

Falling for amiodarone

– a safety analysis in patients 60 years and older

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Background

- Older patients are at high risk of falling because of age-related changes in multiple physiological systems. Falls are the leading cause of injury-related deaths in elderly individuals¹.
- Cardiac arrhythmias affect a large proportion of the world's population and are frequent within the older population².
- Amiodarone is one of the most effective and commonly prescribed antiarrhythmic drugs. It has a very long plasma half-life and a broad toxicity profile^{3,4}.

Objective

To review the risk of falling from amiodarone in older patients.

Methods

A quantitative analysis of data in VigiBase, WHO's global database of potential side effects of medicinal products.

378 

cases reporting the MedDRA preferred term "Fall" and the substance amiodarone as suspected or interacting agent.

DE-DUPLICATION

335 

reports identified for analysis

279 

concerned patients aged 60 years or older.

Results

Patients' median age was 81 years and ranged from 60 to 96 years. In around one third of cases (n=108), amiodarone was reported as the only suspected drug. Most patients received more than one drug with a median of two drugs being administered concomitantly, ranging from 1 to 15 medicinal products. In 20 cases, a drug-drug interaction between amiodarone and one or more substances was identified and flagged by the reporter.




An analysis of case characteristics comparing patients based on the number of reported drugs is presented in Table 1.

Conclusion

Prescribers should be aware that adding drugs – especially drugs able to cause extensive toxicity and drug-drug interactions, such as amiodarone – to an established multi-drug therapy regime in an older patient population may significantly increase the risk of falling and experiencing potentially severe adverse outcomes.



Table 1.
Comparison of cases based on the number of reported drugs

		 All cases n = 279 (100%)	 Patients receiving ≤ 5 drugs n = 237 (85%)	 Patients receiving > 5 drugs n = 41 (15%)**
Sex	Female	133 (48)	109 (46)	23 (56)
	Male	144 (52)	127 (54)	17 (41)
	Unknown	2 (0.7)	1 (0.4)	1 (2.4)
Age	Median (range)	81 (60–96)	80 (60–96)	82 (60–94)
Number of drugs*	Median (range)	2 (1–15)	2 (1–5)	7 (6–15)
Seriousness	Yes	221 (79)	184 (78)	36 (88)
	Fatal	30 (11)	22 (9.3)	8 (20)
Time-to-onset	Median (range)	6 months (0 days–15 years)	7 months (0 days–15 years)	2 months (4 days–1 year)

*Only suspected/interacting drugs

**One case was excluded from the subgroup analysis due to an unreasonably high number of concomitant drugs

References

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