

ARE MEDICATIONS INVOLVED IN VISION AND INTRACRANIAL PRESSURE CHANGES SEEN IN SPACEFLIGHT?

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INTRODUCTION

The Food and Drug Association Adverse Event Reports (FDA AER) from 2009-2011 were used to create a database from millions of known and suspected medication-related adverse events among the general public. Vision changes, sometimes associated with intracranial pressure changes (VIIP), have been noted in some long duration crewmembers. Changes in vision and blood pressure (which can subsequently affect intracranial pressure) are fairly common side effects of medications. The purpose of this study was to explore the possibility of medication involvement in crew VIIP symptoms.

METHODS

Reports of suspected medication-related adverse events may be filed with the Food and Drug Administration (FDA) by medical professionals or consumers. Quarterly compilations of these reports are available for public download. Adverse Event Reporting System (AERS) reports from 1/1/2009- 6/30/2012 were downloaded and compiled into a searchable database for this study. Reports involving individuals under the age of 18 and older than 65 were excluded from this analysis. Case reports involving chronic diseases such as cancer, diabetes, multiple sclerosis and other serious conditions were also excluded. A scan of the medical literature for medication-related VIIP-like adverse events was used to create a list of suspect medications. These medications, as well as certain medications used frequently by ISS crew, were used to query the database. Queries for use of suspected medications were run, and the nature of the symptoms reported in those cases were tabulated. Symptoms searched in the FDA AERS were chosen to include the typical symptoms noted in crewmembers with VIIP. Vision symptoms searched were: visual acuity reduced, visual impairment, and vitreous floaters. Pressure changes included: abnormal sensation in eye, intracranial pressure increased, intraocular pressure increased, optic neuritis, optic neuropathy, and papilloedema. Limited demographic information is included with the FDA AERS; relevant data were also sorted by age and sex from each report.

RESULTS

Steroid-containing oral contraceptives had the highest number of reports associated with vision (n=166) and pressure symptoms (n=54). Corticosteroid-containing medications were also high; prednisone, for example, had 137 reports of vision issues and 79 of pressure issues. Pain relievers were also a medication class with vision and pressure-related adverse events reported. Common over-the-counter medications such as acetaminophen, aspirin and ibuprofen each had multiple reports for both vision and pressure symptoms. Antimicrobial medications ciprofloxacin and diflucan were also associated with a number of vision and pressure-related AERS. Unexpectedly, pseudoephedrine and promethazine were mentioned in fewer than 20 reports each over the 3.5 years of data examined.

CONCLUSION

The FDA AERS represents a wealth of data, but there are several limitations to its use. The data are entered by the public or medical professionals, but are not checked for accuracy or completeness and may even be entered multiple times. The causal relationship between a particular adverse event and a particular medication is not tested. The cases represent a broad spectrum of demographics, occupations, and health histories, and thus do not model the astronaut population well. There is no information on the frequency of use of a medication for comparison purposes; it is not possible to assign a rate for any particular adverse event. Nonetheless, there are compelling trends. Use of corticosteroid-containing medications, pain relievers (even over-the-counter), and oral contraceptives were associated with higher numbers of vision- or intracranial pressure-related adverse events. In general, there were more vision problems than pressure problems reported. Certain medications that were once suspected of playing a role in the crew VIIP syndrome, namely pseudoephedrine and promethazine, were found to have extremely low numbers of VIIP-like AERS in the FDA data. However, crew use of corticosteroid-containing medications and pain relievers may warrant additional investigation.