

Original Article

Optimise diuretic therapy in cirrhotic care: predictive model development for enhanced fluid management for better outcomes

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ABSTRACT

Objectives: Diuretic therapy in liver cirrhosis is traditionally adjusted through a trial-and-error process, characterised by inefficiencies, frequent therapy modifications, prolonged hospital stays and high economic costs. Predictive analytics powered by machine learning (ML) offers a transformative solution, enabling personalised and precise interventions that minimise regimen changes, expedite recovery and enhance healthcare efficiency. This study evaluates the impact of ML-guided diuretic therapy on reducing treatment modifications, hospitalisations and associated costs, ultimately delivering precision-driven outcomes.

Materials and Methods: An ambidirectional cohort study analysed 481 cirrhotic patients receiving diuretic therapy. Key clinical data, including liver function markers, serum electrolytes and urinary output, were collected to analyse therapy modifications and identify predictors of suboptimal outcomes. ML classification models were trained to predict optimal diuretic regimens using one-hot encoding for categorical variables. Model performance was assessed through the area under the curve, accuracy, sensitivity and specificity. Hyperparameter optimisation enhanced predictive accuracy, while feature importance analysis identified critical predictors of diuretic response.

Results: Under the conventional approach, 71.5% of patients initially received suboptimal therapy, leading to add-on treatments (44%) or complete regimen changes (27%). The ML model reduced therapy modifications by 58%, achieving 81% accuracy in predicting optimal regimens. Key predictors of diuretic response included serum albumin, bilirubin and creatinine levels. Incorporating ML reduced the time to optimal therapy from 7–8 days to 4 days, shortened hospital stays by 40% and significantly lowered healthcare costs.

Conclusion: ML-guided diuretic management in liver cirrhosis represents a paradigm shift, delivering precision-driven care that minimises therapy changes, shortens hospital stays and reduces economic burden. By leveraging key clinical predictors, this approach accelerates recovery and enhances treatment precision. Further validation in larger datasets and real-world settings is critical to establishing ML as a cornerstone of fluid management in cirrhosis, enabling cost-effective, patient-centred care.

Keywords: Ascites, Diuretic, Liver cirrhosis, Machine learning model, Predictive model

INTRODUCTION

The cornerstone of ascites management is diuretic therapy, typically involving furosemide, spironolactone, aldactone, torsemide and albumin supplementation. However, approximately 10% of patients with cirrhotic ascites develop diuretic resistance, which is associated with poor outcomes, including increased rates of hospitalisation and mortality. Ineffective diuretic

use can also result in serious complications, including hyponatraemia, hyperkalaemia and acute kidney injury (AKI), highlighting the need for optimised diuretic therapy in cirrhosis management.^[1] Ineffective diuretic therapy is defined as a failure to achieve sufficient fluid removal (e.g., urinary output <200 mL/day) or therapy resulting in complications such as hyponatraemia, hyperkalaemia or AKI, consistent with established guidelines.^[2,3] For instance, persistent ascites despite spironolactone 100 mg with rising creatinine levels would indicate ineffective therapy. These challenges highlight the need for optimised diuretic therapy in cirrhosis management.

At present, diuretic regimens are adjusted through a trial-and-error approach, where clinicians empirically modify dosages based on patient response. This may involve stopping or switching diuretics, increasing doses or adding additional therapies. However, this approach is time-consuming, resource-intensive. Moreover, it often requires frequent hospitalisation, placing a substantial burden on healthcare systems and reducing patients' quality of life.

Given these limitations, there is growing interest in using predictive models to streamline and personalise treatment. Machine learning (ML), an advanced tool in artificial intelligence, has demonstrated tangible clinical utility in recent years by analysing complex datasets and predicting outcomes based on patient-specific factors. Real-world applications include a deep learning model for breast cancer screening,^[4] an automated insulin delivery system in type 1 diabetes,^[5] and a dose prediction approach for warfarin.^[6]

In this study, we aim to develop a predictive ML model tailored to optimise diuretic therapy in patients with cirrhosis. Here, optimisation refers to the selection of the most appropriate diuretic regimen, recommended drug, dose ranges and need for dose escalation or modification, based on individual clinical and biochemical profiles. This personalised approach is intended to reduce complications and improve therapeutic efficacy compared to traditional empirical adjustment methods. Our model is designed to predict individual responses to diuretic regimens, thereby minimising therapeutic inefficacy and reducing the risk of complications. This approach not only promises to improve patient care but also has the potential to decrease hospitalisation rates and alleviate the strain on healthcare resources. This personalised approach is intended to reduce complications and improve therapeutic efficacy compared to traditional empirical adjustment methods.

MATERIALS AND METHODS

Study design and patient selection

This ambidirectional study involved both retrospective and prospective data collection. Clinical and biochemical data

from previously treated cirrhotic patients were retrospectively retrieved from medical records, while additional data were prospectively collected from newly enrolled patients over a 6-month period prior to. Due to the limited enrolment phase, retrospective data covering an additional 6 months were incorporated from the hospital medical records department. The study aimed to explore the challenges and inefficiencies in traditional diuretic therapy for cirrhosis-related ascites, while leveraging predictive analytics as a potential solution. A total of 481 patients, aged 18–75 years, were enrolled from the Department of Gastroenterology, PSG IMS&R, a tertiary care teaching hospital, using a consecutive sampling method. As this was an observational study focusing on ML model development, no randomisation was performed. Sample size was not calculated; instead, the sample size was determined based on institutional patient flow, aiming for at least 450 eligible patients over a one-year period to ensure data adequacy. Patients with incomplete records were excluded from the final analysis. Eligibility criteria included patients undergoing ascites management with diuretic therapy, specifically furosemide, spironolactone or their combination. In addition, patients receiving albumin-based therapies – either as monotherapy or in combination with diuretics for the management of cirrhosis-related complications – were included in the study. To broaden the scope of observed therapeutic approaches, patients were excluded if they had any renal insufficiency, insufficient clinical data or declined participation. The study received ethical clearance from the Institutional Human Ethics Committee (PSG IMSR IHEC) on 20 April 2024.

Data collection

Comprehensive clinical data were systematically collected for all enrolled patients to enable predictive analytics in identifying optimal therapy outcomes. Key parameters included liver function tests, prothrombin time international normalised ratio (INR) and scoring systems such as the model for end-stage liver disease (MELD) score, which estimates mortality risk and the Child-Turcotte-Pugh (CTP) score, which assesses liver disease severity. Serum sodium and potassium levels were recorded to assess electrolyte balance and therapy safety, especially due to risks such as hyponatraemia (<135 mEq/L) and hyperkalaemia (>5 mEq/L). Serum creatinine (>1.2 mg/dL) was monitored to evaluate renal dysfunction. Urinary output (24-h) served as the primary marker of diuretic effectiveness. Therapy adequacy was also assessed through symptomatic relief, including clinical signs such as reduced ascites, decreased peripheral oedema and patient-reported relief from abdominal discomfort or breathlessness, and hospitalisation was assessed based on the total number of days spent in the hospital for therapy.

Diuretic regimens considered

The following regimens were documented to capture real-world therapeutic approaches and were not protocol-driven. The therapeutic approach to diuretic management involved a tiered strategy beginning with spironolactone monotherapy, titrated based on response. The following are the therapy options presented as a set of guidelines with specific dosages:

- Spironolactone: Initiate at 50 mg, with potential titration up to 100 mg based on diuretic response
- Lasilactone (20/50 mg): Consider transitioning to this fixed-dose combination of a loop diuretic and an aldosterone antagonist in cases of suboptimal response to spironolactone. Administer either twice daily (BID) or thrice daily (TID), depending on the degree of fluid retention
- Furosemide: Initiate at 20 mg, with potential escalation to 40 mg if adequate diuresis is not achieved
- Combination therapy for enhanced volume management:
 - Furosemide (20 mg) may be combined with lasilactone (20/50 mg)
 - Furosemide (20 mg) may be combined with human albumin 20%
- Human albumin 20% monotherapy: Consider in patients with hypoalbuminaemia or refractory ascites, particularly when traditional diuretic therapy alone is inadequate
- Combination therapy for intensive fluid mobilisation:
 - Human albumin 20% may be combined with furosemide (20 mg)
 - Human albumin 20% may be combined with lasilactone (20/50 mg).

These therapy regimens outline a flexible approach to diuretic management, adapting the choice and dosage of medication based on individual patient characteristics and their response to treatment.

Therapy classification for predictive modelling

For ML purposes, patient therapies were classified into four distinct categories:

1. Spironolactone monotherapy
2. Furosemide monotherapy
3. Combination diuretic therapy (furosemide + spironolactone)
4. Human albumin-based therapy (monotherapy or combined with diuretics).

These categories reflected typical clinical decision-making pathways in the management of cirrhosis-related ascites.

Data preprocessing and cleaning

The dataset underwent a rigorous cleaning process before model development. Missing values for continuous variables (e.g., serum sodium, MELD score) were imputed using median values. Implausible outliers (>3 standard deviations from the mean) were reviewed and excluded if determined to be clinically invalid. Categorical variables were transformed using one-hot encoding to facilitate ML processing.

Data analysis

Statistical methods were employed to analyse the relationships between clinical variables and therapy outcomes, laying the groundwork for subsequent predictive analytics models. Pearson correlation assessed linear associations between continuous variables, such as serum sodium and urinary output. The Chi-square test examined associations between categorical variables, including gender and therapy response, with statistical significance set at $P < 0.05$. Odds ratios were calculated to evaluate the impact of clinical factors on therapy modifications. These analyses highlighted the intricate nature of optimising diuretic therapy and provided crucial foundational insights for predictive modelling.

ML model development

We employed a supervised ML approach, where the model learns patterns from labelled clinical data to predict outcomes, in this case, the optimal diuretic therapy for patients with cirrhosis. We evaluated several common classification algorithms, including Decision Trees, Logistic Regression, Random Forest, XGBoost and Artificial Neural Networks, to categorise data into predefined therapy groups.

Categorical variables, such as medication types and patient characteristics, were transformed into a binary format using one-hot encoding to facilitate ML model processing. Before model development, the dataset underwent a rigorous cleaning process to ensure data integrity and consistency. Classification models were trained to predict the optimal therapy, incorporating both initial diuretic regimens and subsequent modifications during the course of treatment. To enhance model robustness and minimise overfitting, a 10-fold cross-validation technique was employed. Model performance was assessed using key metrics, including the area under the curve of the Receiver Operating Characteristic curve, overall accuracy, sensitivity and specificity.

Initially, model performance was limited, with accuracies between 23% and 40%, due to an imbalance in the number of cases across therapy categories. To mitigate this, the Synthetic Minority Oversampling Technique (SMOTE) was applied to generate synthetic instances of underrepresented classes,

thereby enhancing model learning. Following the SMOTE application, the Decision Tree algorithm, which operates by sequentially partitioning data based on key features, demonstrated the most significant improvement, achieving an accuracy of 81%.

The dataset was partitioned into training (70%) and testing (30%) cohorts using stratified sampling to ensure proportional representation of all therapy types in both subsets.

Model optimisation and evaluation

The classifier was trained to predict three clinically relevant outcomes: (1) the recommended diuretic regimen; (2) the probability of reducing therapy-related complications; and (3) the expected decrease in total hospital stay. For each outcome, hyperparameter tuning was performed using grid search to optimise predictive performance. Feature importance analysis was subsequently conducted to identify the most influential clinical variables.

Feature importance analysis revealed key clinical predictors influencing diuretic therapy outcomes, providing actionable insights through predictive analytics. Model selection prioritised both accuracy and clinical interpretability to ensure patient safety and effective treatment recommendations. Specifically, the classifier model utilised the following clinically relevant features to predict the optimal diuretic therapy: Total bilirubin, serum creatinine, serum potassium, serum sodium, age, MELD score and key comorbid conditions (diabetes, hypertension, oesophageal varices and portal hypertension). These variables were selected based on their established relevance to fluid balance, renal function and overall prognosis in cirrhotic patients.

Clinical interpretability was ensured by employing a Decision Tree model. This model provided transparent, rule-based logic that aligned with clinical reasoning, enabling clinicians to input patient demographics and baseline parameters and receive therapy suggestions in an intuitive, easy-to-understand format.

All statistical analyses and predictive analytics models were developed and implemented using Python, leveraging robust libraries and frameworks to ensure precision and reproducibility.

RESULTS

Challenges in standard diuretic therapy

The study identified several critical inefficiencies in traditional diuretic therapy for liver cirrhosis patients. Among the 481 participants, 71.5% did not respond adequately to initial diuretic regimens, necessitating adjustments. This process

often required multiple therapy modifications, with an average of 1.2 adjustments per patient (577 total adjustments across 481 patients), as shown in Table 1. The trial-and-error approach led to a median duration of 7–8 days to achieve optimal therapy, and hospitalisation periods averaged 12 days per patient. Key clinical parameters, such as MELD and CTP scores, highlighted the severity of liver disease among patients: 62% had a MELD score >19 and 70% were classified as Grade B or C, underscoring the need for effective therapeutic strategies.

Relationship between clinical parameters and therapy outcomes

The relationship between baseline clinical parameters and diuretic responses highlighted significant findings, underscoring diuretic insufficiency.

Parameters such as serum creatinine, INR and serum albumin demonstrated strong associations with 24-h urinary output. Serum albumin exhibited a positive correlation ($r = 0.131$, $P = 0.003$), whereas serum creatinine and INR were inversely correlated ($r = -0.156$, $P = 0.0006$; $r = -0.173$, $P = 0.0001$, respectively) [Table 2]. Conversely, age, body mass index and serum sodium levels showed no notable impact on diuretic response.

Therapy adjustments were significantly influenced by total bilirubin and serum albumin levels, as determined by Chi-square test P -values [Table 3]. Patients with elevated bilirubin levels have 11.25 times higher odds of requiring therapy modifications compared to patients with lower bilirubin levels. While those with lower serum albumin levels had a significantly reduced likelihood (odds ratio, 0.16) of therapy changes.

Outcomes of standard therapy

Patients with inadequate initial responses – inadequate response was defined as the presence of any one or more of the following criteria: Urinary output <200 mL/day despite initial diuretic therapy; development of AKI (serum creatinine ≥ 1.2 mg/dL) or occurrence of electrolyte

Table 1: Distribution of patients by number of diuretic therapy adjustments.

Number of adjustments	Number of patients	Total adjustments	Percentage
0	40	0	8.30
1	281	281	58.40
2	120	240	24.90
3	30	90	6.20
4	10	40	2.10
Total	481	577	100

Table 2: Relationship between clinical parameters and 24-h urinary output ($n=481$, Pearson correlation test).

Parameters	r-value	P-value
Age	-0.014	0.75
BMI	-0.031	0.49
Serum Sodium	-0.024	0.59
Serum potassium	0.056	0.43
Serum creatinine	-0.156	0.0006
INR	-0.173	0.0001
Total bilirubin	-0.132	0.0037
Direct bilirubin	-0.107	0.081
Serum albumin	0.131	0.003

BMI: Body mass index, INR: International normalised ratio, Significance level set at $p < 0.05$

Table 3: Association between therapy change and clinical variables ($n=481$, Chi-square test).

Variable	P-value	Odds ratio	CI 95%
Age	0.603	0.88	0.59, 1.131
BMI	0.862	1.062	0.71, 1.57
Serum sodium	0.623	0.89	0.60, 1.32
Serum potassium	0.065	1.49	1.00, 2.22
Serum albumin	0.001	0.16	0.10, 0.25
Total bilirubin	0.001	11.25	6.61, 19.16

BMI: Body mass index, CI: Confidence interval, Significance level set at $p < 0.05$

imbalances, specifically hyponatraemia (serum sodium <130 mEq/L) or hyperkalaemia (serum potassium >5.0 mEq/L), often received human albumin 20% + lasix 20 mg or lasilactone combinations as adjustments, yet the trial-and-error approach increased the burden of care. Prolonged time to stabilisation, extended hospital stays and higher complication rates were observed in patients exhibiting suboptimal response patterns to initial diuretic regimens.

Impact of data-driven optimisation

Following the development of an ML model, three clinically relevant outcomes were evaluated:

1. Prediction of the recommended diuretic regimen
2. Probability of reducing therapy-related complications (indirectly inferred through reduced therapy adjustments)
3. Expected decrease in total hospital stay (direct measure)

The ML model significantly improved therapeutic outcomes compared to traditional methods. While the traditional approach typically requires an average of 7–8 days to achieve

optimal therapy, the ML model achieved this during the initial therapy itself. On average, hospital stays decreased from 7–8 days to 3–4 days, with maximum stays reduced from 12 days to 7 days. In addition, the number of therapy changes dropped from 2 to 3 per patient to an average of 0.5 adjustments per patient.

Performance evaluation metrics are summarised in Table 4, while the confusion matrix depicting classification performance is illustrated in Figure 1. The model demonstrated precision and recall scores exceeding 80% across key therapeutic categories. Notably, prediction accuracies for human albumin + lasix and human albumin + lasilactone regimens were 81% and 87%, respectively.

A comparative analysis between predicted and actual therapy outcomes is presented in Figure 2, illustrating the model's alignment with successful therapeutic regimens while highlighting areas for refinement. Although the model was not deployed in real-time decision-making during the study period, the alignment of its recommendations with effective therapeutic regimens suggests potential for future clinical application.

DISCUSSION

Optimising diuretic therapy in liver cirrhosis remains a critical challenge due to the complex interplay of disease severity, variability in patient responses and the high prevalence of diuretic resistance.^[7,8] This study's key clinical outcomes underscore the necessity for more effective therapeutic strategies. Reducing the time to achieve optimal therapy, thereby shortening hospital stays, minimising therapy changes, lowering economic burdens and enhancing recovery, emerged as pivotal goals, driven by evidence from a cohort of 481 cirrhotic patients undergoing diuretic therapy.

The results revealed that 71.5% of patients experienced inadequate responses to initial diuretic therapy, emphasising the limitations of conventional management approaches. Clinical factors such as elevated bilirubin, low serum albumin and serum potassium levels were identified as significant predictors of poor diuretic response, consistent with earlier findings that liver dysfunction disrupts renal perfusion and sodium excretion, aggravating diuretic resistance.^[9-11] In addition, comorbidities such as diabetes, hypertension, portal hypertension and oesophageal varices were included as features during model training. These variables were encoded appropriately during preprocessing and were part of the input dataset for all tested models. These categorical variables were transformed using one-hot encoding to ensure compatibility with the ML algorithms. These factors necessitated frequent therapy adjustments, increasing the economic and clinical burden on patients.

The effectiveness of various diuretic regimens was also analysed. These included furosemide (20 mg, 40 mg),

Table 4: Summarises the performance metrics of the predictive model across various diuretic therapy adjustments. The metrics include precision, recall, F1-score, support and the AUC for the receiver operating characteristic curve, which collectively describe the model's ability to correctly classify and adjust therapy.

Class	Therapy adjustment	Precision	Recall	F1-score	Support	AUC
0	Aldactone 50 mg→Aldactone 100 mg	1	0.92	0.96	12	0.49
1	Lasix 20 mg→Lasix 40 mg	0.5	1	0.67	1	0.49
2	Lasix 20 mg	0.7	0.85	0.77	27	0.56
3	Lasilactone 20/50 mg	0.75	0.67	0.71	18	0.55
4	Lasilactone 20/50 mg BID→TID	0.83	0.62	0.71	16	0.49
5	Aldactone 50 mg→Lasilactone 20/50 mg	0.76	0.78	0.77	58	0.48
6	Lasix 20 mg+Lasilactone 20/50 mg	0.82	0.75	0.78	36	0.56
7	Lasix 20 mg→Lasilactone 20/50 mg	1	0.73	0.84	11	0.5
8	Aldactone 50 mg	0.78	0.88	0.82	56	0.46
9	Human albumin 20%+Lasix 20 mg	0.81	0.88	0.84	43	0.68
10	Human albumin 20%+Lasilactone 20/50 mg	1	0.73	0.84	11	0.66
11	Human albumin 20%	0.87	0.84	0.86	96	0.58
	Accuracy	-	-	0.81	385	-
	Macro average	0.82	0.80	0.80	385	-
	Weighted average	0.82	0.81	0.81	385	-

AUC: Area under the curve, BID: twice daily, TID: thrice daily

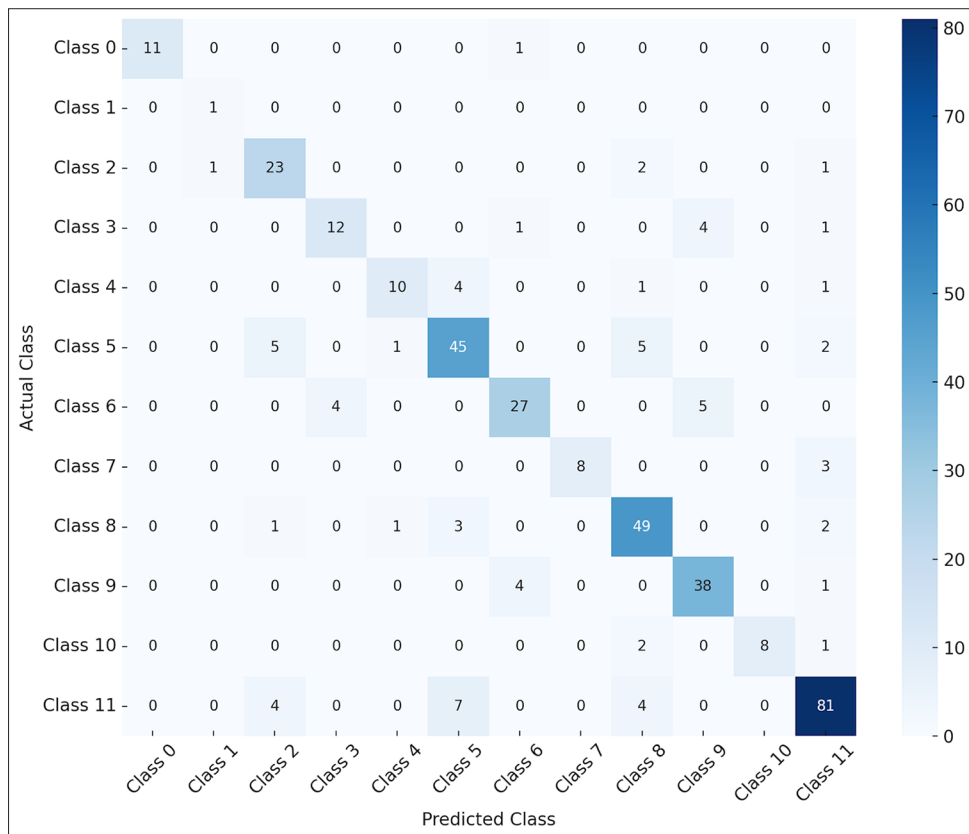


Figure 1: Presents the confusion matrix summarising the predictive performance of the model across 12 classes (Class 0–Class 11). The rows represent the actual classes, while the columns correspond to the predicted classes. The diagonal elements indicate the correct predictions made by the model for each class, while off-diagonal elements represent misclassifications.

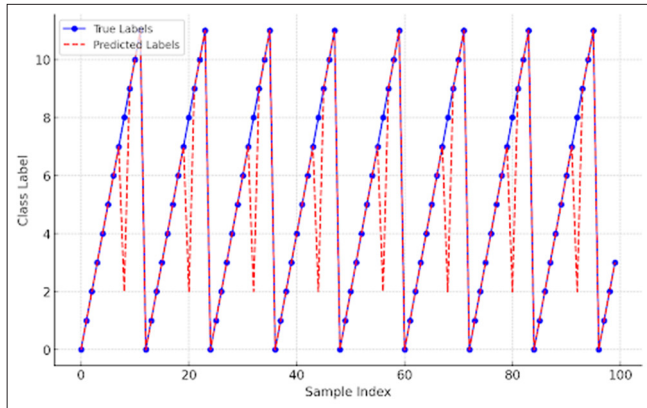


Figure 2: Illustrates the model's predictions (shown as dashed lines) closely match the actual therapies administered (represented by solid lines) across a series of sample patients. Deviations between the two lines highlight cases where the model's predictions differ from clinical decisions, indicating areas for improvement.

spironolactone (50 mg, 100 mg), lasilactone (20/50 mg BID or TID) and combination therapies such as human albumin 20% with lasix 20 mg or lasilactone 20/50 mg. Notably, human albumin monotherapy demonstrated superior outcomes in managing fluid retention. Combination therapy with albumin and furosemide showed enhanced efficacy, likely due to albumin's role in improving haemodynamic stability; however, it also introduced a higher risk of electrolyte imbalances.^[12,13] These findings reaffirm the importance of tailored therapy, as one-size-fits-all approaches often fail to address individual variability.

While the selected ML models have precedent in clinical research for predicting treatment responses and outcomes, their specific application to guide diuretic therapy decisions in cirrhosis represents a novel and clinically relevant extension. Notably, the interpretability of Decision Trees renders them particularly suitable for healthcare applications, enabling clinicians to understand the basis of each prediction.

Building upon these insights, an ML model was developed to predict optimal diuretic regimens. The model demonstrated an accuracy of 81%, effectively reducing the reliance on trial-and-error adjustments. By incorporating clinical variables such as total bilirubin and serum albumin into its decision-making process, the model provided actionable recommendations that aligned with observed outcomes. Shah *et al.* noted that decision tree-based algorithms are particularly well-suited for healthcare datasets with non-linear relationships, supporting the utility of this approach.^[14]

The model highlighted key clinical features, such as total bilirubin and serum albumin, reinforcing its relevance to real-world practice. Although not yet implemented in clinical workflows, the model demonstrated future potential to assist clinicians in selecting appropriate diuretic regimens

with minimal input, thereby simplifying and supporting individualised patient care. Ongoing work focuses on increasing data volume to enhance precision for clinical use.

This innovation led to tangible clinical benefits. Hospital stays were shortened by up to 5 days, significantly reducing healthcare costs. Fewer therapy changes minimised treatment disruptions, enhancing patient recovery. The economic burden was reduced due to shorter hospital stays and fewer treatment changes. While the exact savings may vary depending on the institution and specific circumstances, this reduction serves as a notional benefit in optimising healthcare resources.

The model's contribution to systemic healthcare efficiency parallels findings by Xu and Xu^[15] who reported that predictive ML models enhance treatment precision, resulting in shorter treatment durations and fewer complications. Similarly, Angeli *et al.*^[16] highlighted that personalised diuretic regimens reduce adverse events, further supporting the potential of this innovation to transform diuretic management in cirrhosis.

While the results demonstrate promise, this pilot model requires further development and validation. Expanding the dataset to include diverse patient populations will enhance its generalisability, while improving model interpretability will be essential for gaining clinician trust. Integration into real-world clinical workflows, supported by continuous feedback, is critical to establishing its role in routine care.

By addressing the challenges of diuretic therapy, such as improving treatment outcomes, reducing hospital stays and potentially lowering economic burdens, this study presents an initial step toward exploring precision-guided treatment for liver cirrhosis. However, it is important to note that the model's performance has been evaluated solely on test and validation datasets, and its clinical application in real-time settings remains to be explored further. While the model shows promising results, its accuracy could be enhanced with more data, and we are actively working on refining the model to improve its predictive power for future clinical applications. It highlights the transformative potential of ML in personalised medicine, offering a pathway to more effective, efficient and equitable healthcare.

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CONCLUSION

This study emphasises the challenges in managing diuretic therapy for cirrhotic patients. Key markers, including elevated bilirubin and low serum albumin, were strongly associated with the need for therapy adjustments, emphasising the

importance of tailored treatment. Addressing these issues, the findings demonstrated the potential to reduce hospital stays, minimise therapy changes and lower economic burdens through personalised approaches. Building on this evidence, an ML model was developed, achieving 81% accuracy in predicting optimal diuretic regimens by integrating clinical parameters, thereby reducing reliance on trial-and-error methods. While the model requires further validation across diverse populations, its integration with clinical expertise could transform cirrhotic ascites management, enhancing recovery and optimising healthcare resources. This work paves the way for precision-driven care and improved outcomes in chronic disease management.

Ethical approval: The research/study was approved by the Institutional Review Board at PSG IMSR IHEC, approval number 24/020, dated 3rd April 2024.

Declaration of patient consent: The authors certify that they have obtained appropriate ethical clearance for this study. As this was a retrospective chart review, the Institutional Ethics Committee granted a waiver of patient consent.

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Conflicts of interest: There are no conflicts of interest.

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