

Use of Hypertonic Hyperoncotic Solutions (HHS) in Clinical Routine in Austria

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Objective of the Study:

Austria is the only European country where HHS market authorisation was already obtained a few years ago and where HHS have been widely used in clinical routine for a comparatively long time: Osmohes (Laevosan Company / Fresenius Kabi Austria, 7.2% NaCl + 10% HES 200/0.5), Hyperhes (Fresenius Kabi Austria, 7.5% NaCl + 6% HES 200/0.62). This analysis gives an over-view of the experience gained in the use of HHS in 9 years of clinical routine in Austria.

Methods:

Marketing and pharmacovigilance data were provided by Fresenius Kabi Austria. Further investigations were performed to complete safety information. On the basis of a binomial distribution, a one-tailed (95% and 99%) confidence interval was used to calculate the percentage p of the occurrence of adverse drug reactions (ADR).

Results:

From Sept 1991 to Dec 2000 5892 HHS units were sold in Austria. Within this period, the following ADR connected with prescribed application were reported: Osmohes: 1 case with decrease in heart rate, blood pressure and cardiac output [1]; Hyperhes: 2 cases with erythemous rash, agitation, depression and dyspnoea (case 1) resp. fever and chills (case 2). All 3 patients recovered. Causal relationship was most probable in the Osmohes case (detection of HES-reactive antibodies) and Hyperhes case 1 (positive re-exposition). All ADR were probably related to the colloid component (HES) of HHS. Additionally, 1 case of ADR due to extreme overdosage of Osmohes (fivefold dosage within 6 hours)

with typical hypernatremia- and hyperosmolarity-related symptoms could be verified. It is estimated, that ~95% of the HHS units sold (~56000 HHS units) were used, and that an average of 1.5 to 3 HHS units per patient were administered (18500 to 37000 HHS-treated patients). On this basis, frequencies and frequency probabilities of ADR related to prescribed application of HHS can be calculated: a) (100% = 56000 HHS units used:) 0.005% (p<0.05: max 0.014%); b) (100% = 37000–18500 patients treated with HHS:) 0.008 – 0.017% (p<0.05: max 0.025 – 0.049%).

Conclusion:

9 years of experience in the use of HHS in clinical routine in Austria show that the prescribed application of hypertonic NaCl combined with HES is safe.

Reference:

- 1) Kreimeier U, Christ F, Kraft D, et al. Anaphylaxis due to hydroxyethylstarch-reactive antibodies. *Lancet* 1995; 346: 49-50.

The biostatistical analysis (Biometrie Ambulanz, ASOKLIF) was supported by a grant of the Government of Upper Austria.

Original publication:

Schimetta W, Schöchel H, Kröll W, Pölz W, Pölz G, Mauritz W.

Safety of hypertonic hyperoncotic solutions – A survey from Austria.

Wien Klin Wochenschr 2002; 114/3: 89-95.