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Original Research Article

Drug utilization pattern, drug-related problems and associated risk factors in patients with hepatic impairment: a prospective observational study at a tertiary care teaching hospital

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ABSTRACT

Background: Because the liver drives the clearance of most medicines, any decline in hepatic function reshapes drug handling and leaves patients open to drug-related problems (DRPs). We set out to map the drug utilization pattern, characterise the DRPs, and identify the risk factors linked to hepatic impairment in admitted patients.
Methods: A sample of 60 inpatients with hepatic impairment was studied prospectively over six months (February to August 2025) in the medicine ward of a tertiary care teaching hospital. Demographic, clinical, and prescription details were captured on structured forms. Severity was graded by the Child-Pugh score, prescribing quality was benchmarked against WHO core indicators, and DRPs were categorised by the Cipolle-Strand-Morley framework. Categorical associations were tested by chi-square, with the exact test for sparse cells; significance was set at $p<0.05$.
Results: Most patients were men (95.0%); the 41-60-year band was largest (45.0%) and moderate disease (Child-Pugh B) prevailed (76.7%). Altogether 714 drugs were prescribed (mean 11.9 per patient); antibiotics (19.2%) and proton-pump inhibitors (13.2%) led non-hepatospecific classes, and ursodeoxycholic acid (16.1%) the hepatospecific agents. Generic prescribing reached only 25.6%, while 74.9% featured on the WHO Essential Medicines List. Fifty DRPs occurred in 42 patients (70.0%), chiefly drug-drug interactions (40.0%) and adverse drug reactions (20.0%). Comorbidity was significantly associated with DRPs (exact test, $p=0.024$), and alcohol overconsumption was the leading risk factor (88.3%).
Conclusions: Prescribing leaned on antibiotics, acid suppressants, and hepatospecific agents, yet weak generic prescribing and a heavy comorbidity-driven DRP load mark clear openings for pharmacist-led optimisation and structured alcohol-abstinence counselling.

Keywords: Adverse drug reactions, Child-Pugh score, Drug-related problems, Drug utilization, Hepatic impairment, Rational prescribing

INTRODUCTION

The liver is where most medicines are broken down, and it carries a workload that touches almost every step of drug handling. It manufactures the plasma proteins that ferry circulating drugs, secretes the bile that clears lipophilic metabolites, keeps blood glucose in balance, and strips endogenous and exogenous toxins out of the portal blood. Once hepatic function falters, each of these tasks is thrown off, and the knock-on effects for pharmacotherapy are considerable.

Hepatic impairment, sometimes called liver insufficiency or liver failure, describes a state in which the organ can no

longer meet these basic demands. It may creep in over years, as in chronic liver disease and cirrhosis, or erupt within days, as in acute liver failure. The triggers are wide-ranging and take in viral hepatitis (types A through E), heavy alcohol use, non-alcoholic steatohepatitis, drug-induced liver injury, biliary and cholestatic disease, vascular insults, and inherited disorders such as Wilson's disease.[1] Hepatitis B alone remains a major driver of chronic liver disease worldwide, underscoring the diverse aetiology clinicians must weigh at the bedside.[2]

Falling hepatic clearance, portosystemic shunting, weaker plasma-protein binding, and blunted drug-metabolising enzyme activity can each push systemic drug exposure upward and raise the odds of toxicity. Since the majority of medicines pass through the liver, patients with liver dysfunction are especially prone to adverse drug reactions, drug-drug interactions, and dosing errors. Studies of how medicines are chosen, distributed, and consumed in practice, along with their clinical, social, and economic repercussions, give clinicians a disciplined lens through which to judge whether prescribing in this group is truly rational.[3]

With this in view, we set out to map how medicines are used in hepatic impairment, to catalogue the drug-related problems that emerge during a hospital stay, and to weigh the factors that predispose to liver dysfunction, thereby marking out concrete openings for pharmacist-led refinement of therapy. This study aimed to study the drug utilization pattern in patients with hepatic impairment admitted to a tertiary care teaching hospital.

METHODS

Study design, setting, and duration

The work took the form of a prospective, observational enquiry running from February to August 2025 in the medicine ward of S. Nijalingappa Medical College and HSK Hospital, Bagalkot, Karnataka, India, a tertiary care teaching hospital attached to a college of pharmacy. Every inpatient meeting the entry criteria was reviewed each day from admission through to discharge.

Eligibility criteria

Adults of both sexes above 18 years, admitted with hepatic impairment for a minimum of 24 hours and consenting to participate, qualified for enrolment. Excluded were those below 18 years, cases seen only on an outpatient basis, women who were pregnant or breastfeeding, and any patient who declined to take part.

Sample size

The required sample size was computed in OpenEpi version 2.3.1. Taking an anticipated prevalence of 28%, 12% relative precision, and 95% confidence, the calculation returned 54; this was rounded up to give a final sample size of 60 patients.

Data collection

Case notes, treatment charts, laboratory reports, and face-to-face interviews supplied the source data. A profile form recorded background details (age, sex, weight, height), the clinical picture (presenting complaint, past history, allergies), and a full medication history. To gauge the depth of dysfunction, hepatic biochemistry was noted, covering the aminotransferases (ALT and AST), bilirubin, prothrombin time with INR, and serum albumin. Severity followed the Child-Pugh grade, and the quality of prescribing was appraised through the WHO prescribing indicators alongside the 2023 WHO Model List of Essential Medicines.[4]

Classification of drug-related problems

Each problem was sorted through the Cipolle, Strand, and Morley scheme into one of eight categories: untreated indication, drug use without indication, adverse drug reaction, drug-drug interaction, subtherapeutic dosage, overdosage, failure to receive the prescribed drug, and a medical condition traceable to an unindicated drug. For every adverse drug reaction, causality was rated with the WHO-UMC scale and the Naranjo algorithm, and preventability and predictability with the customary criteria. Interventions proposed by the pharmacist, together with the treating team's response to them, were logged.

Statistical analysis

Continuous variables were described as means, and categorical variables as frequencies and proportions. Because the two-by-two table relating comorbidity to DRP occurrence contained a cell with an expected count below five, the association was tested by Fisher's exact test rather than Pearson's chi-square. Whether the three risk factors were evenly distributed was assessed with a chi-square goodness-of-fit test against a uniform expectation. The link between age band and DRP occurrence was examined with Pearson's chi-square. A two-tailed p-value below 0.05 denoted statistical significance. Computations were carried out in SPSS (version 25.0).

Ethics

Ethical clearance for the protocol was granted by the Institutional Ethics Committee of Hanagal Shri Kumareshwar College of Pharmacy, Bagalkot (Reference No. HSKCOP/IEC/25/7, dated 13 February 2025). Each participant, or a caregiver where appropriate, signed a consent form after the study had been explained, and retained a duplicate for their records.

RESULTS

Demographic and clinical profile

Sixty patients with hepatic impairment were enrolled. Men dominated sharply, making up 57 patients (95.0%) against 3 women (5.0%). The 41-60-year band was largest (27 patients, 45.0%), trailed by 21-40 years (22 patients, 36.7%) and 61-80 years (11 patients, 18.3%). On Child-Pugh grading, most patients sat in class B (moderate disease, 46 patients, 76.7%), with fewer in class A (mild, 8 patients, 13.3%) and class C (severe, 6 patients, 10.0%) (Tables 1 and 2).

Table 1: Demographic distribution of the study participants (n=60).

Age group (years)	Male, N (%)	Female, N (%)	Total, N (%)
21-40	21 (35.0)	1 (1.7)	22 (36.7)
41-60	26 (43.3)	1 (1.7)	27 (45.0)
61-80	10 (16.7)	1 (1.7)	11 (18.3)
Total	57 (95.0)	3 (5.0)	60 (100)

Table 2: Distribution of participants by Child-Pugh severity class (n=60).

Child-Pugh class	Number	Percent
Class A (mild)	8	13.3
Class B (moderate)	46	76.7
Class C (severe)	6	10.0
Total	60	100

Comorbid conditions were common and shifted with the underlying diagnosis. Across the cohort, 75 comorbidity events were logged (mean 1.25 per patient). Portal hypertension was the most frequent, especially in chronic liver disease (14.7%) and decompensated chronic liver disease (8.3%), followed by ascites, hepatic encephalopathy, anaemia, and diabetes mellitus.

Prescription pattern and rational-use indicators

The 60 patients received 714 drugs in all, averaging 11.9 each. Hepatospecific agents made up 298 of these (41.7%) and non-hepatospecific agents the remaining 416 (58.3%). Judged against the WHO prescribing indicators, 535 drugs (74.9%) belonged to the WHO Essential Medicines List, but generic naming was applied to only 183 (25.6%), a clear shortfall in generic prescribing (Table 3).

Among the non-hepatospecific drugs, antibiotics formed the largest class (80 drugs, 19.2%), ahead of proton-pump inhibitors (55, 13.2%), miscellaneous agents (59, 14.2%), antiemetics (43, 10.3%), and antihypertensives (36, 8.7%). Among the hepatospecific drugs, ursodeoxycholic acid was the single most prescribed agent (48 prescriptions, 16.1%), followed by rifaximin (37, 12.4%) and lactulose (36, 12.1%); silymarin was the most frequent hepatoprotectant (23, 7.7%) (Table 4).

Table 3: Prescription analysis using WHO core drug-use indicators.

Indicators	Value
Prescriptions analysed	60
Total drugs prescribed	714
Mean drugs per prescription	11.9
Drugs prescribed by generic name, N (%)	183 (25.6)
Drugs from WHO Essential Medicines List, N (%)	535 (74.9)
DRPs per patient (50/60)	0.83

Table 4: Most frequently prescribed drug classes (selected).

Non-hepatospecific	Number (%)	Hepatospecific	Number (%)
Antibiotics	80 (19.2)	Ursodeoxycholic acid	48 (16.1)
Proton-pump inhibitors	55 (13.2)	Rifaximin	37 (12.4)
Miscellaneous	59 (14.2)	Lactulose	36 (12.1)
Antiemetics	43 (10.3)	Silymarin	23 (7.7)
Antihyper-tensives	36 (8.7)	Spironolactone	16 (5.4)

Drug-related problems

Across the cohort, 50 drug-related problems were recorded in 42 patients, a prevalence of 70.0% and a mean of 1.19 problems per affected patient. Drug-drug interactions headed the list (20 problems, 40.0%), trailed by adverse drug reactions (10, 20.0%), failure to receive the prescribed drug (6, 12.0%), subtherapeutic dosage (5, 10.0%), untreated indication (4, 8.0%), drug use without indication (3, 6.0%), and overdosage (2, 4.0%) (Table 5, Figure 1).

Table 5: Classification of drug-related problems (Cipolle-Strand system).

Drug-related problems	Number	Percent
Drug-drug interaction	20	40.0
Adverse drug reaction	10	20.0
Failure to receive drug	6	12.0
Subtherapeutic dosage	5	10.0
Untreated indication	4	8.0
Drug use without indication	3	6.0
Overdosage	2	4.0
Total	50	100

Ten adverse drug reactions were documented (incidence 16.7%), hepatotoxicity and electrolyte disturbance being the commonest. Furosemide-led diuretic therapy was the

principal driver of hypokalaemia, whereas anti-tubercular therapy (isoniazid, rifampicin, pyrazinamide, ethambutol) and pioglitazone were implicated in hepatotoxicity. Causality on the WHO-UMC and Naranjo instruments fell mostly in the probable and possible bands, and every reaction was rated definitely preventable and predictable.

Pharmacist interventions were proposed for the problems found; the commonest were a change in dosing frequency (41.0%) and monitoring for drug-drug interactions (30.0%). Of the 39 interventions documented, 23 (59.0%) were accepted by the treating team.

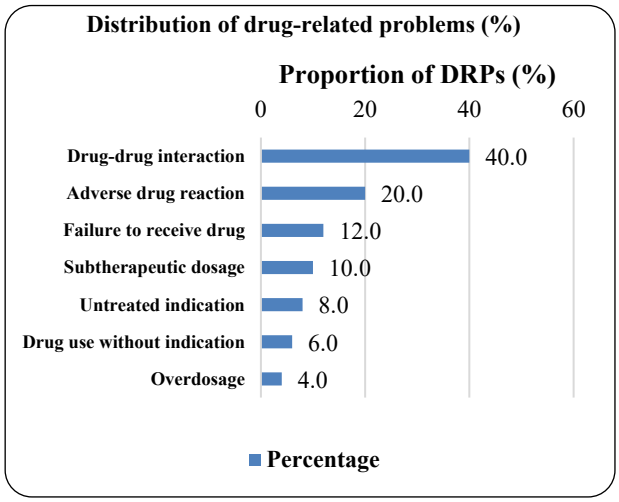

Figure 1: Distribution of drug-related problems by category (Cipolle-Strand system; n=50).

Association of comorbidity, risk factors, and DRPs

Comorbidity and DRP occurrence moved together clearly. Of the 57 patients carrying at least one comorbid condition, 42 developed a DRP, while none of the 3 patients free of comorbidity did so; the difference was significant on Fisher's exact test (p=0.024). The burden also mounted with comorbidity load, climbing from a mean of 0.67 problems per patient at one comorbidity to 1.29 at three (Table 6, Figure 2).

Table 6: Relationship between comorbidity burden and drug-related problems.

No. of comorbidities	Patients	Total DRPs	Mean DRPs/patient
0	3	0	0.00
1	27	18	0.67
2	23	23	1.00
3	7	9	1.29

Fisher's exact test for comorbidity (present vs absent) versus DRP (yes vs no): p=0.024.

Three principal risk factors for hepatic impairment stood out. Alcohol overconsumption was overwhelmingly dominant, present in 53 patients (88.3%), with long-term drug therapy (3 patients, 5.0%) and viral exposure (4 patients, 6.7%) far rarer. The distribution strayed sharply from a uniform expectation (chi-square goodness-of-fit=81.70, df=2, p<0.001), confirming alcohol as the leading contributor (Table 7). Age group, by contrast, showed no significant link with DRP occurrence (chi-square test, p=0.55).

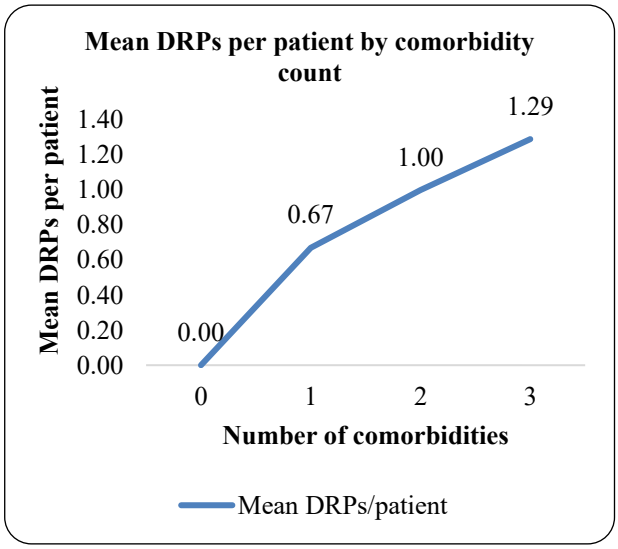

Figure 2: Mean number of drug-related problems per patient across increasing comorbidity burden.

Table 7: Risk factors associated with hepatic impairment (n=60).

Risk factors	Number	Percent
Alcohol overconsumption	53	88.3
Viral exposure	4	6.7
Long-term drug therapy	3	5.0

Chi-square goodness-of-fit against a uniform distribution: χ^2=81.70, df=2, p<0.001.

DISCUSSION

This study set out the drug utilization pattern, drug-related problems, and risk factors among hospitalised patients with hepatic impairment, and its findings carry practical weight for safer prescribing in a high-risk group. The pronounced male preponderance (95.0%) and the clustering of cases in the 41-60-year band echo the broader literature, where liver disease in this setting is driven chiefly by alcohol and falls disproportionately on working-age men.[5,6]

Most patients arrived with moderate (Child-Pugh class B) disease, hinting that many sought care while pharmacological optimisation could still shift the outcome. The comorbidity profile, led by portal hypertension, ascites, and hepatic encephalopathy, tracks the natural history of decompensating chronic liver disease and shaped much of the prescribing seen here.

The prescribing pattern, dominated by antibiotics and proton-pump inhibitors among non-hepatospecific drugs and by ursodeoxycholic acid, lactulose, and rifaximin among hepatospecific agents, sits comfortably alongside earlier tertiary-care work.[5,7] The mean of 11.9 drugs per patient captures the polypharmacy that comes with managing decompensated liver disease and its complications. Adherence to the WHO Essential Medicines List was fair at 74.9%, but generic prescribing stayed low at 25.6%, repeating a familiar gap in rational-prescribing audits and marking an actionable target for stewardship.[8]

The DRP burden was heavy: 70.0% of patients had at least one problem, with drug-drug interactions and adverse drug reactions to the fore. The adverse-reaction picture, hepatotoxicity from anti-tubercular agents and pioglitazone alongside electrolyte disturbance from diuretics, is clinically coherent in a population with limited hepatic reserve, and every documented reaction was judged preventable. The significant association between comorbidity and DRP occurrence (p=0.024), together with the climbing DRP count as comorbidities stacked up, restates a familiar rule: therapeutic complexity multiplies the chances for harm.[9] This is exactly where a clinical pharmacist woven into the medical team pays off, as the 59.0% acceptance of pharmacist interventions in this cohort suggests.[10]

Alcohol overconsumption emerged as the leading risk factor (88.3%), in step with regional and international evidence tying sustained alcohol intake to progressive hepatic injury.[11] The strongly skewed distribution of risk factors places alcohol-abstinence counselling at the heart of any preventive strategy for this population.

This study has several limitations. The single-centre design and modest sample of 60 patients limit generalisability, and the marked sex imbalance restricts inference in women. The observational design rules out causal claims, and reliance on documented records may have missed some DRPs. Even so, the prospective daily review and structured causality assessment lend confidence to the patterns described.

CONCLUSION

Within this tertiary-care cohort, therapy for hepatic impairment leaned on polypharmacy and on antibiotics, acid suppressants, and hepatospecific agents, all against a heavy backdrop of drug-related problems. Comorbidity tracked closely with DRP occurrence, and sustained alcohol use stood out as the chief predisposing factor. On balance, the findings make a strong case for embedding a clinical pharmacist in routine care to catch and resolve DRPs, for wider use of generic names, and for structured abstinence counselling, each a practical lever for making pharmacotherapy in liver dysfunction both safer and more rational.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee, Hanagal Shri Kumareshwar College of Pharmacy, Bagalkot (HSKCOP/IEC/25/7, dated 13 February 2025)

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