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CLINICAL CASE

Pseudohiponatremia secondary to hypertriglyceridemia during the treatment of lymphoblastic lymphoma with corticoids and L-asparaginase

Pseudohiponatremia secundaria a hipertrigliceridemia durante tratamiento de linfoma linfoblástico con corticoides y L-asparaginasa

Annex 1. Modified Karch and Lasagna causality criteria and WHO causality categories. (Algorithm of the Spanish Pharmacovigilance System)			
I) Temporal sequence	Medication administration interval and undesirable effect	A) Compatible (F intake before the appearance of RA)	+2
		B) Not totally compatible (F intake before the appearance of RA, but not totally compatible with mech action and/or mech. Physiopathological (e.g. appearance after a long time)"	+1
		C) No Information	0
		D) Incompatible chronology (or incompatible with mechanism of action and/or pathophysiological process, e.g. Neoplasia or cirrhosis after a few days of starting the treatment.)"	-1
		E) Particular case as a consequence of withdrawal of the F (e.g. Withdrawal syndrome, tardive dyskinesias)	+2
II) Prior knowledge	Level of knowledge in the literature of the F-RA relationship	A) Known causal relationship in reference books, epidemiological studies and/or pharmacological profile of the F in question, whenever the mech. The RA is well established and compatible with the mech. F action	+2
		B) Known from occasional observations or sporadic and without apparent or compatible connection with the mech. action of F	+1
		C) F-RA relationship not known	0
		D) There is sufficient pharmacological information against F-RA relationship	-1
III) Effect of Withdrawal	Evolution of the undesirable effect	A) Improves with withdrawal or reduction of the dose of F (regardless of whether it has received tto. for the RA	+2
		B) Does not improve with withdrawal of F, except in fatal ARs or irreversible	-2
		C) The suspicious F has not been removed and the RA does not improve either	+1
		D) The F is not removed but the RA improves (if the possibility of developing tolerance)	-2
		E) No Information	0
		F) Outcome of fatal AR or irreversible effect (it is includes congenital malformations)	0
		G) Although the F has not been retired, the RA improves due to emergence of tolerance	+1
		H) If F is not removed, AR improves due to treatment symptomatic retirado el F, la RA mejora debido a tratamiento sintomático	+1

IV) Readministration	Effect of reexposure to suspected F	A) Positive: RA appears after readministration of F	+3
		B) Negative: RA does not reappear	-1
		C) There is no re-exposure or there is no information	0
		D) RA with irreversible characteristics (death, malformations congenital and permanent consequences	0
		E) Positive: There is similar previous RA with specialties different, but containing the same p.a. of the considered F."	+1
		F) There is a similar previous RA with another F that has the same mech. From the RA, or when it is reasonable to think of a cross reactivity	+2
V) Existence of alternative cause to the medication	Evaluate other non-pharmacological causes	A) Alternative explanation (either an underlying disease or another F taken simultaneously) is more plausible than the causal relationship with F evaluated	-3
		B) Possible causal relationship of RA with the disease or the medication taken simultaneously, presents similar or less similarity than the causal relationship between F and RA"	-1
		C) There is not enough information to evaluate a causal relationship, although this may be suspected	0
		D) With the available data, a cause cannot be found alternative	+1
VI) Factor		Laboratory Alteration	+1

Definitive	> 8
Likely	6 -7
Possible	4-5
Conditional (or doubtful)	1 - 3
Unlikely	= < 0

Score = 8