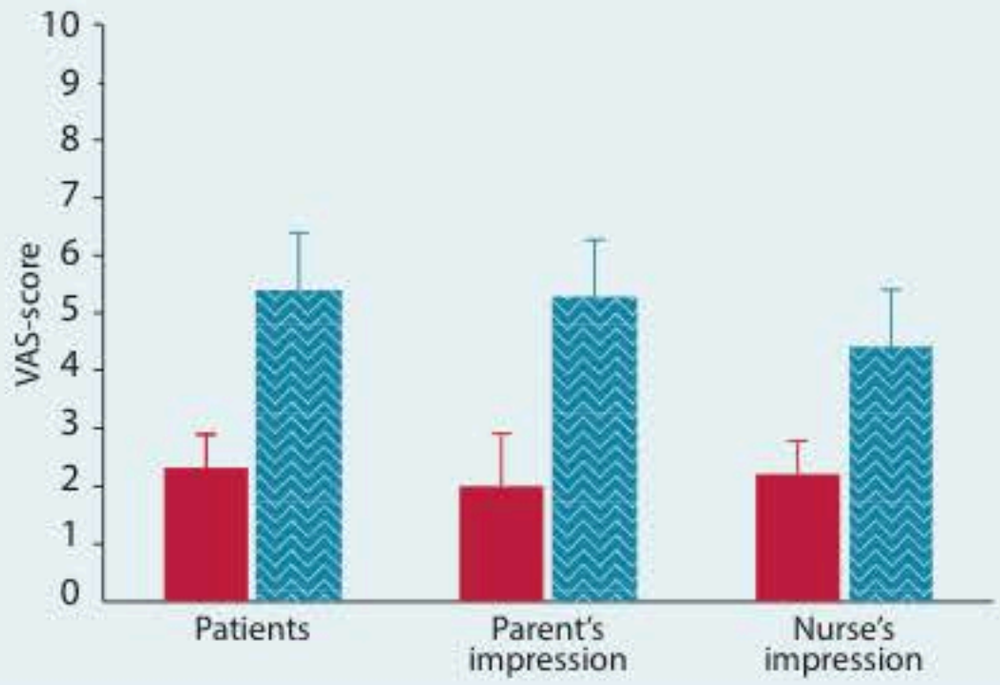
SC epoetin alfa and darbepoetin alfa injections are more significantly painful than equivalent doses of epoetin-beta[7, 8, 9, 10].

LESS PAINFUL THAN COMPARABLE DOSES OF OTHER ERYTHROPOIETINS IN SC INJECTION

Visual analogue scale (VAS) records of SC administration of saline (SAL), Epoetin Beta, phosphate-buffered Epoetin Alfa (EPO-αph) and citrate buffered Epoetin Alfa (EPO-αci). EPO-αph scored significantly higher compared to SAL and EPO-β (P≤ 0.001) and EPO-αci scored significantly higher than EPO-αph (p ≤ 0.001)[7].



Visual Analogue Scale (VAS) is a subjective measure of pain. It consists of a 10cm line with two end points representing "no pain" and "worst pain imaginable".



Pain perception after subcutaneous injection of epoetin-b (filled columns) and darbepoetin-a (hatched columns) as documented on the visual analogue scale (VAS)[1] by patients, parents and the care giving nurse[8].

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References

1. Ludwig H. Epoetin beta in oncology: examining the current evidence. Future Oncol.2006; 2(1), 21–38.

2. Ordóñez A, González-Barón M, Isla D, Sánchez A, Arrivi A, Manzano JL: Epoetin beta treatment to prevent anemia in solid tumor patients receiving platinum-based chemotherapy. J. Clin. Oncol.2005; 23(16S), 785s (Abstract 8230).

3. Oberhoff C, Neri B, Amadori D et al. Recombinant human erythropoietin in the treatment of chemotherapy-induced anemia and prevention of transfusion requirement associated with solid tumors: a randomized, controlled study. Ann. Oncol. 1998; 9, 255–260.

ALWAYS AVAILABLE

4. Österborg A, Brandberg Y, Molostova V et al. Randomized, double-blind, placebocontrolled trial of recombinant human erythropoietin, epoetin beta, in hematologic malignancies. J. Clin. Oncol.2002; 20, 2486–2494.

5. Boogaerts M, Coiffier B,Kainz C. Impact of epoetin beta on quality of life in patients with malignant disease. Br. J. Cancer 2003;88, 988–995.

6. Pujade-Lauraine E, Richard AJ, Sapède C, Hayward C. Erythropoietic agents in anemic patients with cancer: a retrospective observational survey of epoetin alfa, epoetin beta and darbepoetin alfa use in routine clinical practice. Oncol. Rep.2005;14, 1037–1044

7. Veys N, Dhondt A, Lameire N. Pain at the injection site of subcutaneously administered erythropoietin: phosphate-buffered epoetin alfa compared to citrate-buffered epoetin alfa and epoetin beta. Clin. Nephrol. 1998; 49, 41–44.

8. Schmitt CP, Nau B, Brummer C, Rosenkranz J, Schaefer F. Increased injection pain with darbepoetin-alfa compared to epoetin-beta in paediatric dialysis patients. Nephrol Dial. Transplant 2006; 21, 3520–3524.

9. Veys N, Vanholder R, Lameire N. Pain at the injection site of subcutaneously administered erythropoietin (EPO) in maintenance hemodialysis patients: a comparison of two brands of EPO. Am J Nephrol 1992; 12: 68-72

10. Oudard S, Berthoux F, Fiorentini P et al. Results of a cross-over study on injectionsite pain comparing subcutaneous epoetin beta and darbepoetin alfa in healthy volunteers. Eur. J. Cancer. Suppl.2005; 3, 372 (Abstract 1288).