E-Poster

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Complications of Intrathecal Baclofen Therapy for Spasticity: A Nationwide Pharmacovigilance Study of Adverse Drug Reactions Reported in France Between 1994 and 2024

Topic: Pharmacological Agents

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BACKGROUND

Since the pivotal study by Penn et al. published in the NEJM in 1989, intrathecal baclofen therapy has become a reference treatment for severe lower-limb spasticity in non-walkers. However, it is a therapy with a high risk of complications, notably if caregivers are not aware of its characteristics. While complications directly related to the intrathecal pump device, or related procedures, are well described in literature, much less is known about complications directly related to the drug itself. Since, to our knowledge, there is no pharmacovigilance study specifically describing the clinical features and prognosis of intrathecal baclofen related complications. This study aims to characterize them.

METHODS

We conducted an observational, retrospective study of all reports related to the intrathecal use of baclofen for spasticity in adults registered in the French Pharmacovigilance Database from 1994 to December 2024. Administrative data, individual's characteristics, drug characteristics and reaction characteristics were extracted from the database.

RESULTS

We identified 53 cases in the database, 64% of whom were men, with an average age of 50 (17) years. The most frequent etiologies for spasticity were spinal cord injury (32/53; 60%), stroke or traumatic brain injury or brain anoxia (7/53; 13%), cerebral palsy (7/53; 13%) and multiple sclerosis (5/53; 10%). Overdose and withdrawal syndromes were predominant as they respectively represented 53% (28/53) and 23% (12/53) of the cases. Half of them require admission to intensive care (20/40; 50%). Withdrawal syndromes were device related in 3/12 (25%) cases, procedure related in 2/12 (17%) cases and drug/drug management related in 7/12 (58%) cases. Contrary to overdose syndrome which did not lead to death and were recovered or recovering in 93% (26/28) of cases on the date of notification, withdrawal syndrome led to death in 25% (3/12) of cases (death from multivisceral failure secondary to a malignant hyperthermia syndrome with rhabdomyolysis).

CONCLUSION

Although both overdose and withdrawal syndromes can be life-threatening and require admission to intensive care, only withdrawal syndromes led to death in this observational study. This may be explained by a higher risk of delayed diagnosis in the case of withdrawal syndrome.

Statement of Disclosures

None

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