

Accessibility and Safety of Antipsychotics in the Treatment of Autism Spectrum Disorder in Children and Adolescents

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INTRODUCTION

Risperidone and aripiprazole (RiAr) are antipsychotic drugs approved by the Food and Drug Administration (FDA) for the management of irritability associated with Autism Spectrum Disorder (ASD) in children and adolescents.^{1,2}

Cultural, regulatory and economic differences in countries like India and Malta may affect the prescribing behaviour of these drugs in ASD.

AIMS

To study prescribing behaviour, safety and accessibility of RiAr in children and adolescents in India and Malta.

METHOD

- An ASD comparative questionnaire (ASD-Q_{IND-MT}) intended for psychiatrists in India (n=31) and Malta (n=16) was developed consisting of 28 close-ended, 5-point Likert scale questions.
- ASD-Q_{IND-MT} measured the influence of screening tools; Indian Scale of Assessment of Autism (ISAA) (India) and Childhood Autism Rating Scale (CARS) (Malta) on the prescribing behaviour of RiAr.
- Comparison of the price of RiAr in India and Malta was undertaken to determine accessibility to RiAr.
- Eudravigilance signal detection and assessment to detect potential ADRs were conducted to be included in the SmPC of RiAr (Figure 1).

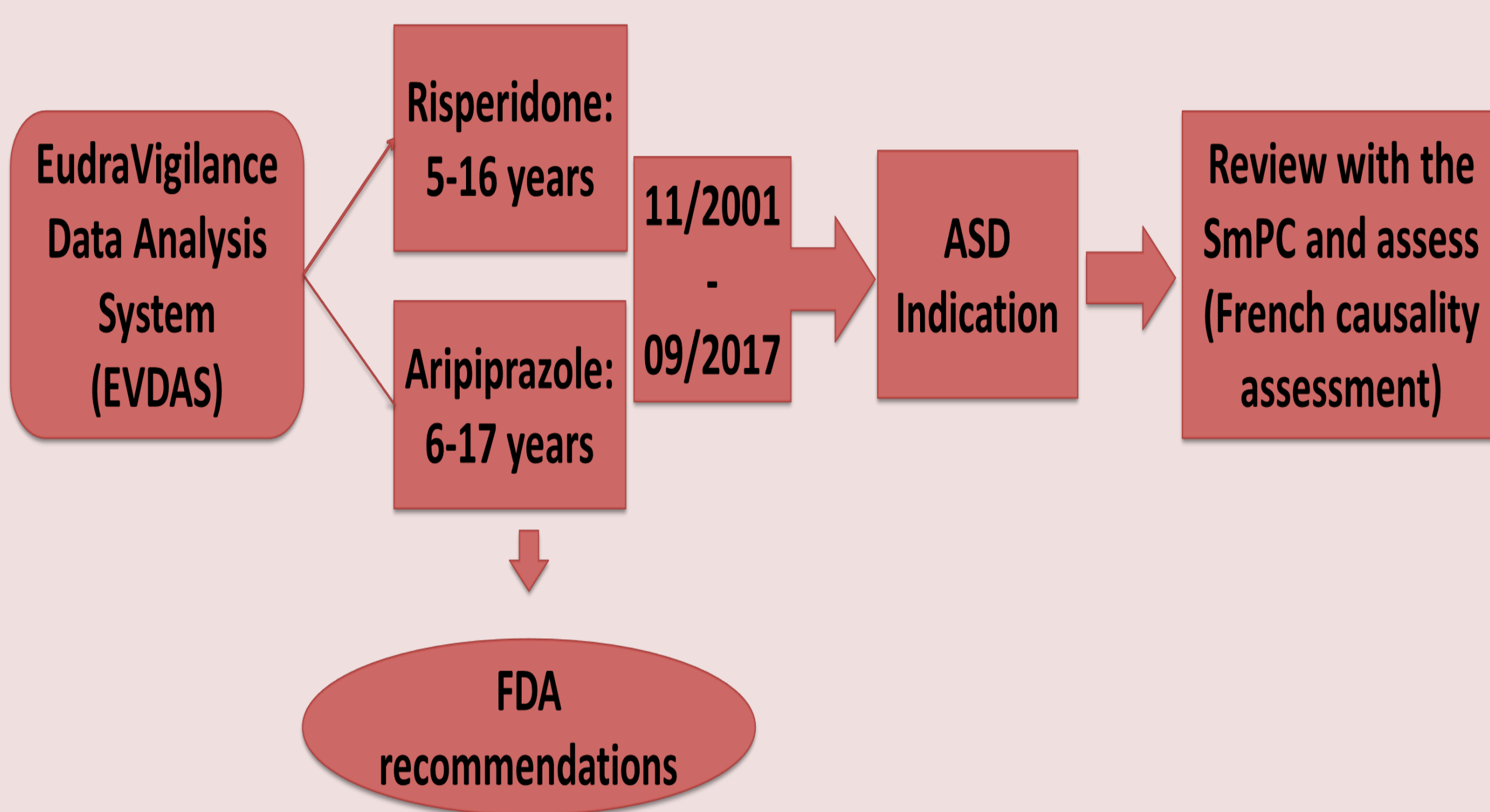


Figure 1: Eudravigilance Signal Detection and Analysis

RESULTS

- Psychiatrists in India (n=31) and Malta (n=16) agreed that the screening tools (ISAA/CARS) influenced the prescribing behaviour of RiAr ($p < 0.001$), with Indian and Maltese psychiatrists assigning a mean score of 4.45 ± 0.506 and 2.56 ± 1.153 respectively indicating higher agreement by Indian psychiatrists.
- The price difference between both countries of a single tablet of risperidone is €0.77 and €0.83 for aripiprazole. The cost of treatment in India is less when compared to Malta, but when cost is measured against the Monthly Per Capita Expenditure, Malta is more affordable than India.
- Five ADR signals were assessed for risperidone and 3 for aripiprazole. The French causality assessment concluded “uncertain” or “unlikely” relation between ADR signals and drugs (Table 1).

Drugs	ADR signals	No of Cases	Outcome
Risperidone	Disturbance in social behavior	2	Unlikely
	Motor dysfunction	1	Unlikely
	Stereotypy	1	Unlikely
	Delusion	1	Uncertain
Aripiprazole	Pituitary tumour benign	1	Uncertain
	Apathy	1	Unlikely
	Homicidal ideation	1	Uncertain
	Insulin resistance	2	Uncertain

CONCLUSION

Accessibility of RiAr is affected by their high cost. Including RiAr on national formularies for the indication of ASD can improve accessibility. Culturally developed screening tools have a different influence on the prescribing behaviour of drugs in India and Malta. The SmPC of RiAr includes all the ADRs indicated through the EudraVigilance signal detection in this study.

REFERENCES

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