



INTRODUCTION

- Adverse drug reactions (ADRs) are one of the leading causes of morbidity and mortality worldwide. A liver disease can be genetic or caused by a variety of factors that damage the liver, such as viruses and persistent alcohol intake.
- These patients are at higher risk of developing potential ADRs due to altered pharmacokinetics and pharmacodynamics.
- Pharmacovigilance is a quintessential element in drug safety.

OBJECTIVE

- To observe the incidence of Adverse Drug Reactions identified in patients with any type of Liver Injury in the Gastroenterology Department.

METHOD

- SETTING:** Inpatients admitted to the gastroenterology department of a tertiary health care hospital
- DESIGN:** Prospective observational study
- PERIOD:** Six months
- PATIENTS:** Patients who have liver injury

RESULTS

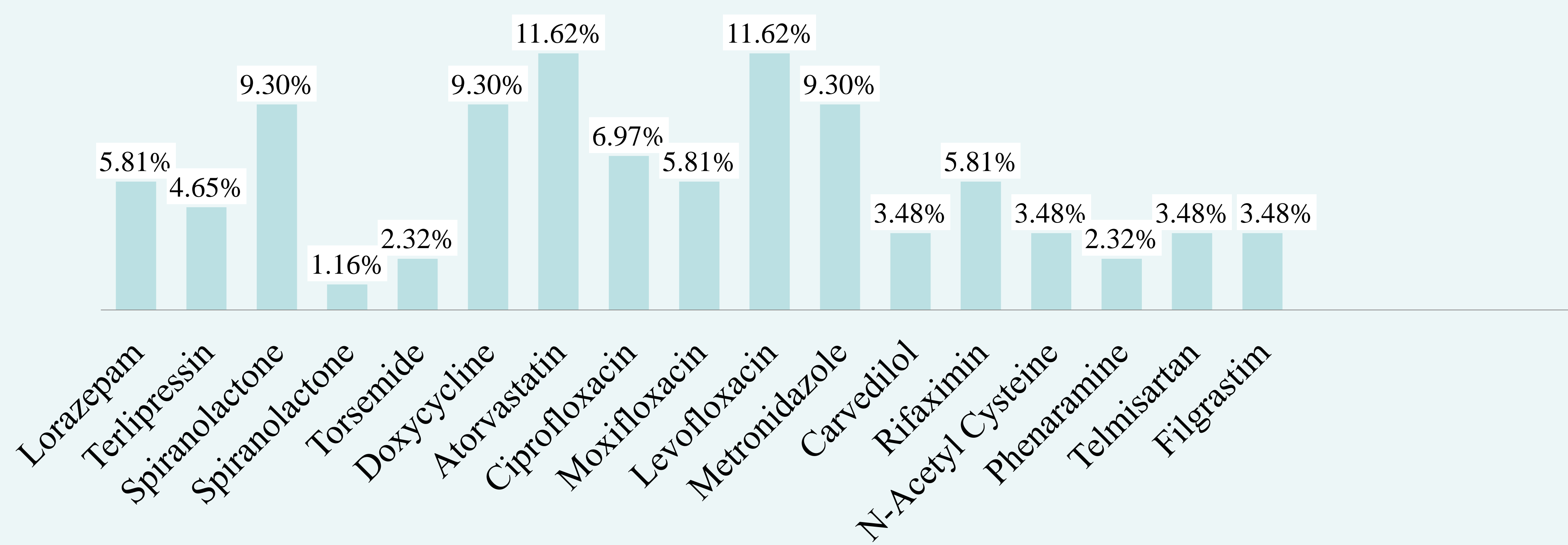


Figure 1: Distribution of hepatotoxic drugs being prescribed

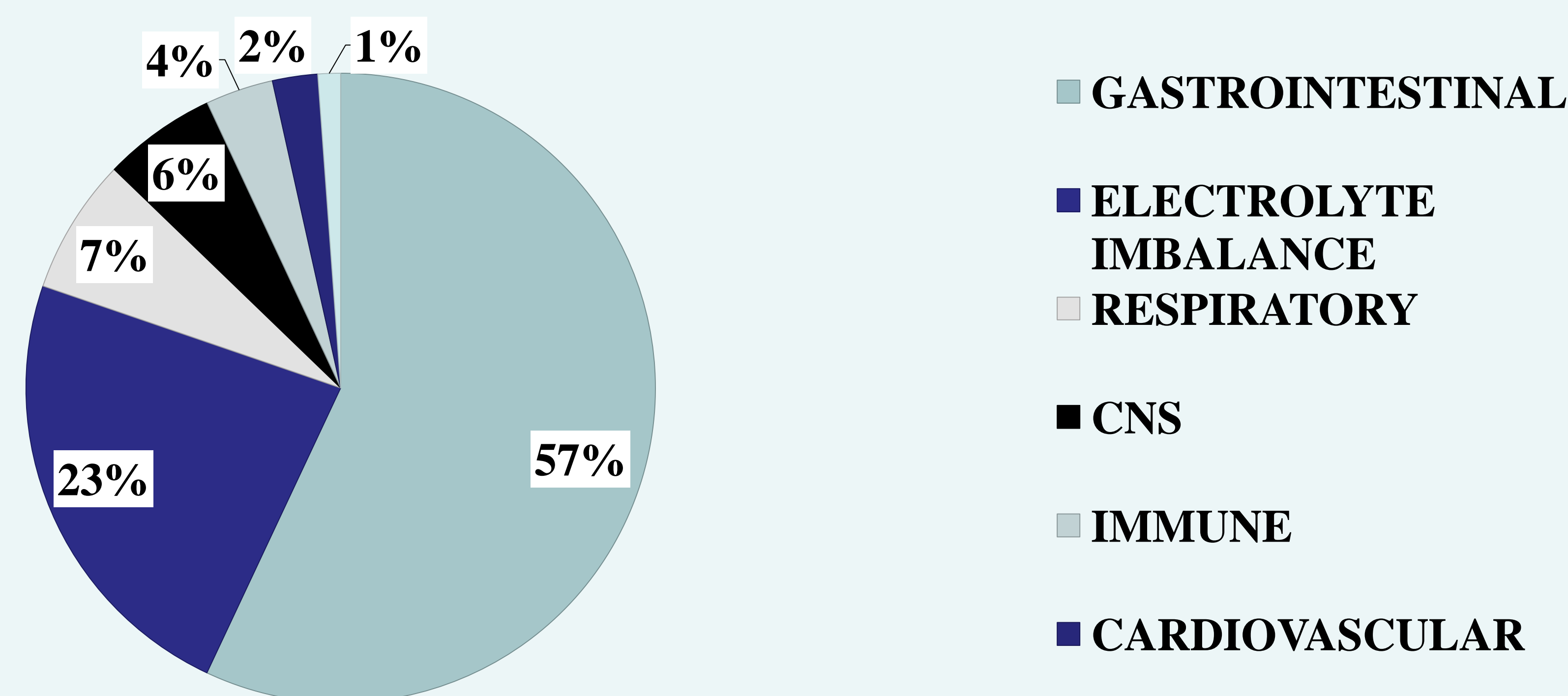


Figure 2: Distribution of drugs that caused the ADR

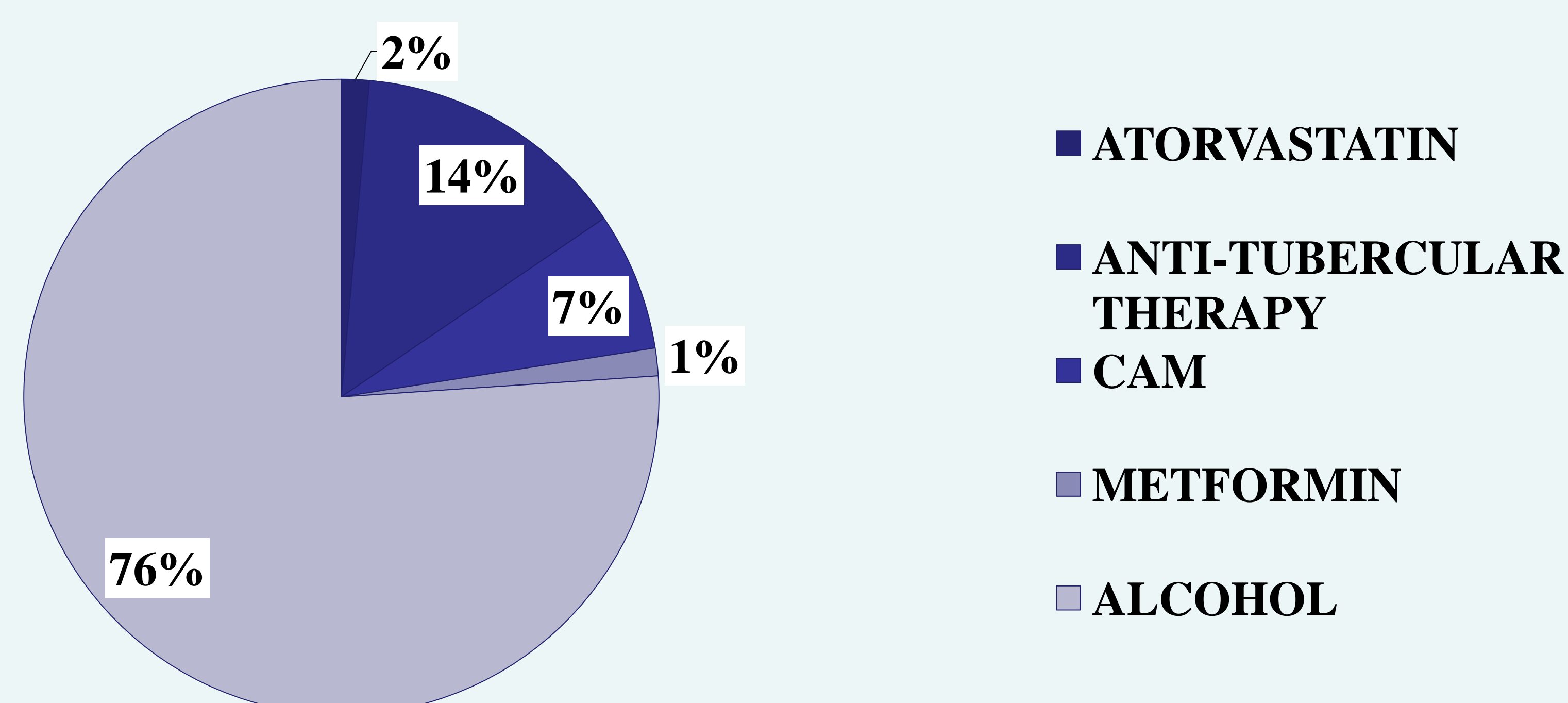


Figure 3: Distribution of drug-induced liver injury (DILI) which led to hospitalisation

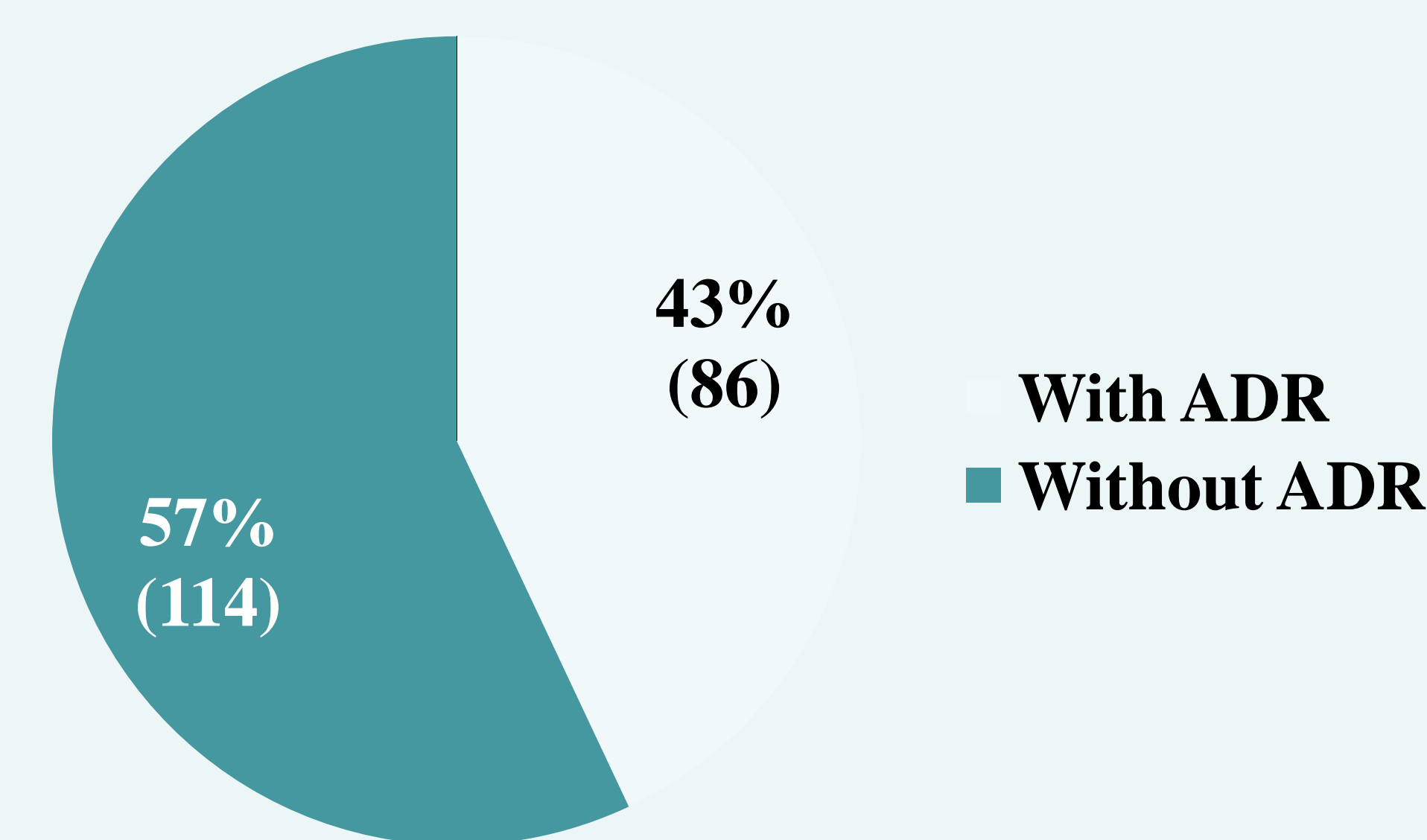


Figure 4: Incidence of ADRs

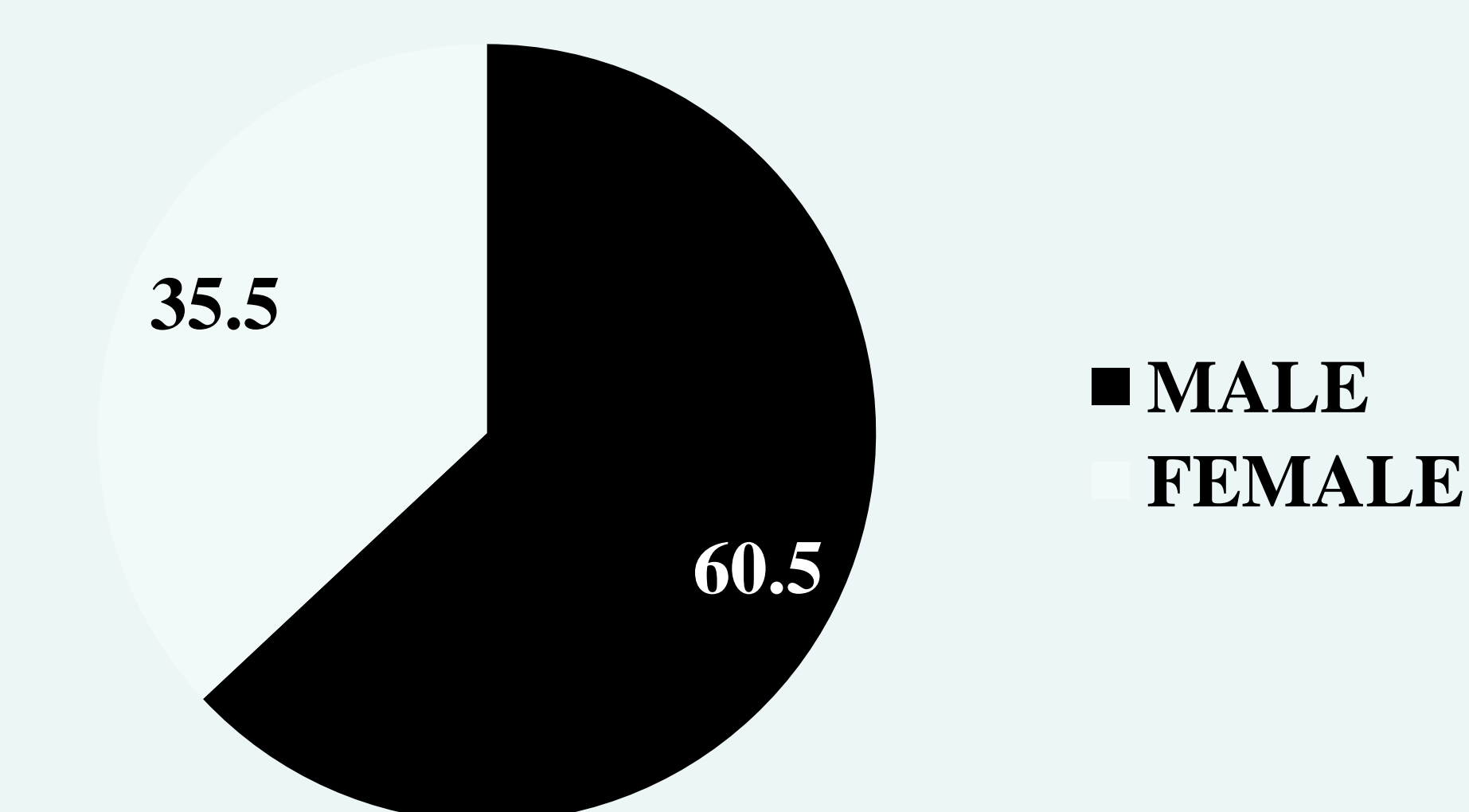


Figure 5: Distribution of gender

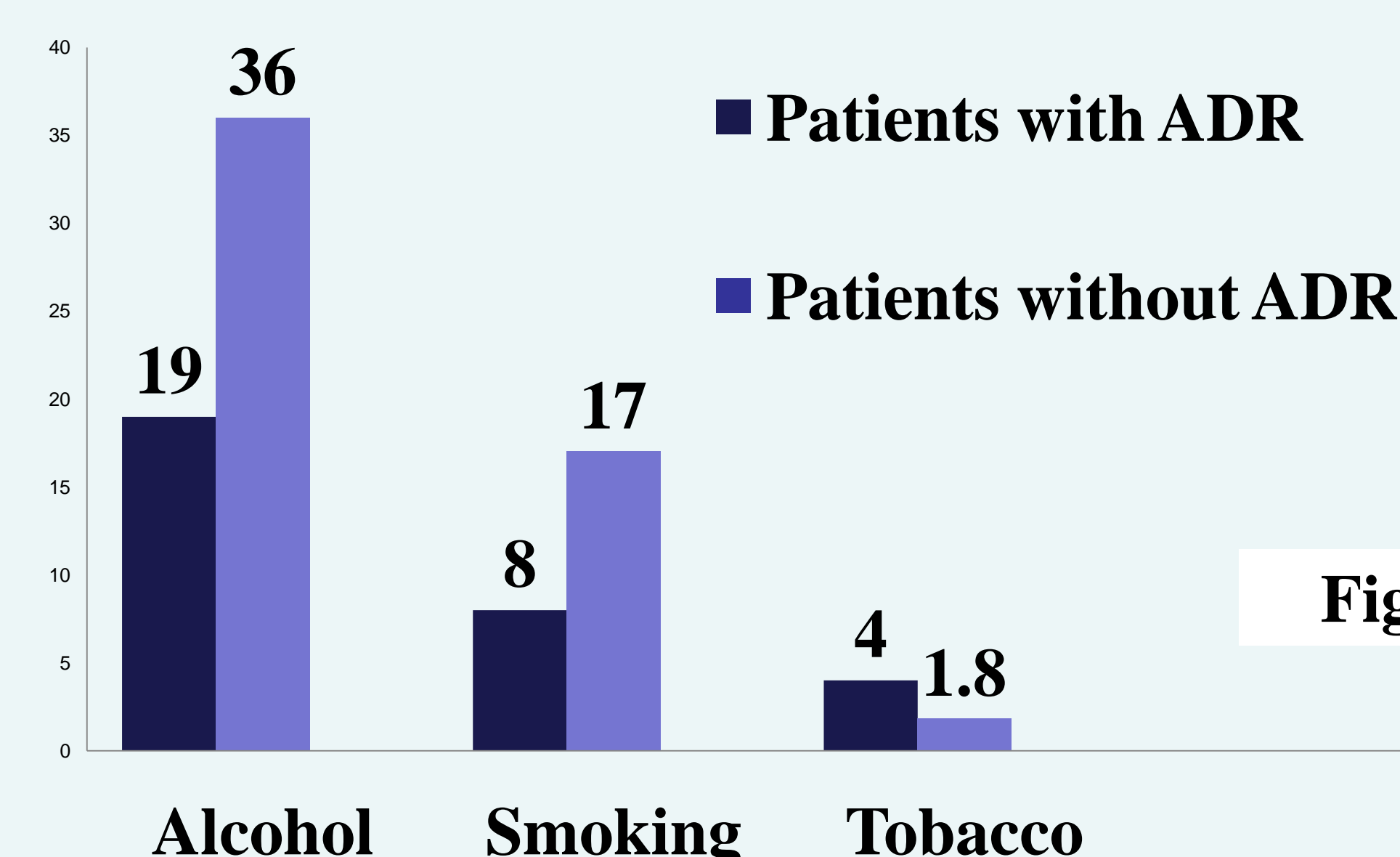


Figure 6: Distribution of social history

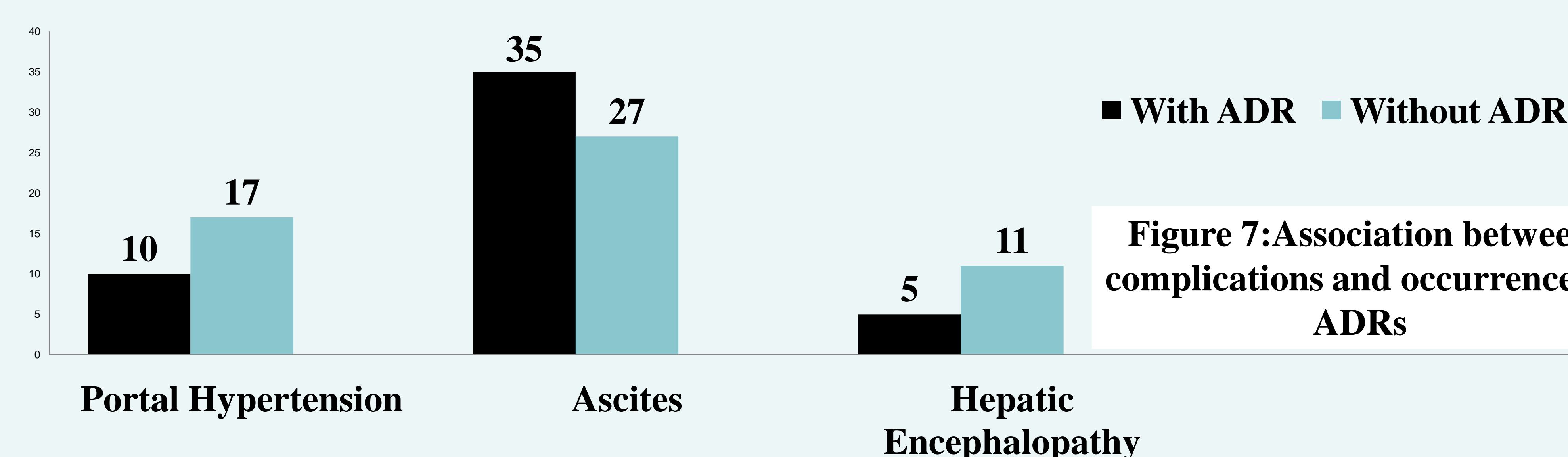


Figure 7: Association between complications and occurrence of ADRs

Table 1: Management of ADRs

Treatment	Number of reactions
Drug withdrawn / Increase or Decrease in Dose	4 (5%)
Specific Treatment	16 (16%)
Monitoring	66 (76%)

Table 3: WHO Casualty Assessment Scale

Scale	Frequency (n)
Certain	0
Probable	51 (59.30%)
Possible	35 (40.69%)
Unclassifiable	0
Unlikely	0
Conditional	0
Total	86

Table 2: Naranjo's Casualty Assessment Scale

Scale	Frequency (n)
Definite	0
Probable	55 (53.93%)
Possible	40 (46.51%)
Doubtful	1 (1.10%)
Total	86

Table 4: Karch and Lasagna's Casualty Assessment Scale

Scale	Frequency (n)
Definite	0
Probable	47 (54.65%)
Possible	13 (15.11%)
Conditional	36 (41.86%)
Total	96

Table 5: Modified Hartwig and Siegel Severity Assessment Scale

Severity	Levels	Frequency (n)
Mild	Level 1	12 (13.95%)
	Level 2	22 (22.58%)
Moderate	Level 3	6 (6.97%)
	Level 4a	18 (20.93%)
Severe	Level 4b	15 (17.44%)
	Level 5	9 (10.46%)
	Level 6	0
Total	Level 7	0
	Total	86

CONCLUSION

A total of 200 patients were recruited for the study out of which 86 patients suffered with at least one ADR. ADRs were more in males (63%) as compared to females (37%). Patients belonging to the age group 18-49 were found to have higher incidence of ADRs (41%). Patients with history of alcohol intake showed significant association with ADRs. The highest rate of ADRs was observed with Atorvastatin and Terlipressin. The organ system most commonly affected was gastrointestinal (57%) followed by electrolyte and fluid imbalance (23%). The causality assessment was done using three different scales which showed that most of the ADRs were probable. Severity assessment showed that 22.58% reactions were Level 2 which signified that most of the ADRs required the suspected drug to be withheld, discontinued, otherwise changed and/or an antidote or other treatment is required. The preventability assessment using Schumack and Thorton scale revealed that 35 (39%) ADRs were probably preventable.