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PEDIAVEN® AP-HP NOUVEAU NE 2 perfusion related extravasations in a neonatal intensive care unit

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PEDIAVEN® AP-HP NOUVEAU NE 2 (PNN2) is a newborns parenteral nutrition solution. In neonatology, the main interest of PNN2 is its possibility of peripheral venous administration (PVA). During PNN2 administration in the neonatal intensive care unit, several cases of extravasation have been reported, two with severe oedema and necrosis. We investigated the role PNN2 played in these extravasations, by three different ways: a pharmacovigilance (PV) report; a questionnaire to the main neonatal intensive care units in the Paris region; and the osmolarity and pH measurements. Five other reports have been compiled by the Pharmacovigilance Regional Center in Angers the last three years. After our report, the French Drug Agency ordered an investigation about PNN2. The questionnaire showed that the rate of extravasations has been trending up in most of the other units. If the responsibility of PNN2 is not clearly established, the cases are more severe with PNN2 than with other solutions. The manufacturer indicates an osmolarity "around 790 mOsm/L" (712 to 870 mOsm/L). Tested osmolarity varied from 778 to 782 mOsm/L and pH was 5.04. There are no guidelines for the osmolarity limits in preterm VPA. The limit used in our unit is 800 mOsm/L. Besides, the pH value for the best tolerance would be within 6.5 and 9. The extremely inaccurate osmolarity value led our unit to ban PNN2 use in PVA. The results of the French Drug Agency investigation and the High Health Authority guidelines on osmolarity limits will help us to improve our practices.

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Sleep disorders related to antidepressant drug use

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Background: Prescription of antidepressants has been increased from the last decade. Also, they are responsible for producing so many ADRs such as dry mouth, blurred vision, weight gain and drowsiness, sleep disorders. Sleep disorders can generally be divided into 3 large groups: (1) Insomnia, (2) those with a primary complaint of daytime sleepiness, and (3) those associated with disruptive behaviors during sleep—the disorders of arousal. So, active surveillance is needed to access these ADRs.

Aim & Objective: To analyze the sleep disturbances as an adverse drug reaction (ADRs) of various antidepressants prescribed to the patients attending the Psychiatry OPD at Teerthanker Mahaveer Medical College & Research Centre.

Materials & Methods: The data were collected from the Red ADR boxes in the department of Psychiatry OPD at TMMC & RC, Moradabad, U.P. The patients, who were prescribed antidepressant drugs for duration of 10 months (Dec, 2013- July, 2014) were included in the study.

Results: Total number of patients enrolled on the basis of inclusion and exclusion criteria = 50

Total number of ADRs=65. Total no of patients with sleep disturbances as ADRs=28

Conclusion: The drug most frequently implicated to cause sleep disturbances was Mirtazapine. Increased sleep was the commonest ADR found to occur. Unusual ADRs such as sleep talking was also seen. However, we assume that more robust reporting is needed as this shall enable us to detect the category of sleep disturbance, based on polysomnography.

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