# DRUG-INDUCED APLASTIC ANAEMIA: AN ANALYSIS OF THE FDA ADVERSE EVENT REPORTING SYSTEM (FAERS).

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## Background and importance >>

Aplastic anaemia (AA) is a rare condition resulting from a deficit in hematopoietic stem and progenitor cells, characterized by a huge social and economic burden. AA is included in the Designated Medical Event (DME) list developed by the European Medicines Agency (EMA), which contains medical conditions that are inherently serious and often medicine-related.

## Aim and objectives >>

In this analysis, we aimed to shed light on the most frequent aplastic anaemia-associated drugs in real life by mining the FDA Adverse Event Reporting System (FAERS).
FAERS is one of the largest spontaneous reporting databases in the world, used to perform signal detection in pharmacovigilance.

## Material and methods >>

A disproportionality analysis of the FAERS was conducted by analysing the Individual Case Safety Reports (ICSRs) from the first quarter of 2004 (2004Q1) to the third quarter of 2021 (2021Q3).
The reporting odds ratio (ROR) with a relevant 95% confidence interval (95% CI) as a disproportional measure was calculated. The ROR was considered statistically significant when the lower limit of the 95% CI of the ROR exceeded 1, with at least 3 cases reported (N≥3).

## Results >>

Overall, during the examined period (2004Q1-2021Q3), on a total of *N*=11631635 reports, *N*=3413 ICSRs containing the preferred term "*aplastic anaemia*" were retrieved. AA affected people with a median age of 49.62 (±25.08) years, mostly female (*N*=1645, 54.9%).
According to the ROR value, ferrous phosphate 594.82 (95% CI 184.68-1915.80), sucrose 98.86 (95% CI 36.89-264.90), aminopyrine 82.04 (95% CI 26.32-255.76), levosimendan 81.41 (95% CI 54.90-120.73) and methenolone 67.86 (95% CI 44.16-104.28) were associated with disproportionate reporting, resulting in a potential signal.
Regarding the number of ICSRs, the most frequent AA-associated drugs on FAERS were eculizumab *N*=431, lymphocyte immune globulin, anti-thymocyte globulin *N*=228, eltrombopag *N*=204, pentamidine *N*=77 and ethosuximide *N*=28.

### *Database mining*

FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)

**N=11631635 ICSRs**
(2004Q1-2021Q3)

**N=3413 ICSRs**
containing "*aplastic anaemia*" MedDRA *preferred term*

### *Sociodemographic data*

**Median age**: 49.62 (±25.08) years

**Female:** 54.9% (*N*=1645)

### *Potential disproprortionality signals*

| DRUG | N | ROR (95% CI) |
|---|---|---|
| *ferrous phosphate* | 3 | 594.82 (184.68 – 1915.80) |
| *sucrose* | 4 | 98.86 (36.89 – 264.90) |
| *aminopyrine* | 3 | 82.04 (26.32 – 255.76) |
| *levosimendan* | 25 | 81.41 (54.90 – 120.73) |
| *methenolone* | 21 | 67.86 (44.16 – 104.28) |
| *eculizumab* | 431 | 28.16 (25.59 – 30.98) |
| *lymphocyte immune globulin, anti-thymocyte globulin* | 228 | 26.54 (23.29 – 30.25) |
| *eltrombopag* | 204 | 37.55 (32.71 – 43.12) |
| *pentamidine* | 77 | 30.59 (24.45 – 38.28) |
| *ethosuximide* | 28 | 42.47 (29.29 – 61.58) |

## Conclusion and relevance >>

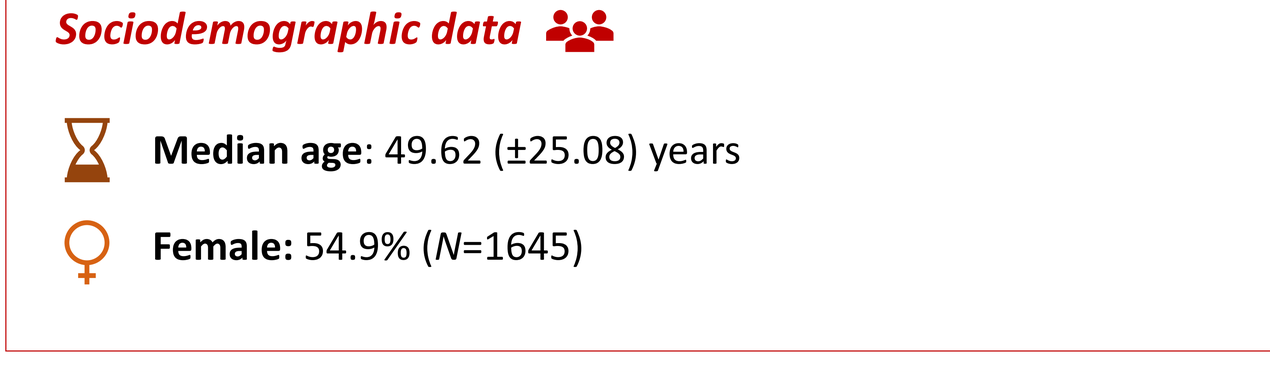
Knowing the drugs associated with aplastic anaemia is essential for promoting appropriate use of them and improving patient safety during therapy. Furthermore, healthcare professionals should be aware of the necessity of strictly monitoring patients treated with these drugs and promptly recognising signs and symptoms of drug-associated AA. Further investigations are required to confirm if these drugs play a role in the development of AA.

## References and/or acknowledgements >>

*Khaleel MA et Al. A Standardized Dataset of a Spontaneous Adverse Event Reporting System. Healthcare (Basel). 2022 Feb 23;10(3):420.*

## Abstract informations >>

Abstract number: **5PSQ-022**
ATC code: **No ATC code**

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