

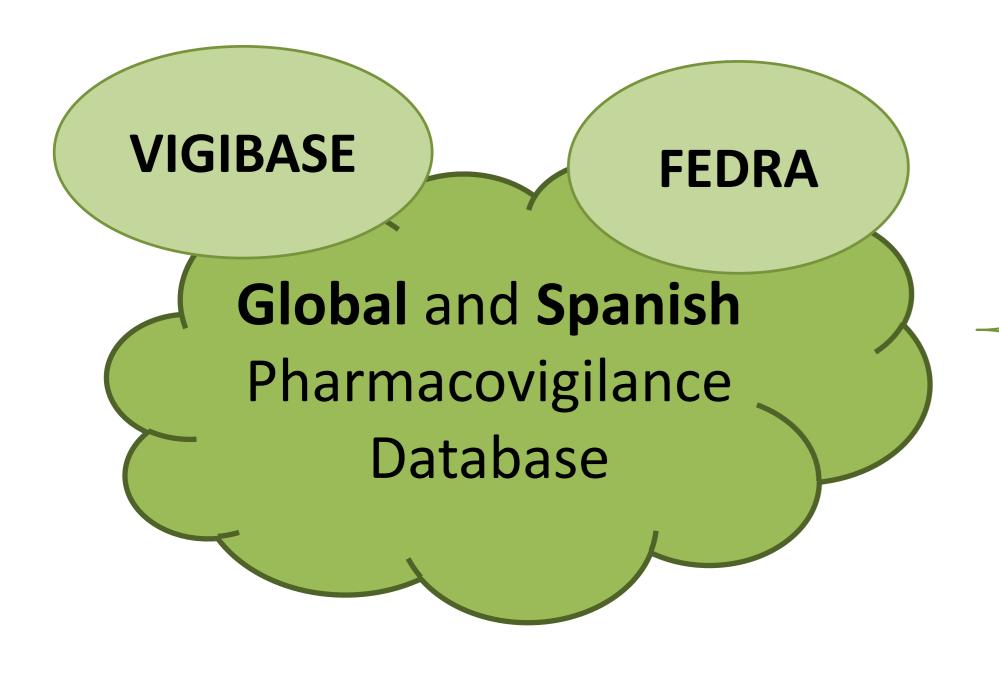
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Objective

To describe all worldwide reported cases in which paediatric population developed breast disorders (BD) associated to spironolactone treatment. We focused on the time it took to develop the disorder since the treatment started. We also focused if there was another reason which can induce it.

Materials and methods



Search about all spontaneous reports performed in patients under 18 years with BD treated with spironolactone.

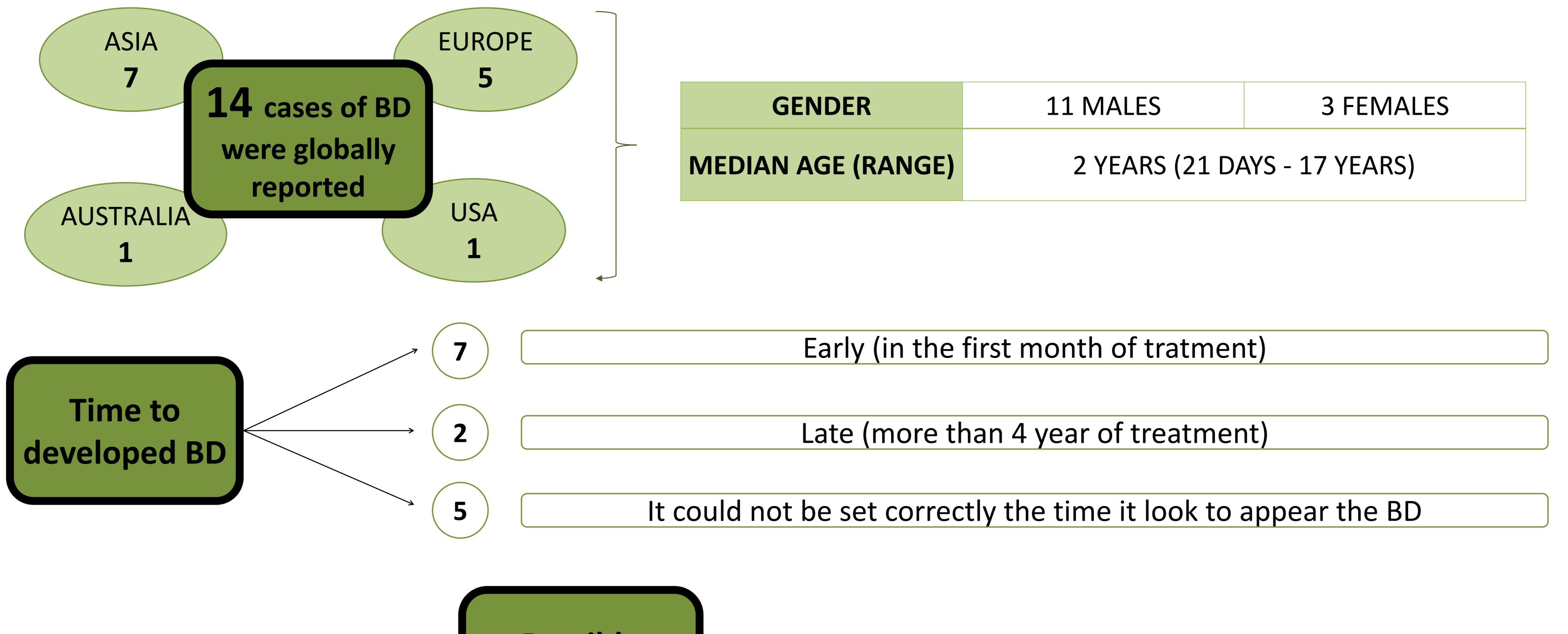
(We included as BD: gynecomastia, breast enlargement, galactorrhea and nipple pain)

Age, gender, reporting country, spironolactone treatment starting date, date of the diagnosis of the BD and list of the concomitant medication were recorded.

We calculated how long the BD soon appeared since the treatment started.

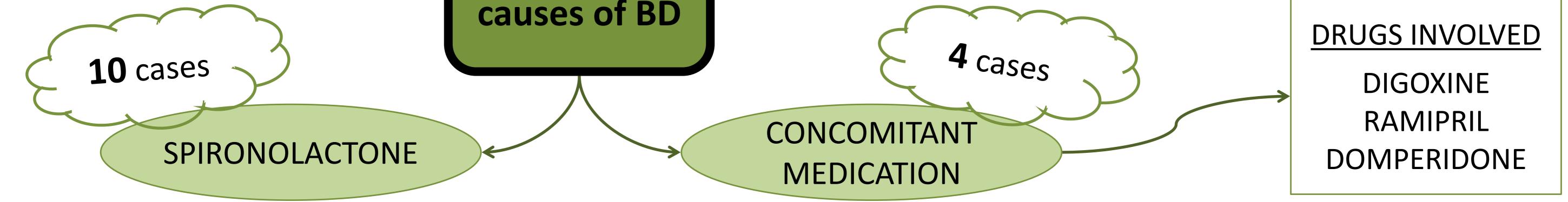
Checked in the Product Information if the rest of concomitant medication could produce this adverse drug reaction (ADR).

Results and Discussion





Possible



Conclusions

Reported cases occurred after a few days of treatment, especially in infants and due to spironolactone. Despite being off-label use, it draws attention to the low incidence of notifications in a drug widely used in paediatrics. While this may be because this ADR is well known and the ADR notifications in paediatrics is generally low.

