

Assessment of Adverse Drug Reactions and Their Associated Risk Factors Among Systemic Autoimmune Disorder Patients

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Background

- Pharmacotherapy management of systemic autoimmune disorders is challenging due to the high disease relapse rate and requires chronic complex treatment regimens.
- Adverse drug reactions (ADRs) are the fourth leading cause of death worldwide. Hence, monitoring of ADRs become essential to achieve desired therapeutic outcomes.
- Therefore, this study was conducted to assess the ADRs and their risk factors among systemic autoimmune disorder patients.

Objectives

- To assess the ADRs among systemic autoimmune disorder patients.
- To identify risk factors associated with ADRs among systemic autoimmune disorder patients.

Methods

Study Design: Cross-sectional study

Study Site: Department of Rheumatology & Immunology, JSS Hospital, Mysuru.

Study Period: 24 months (July 2019–June 2021)

Study Subjects: Patients with rheumatoid arthritis, systemic lupus erythematosus, systemic vasculitis and psoriasis

Study inclusion criteria: Patients of any gender and aged ≥ 16 years and diagnosed with any systemic autoimmune disorders who developed ADRs were included in this study.

Methodology

- A clinical pharmacist participated in daily ward round or visited outpatient clinic to review patients' medical conditions and medication details to identify the suspected ADRs.
- Naranjo probability scale was used for causality assessment, Modified Hartwig and Siegel scale was used for severity assessment and Schumock and Thornton scale was used for assessment of preventability.
- Logistic regression analysis was used to identify the associated risk factors of ADRs, using SPSSv25.

Results & Discussion

- A total of 860 patients were investigated with average mean age of 48.1 ± 20.3 years, majority were female.
- Of them, 226 ADRs were identified among 184/860 (21.3%) patients.
- Most of the identified ADRs were related to methotrexate (87/226, 38.4%) and prednisolone (42/226, 18.5%).
- Causality assessment shows majority of ADRs were probable (119, 52.6%), possible (77, 34.0%) and definite (30, 13.2%) in type.
- Of them, most ADRs were moderate in severity (147, 65.0%) and preventable type (91, 40.2%).

Table 1: Most common drugs involved in ADRs and their assessment

Drugs	Adverse Drug Reactions	Total 226 (%)	WHO scale	Naranjo scale	Severity
Methotrexate [n=87]	Pancytopenia	19 (8.4)	Probable	Probable	Moderate
	Headache	15 (6.6)	Probable	Probable	Moderate
	Oral candidiasis	14 (6.2)	Probable	Probable	Moderate
	Transaminitis	10 (4.4)	Probable	Probable	Moderate
	Nausea, vomiting	13 (5.8)	Probable	Probable	Moderate
	Hair fall	5 (2.2)	Probable	Probable	Mild
	Abdominal pain	5 (2.2)	Possible	Possible	Moderate
	Leukopenia	4 (1.8)	Probable	Probable	Severe
	Thrombocytopenia	2 (0.9)	Possible	Possible	Moderate
Prednisolone [n=42]	Hyperglycemia	13 (5.7)	Probable	Probable	Mild
	Oral candidiasis	9 (3.9)	Probable	Probable	Moderate
	Pancytopenia	5 (2.2)	Probable	Probable	Moderate
	Acne	5 (2.2)	Probable	Probable	Mild
	Hypertension	3 (1.3)	Probable	Probable	Moderate
	Headache	2 (0.8)	Possible	Possible	Moderate
	Myopathy	2 (0.8)	Probable	Probable	Severe
	Pulmonary TB	2 (0.8)	Probable	Probable	Severe
	Osteoporosis	1 (0.4)	Probable	Probable	Moderate

Results & Discussion

Table 2. Predictors of ADRs

Characteristics	Variables	Odds ratio, 95% CI	P value
Age distribution (in years)	<19	1	-
	19-40	2.2 (1.13-4.28)	0.02
	41-60	3.19 (1.61-6.32)	0.0009
	61-80	4.48 (1.97-10.18)	0.0003
Polypharmacy	>80	5.38 (1.58-18.31)	0.007
	≤5 drugs	1	
Number of comorbidities	>5 drugs	5.93 (3.94-8.90)	<0.0001
	1-3	1	
Prescribed drugs	>3	7.38 (4.51-12.07)	<0.0001
	< 5 drugs/patient	1	
	5-9 drugs/patient	2.16 (1.15-6.22)	<0.0001
	≥ 10 drugs/patient	7.04 (4.02-12.24)	<0.0001

Conclusion

- This study reveals that pharmacotherapy management of systemic autoimmune disorders is associated with ADRs development is high.
- Thus, early detection of ADRs and their associated risk factors, and appropriately managing ADRs can help to avoid further complications.

Reference

1. Said MA, Silva LS, Rocha Am, et al. Adverse drug reactions associated with treatment in patients with chronic rheumatic diseases in childhood: a retrospective real life review of a single center cohort. 2020;60(53):1-11.

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