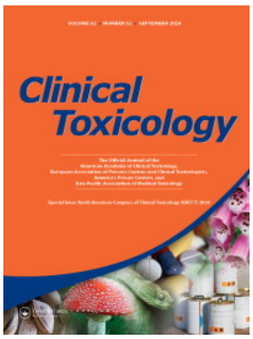

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CLINICAL RESEARCH

Predictors of prolonged supratherapeutic serum lithium concentrations: a retrospective chart review

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ABSTRACT

Introduction: The Extracorporeal Treatments in Poisoning (EXTRIP) workgroup suggests hemodialysis in severe lithium poisoning if specific criteria are met. One criterion is if the expected time to obtain a lithium concentration <1.0 mEq/L with optimal management is >36 h. There are a lack of data regarding which patient characteristics are associated with the rate at which patients achieve a lithium concentration <1.0 mEq/L.

Methods: We conducted a retrospective chart review analyzing hospital electronic medical records. Inclusion criteria consisted of a lithium concentration >1.2 mEq/L during hospitalization. We excluded patients who received extracorporeal treatment before 36 h elapsed from time of initial lithium concentration >1.2 mEq/L. The primary analysis consisted of a Cox regression and a secondary analysis evaluated the nomogram method described by Buckley and colleagues for predicting prolonged supratherapeutic lithium concentration.

Results: One hundred and one patients were included in the study. The median time to reach a lithium concentration <1.0 mEq/L was 42.5 h (IQR: 33.8–51.1). Older patients, patients taking a thiazide, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, patients with a higher initial lithium concentration, and patients with higher sodium concentrations achieved a lithium concentration <1 mEq/L at a slower rate. For the nomogram analysis, sensitivity (61.5%) and specificity (54.5%) were moderate, the positive predictive value (16.7%) was poor, and the negative predictive value (90.6%) was excellent.

Discussion: The results from our primary analysis suggest that identifying higher serum sodium concentration and use of certain antihypertensives that decrease glomerular filtration rate as predictors of an increased time to reach a therapeutic lithium concentration may help identify patients who meet the Extracorporeal Treatments in Poisoning criteria for hemodialysis. The nomogram method performed similarly to prior validation studies.

Conclusions: In this retrospective chart review of patients with supratherapeutic lithium concentrations, we identified several risk factors for prolonged supratherapeutic lithium concentrations.

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Antihypertensive agents; clinical decision rules; extracorporeal treatment; lithium; syndrome of irreversible lithium-effectuated neurotoxicity (SILENT)

Introduction

Lithium is a mood stabilizer that has long been used to treat bipolar disorder. It is an effective medication for treating this disease but has the potential for adverse effects in overdose. Lithium has a narrow therapeutic window (0.6–1.2 mEq/L), increasing the risk for toxicity in the setting of overdose or the unanticipated development of other factors, such as kidney dysfunction leading to decreased lithium clearance [1]. There are various treatment options for patients with lithium toxicity, ranging from intravenous fluid repletion to extracorporeal treatment.

The Extracorporeal Treatments in Poisoning (EXTRIP) workgroup has suggested the use of extracorporeal removal of lithium in severe poisoning if specific criteria are met. One of these suggested criteria is if the expected time to obtain a lithium concentration <1.0 mEq/L with optimal management is >36 h [2].

There was a lack of data regarding which variables in this scenario predict which patients will benefit from prompt extracorporeal treatment and which will achieve a serum lithium concentration <1.0 mEq/L within 36 h with more conservative treatment modalities. The publication of the EXTRIP guidelines spurred various centers to publish their own retrospective data and decision rules [3–5]. Buckley and colleagues [3] developed a nomogram using estimated glomerular filtration rate (eGFR) and initial lithium concentration to predict the rate of fall of lithium concentration after acute-on-chronic poisoning and chronic lithium toxicity. Other authors subsequently used retrospective data to validate the nomogram with varying results [6,7]. Sam and colleagues [8] performed a retrospective review to validate the

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nomogram developed by Buckley and colleagues [3] and found it was moderately sensitive at identifying patients with chronic lithium toxicity who will have a lithium concentration >1 mEq/L at 36 h without extracorporeal treatment. However there has been a lack of data beyond these validation studies analyzing whether other variables besides eGFR and initial lithium concentration could be used to predict which patients will have a prolonged time to reach a lithium concentration <1 mEq/L. In addition, others have highlighted the inherent limitations in using the static variable of single time point estimate of eGFR to predict clinical outcomes in a dynamic process [9].

The primary aim of this study is to identify factors beyond eGFR and initial lithium concentration that are associated with a prolonged time for such patients to achieve a lithium concentration <1 mEq/L. Secondary aims include externally validating the nomogram developed by Buckley and colleagues [3].

Materials and methods

Study design and methods

We conducted an Institutional Review Board approved retrospective study analyzing electronic medical records from three academic hospital systems within the call area of our poison center from January 2010 to December of 2021. Lithium cases were identified by querying our poison center data base for patients with exposure to lithium (America's Poison Centers generic code 101000) cared for at these hospitals.

Inclusion criteria consisted of patients of any age treated within one of three academic hospital systems with a lithium concentration >1.2 mEq/L at any time during hospitalization for which the poison center was consulted. Patients who received extracorporeal treatment (e.g., hemodialysis, continuous kidney replacement therapy) within 36 h of an initial lithium concentration >1.2 mEq/L were excluded.

Patient data including demographics (age, gender, weight, and height), history regarding the lithium exposure including single versus multiple substance ingestion, acuity of exposure to lithium (acute, acute-on-chronic, or chronic), and the formulation of lithium (immediate or sustained release) were collected. Prescribed outpatient medications including nonsteroidal anti-inflammatory drugs, thiazides, angiotensin-converting enzyme inhibitors and angiotensin receptor blockers, were abstracted by reviewing documentation of prescribed outpatient medications. Additional outcome measures collected included initial and subsequent lithium concentration during hospitalization, and initial serum concentrations of creatinine and sodium. Clinical outcomes included length of inpatient stay, disposition from the emergency department visit, and therapies performed (intravenous fluids, extracorporeal treatment after 36 h, plasma exchange, and whole bowel irrigation). If the patient had a follow up visit after discharge in the electronic medical record, the record was evaluated for any documentation suggestive of the syndrome of irreversible lithium-effectuated neurotoxicity (SILENT).

Two non-blinded reviewers (SA, ZI) abstracted data independently. Cases were first identified by reviewing the poison center electronic medical record for exposures including lithium at hospitals in the study. Reviewers then queried individual hospital electronic medical record for data extraction. Interrater reliability was computed using Krippendorff's alpha.

We defined acute ingestion, acute-on-chronic ingestion, and chronic ingestion in a manner consistent with the described literature and prior studies [3,8]. For this retrospective chart review, SILENT was defined as a persistent sequelae of lithium toxicity lasting for at least 2 months after the lithium was discontinued based on the description of SILENT in the available literature, which included symptoms of cerebellar dysfunction (e.g., ataxia), or other known neurologic sequelae of lithium toxicity [10].

Statistical methods

Patient characteristics were described using frequencies and percentages for categorical variables, and medians and interquartile ranges for continuous variables. There were two sets of analyses for the present study. The primary analysis focused on identifying predictors of the rate at which the lithium concentration reached 1 mEq/L or lower. A secondary analysis aimed to evaluate the nomogram decision tool developed by Buckley and colleagues [3].

Time-to-event methods were used to evaluate predictors of reaching a lithium concentration of 1 mEq/L within 36 h. A Cox regression was used to estimate hazard ratios (HR) and 95% confidence intervals (CI). Independent variables were chosen a priori and included: age, gender, weight (in kg), whether multiple substances were involved, the chronicity of the exposure (acute, chronic, acute-on-chronic), the formulation of lithium (immediate versus sustained release), initial lithium concentration, initial sodium concentrations, initial creatinine concentrations, whether whole bowel irrigation was performed, and whether the patient was taking thiazides, nonsteroidal anti-inflammatory drugs, angiotensin-converting enzyme inhibitors, or angiotensin receptor blockers. Whether the patient received intravenous fluids, whether they received extracorporeal treatment after 36 h, and whether they received a plasma exchange were also considered. However, the sample percentages were either 100% or 0% for those variables. An initial evaluation of the Schoenfeld residuals determined that the data were consistent with the proportional hazards assumption. As a sensitivity analysis, we also evaluated eGFR as a potential predictor.

For the nomogram, we calculated eGFR values using serum creatinine concentrations in accordance with the 2021 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula that does not include race [11]. For pediatric patients (age <18 years) we used the Revised Schwartz Equation which incorporates serum creatinine and patient height [12]. We then plotted each patient and stratified them based on their standing relative to the nomogram. To evaluate the performance of the nomogram, we used a 2×2 contingency table to estimate sensitivity, specificity, positive

predictive value (PPV), and negative predictive value (NPV), as well as 95% CI for each estimate. We conducted the same analysis for the full sample as well as for acute, acute-on-chronic, and chronic patients separately. Because prior research has found that the nomogram is most relevant to chronic exposures, we present those findings in our main results [6,8]. The findings for other patients, as well as additional details, can be found in the supplemental materials. Analyses were conducted using R (v4.2; R Core Team).

Results

Sample characteristics

Two-hundred and ninety-four charts were initially identified. One-hundred and seventeen were excluded because each recorded lithium concentration was <1.2 mEq/L, 24 were excluded because they received extracorporeal treatment within 36 h, 16 were excluded because they were redundant with other poison center charts, and 36 were not able to be located within the hospital electronic medical record. The remaining 101 encounters were included in the present study as shown in Figure 1. Baseline patient characteristics are presented in Table 1. The median age was 37 years, and the majority of the patients were female (69.3%). The majority of patients ingested a single substance (56.4%) in an immediate release form (50.4%). The most common type of lithium exposure was chronic (49.5%), followed by acute-on-chronic (43.6%), and acute (6.9%) exposures. The majority of patients were admitted to the medical floor (64.4%). The median initial lithium concentration was 2.1 mEq/L (interquartile range [IQR]: 1.8–2.7 mEq/L) and the median eGFR was 91.5 mL/min/m^2 (IQR: 57.5–119.3 mL/min/m^2). Figure 2 presents the change in lithium concentration over time for each patient. All patients had at least two recorded lithium concentrations.

Predictors of the rate of recovery

The Kaplan-Meier curve representing time to lithium concentration <1 mEq/L is presented in Figure 3. The median time was 42.5 h (IQR: 33.8 – 51.1 h). Cox regression analyses are presented in Table 2. Older patients, patients taking a thiazide, an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, patients with a higher initial lithium concentration, and patients with higher initial sodium concentrations all achieved a lithium concentration <1 mEq/L at a slower rate. Patients taking a nonsteroidal anti-inflammatory drug achieved a lithium concentration <1 mEq/L at a faster rate. Gender, weight, multiple versus single substances, chronicity, formulation, initial creatinine concentration, and the use of whole bowel irrigation, were not associated with time to achieving a lithium concentration <1 mEq/L.

Sensitivity analysis including eGFR

Because eGFR is computed using serum creatinine concentration, age, and sex, it is limited with respect to adding unique information in a regression which includes those constituent variables. Thus, we did not include eGFR in this analysis. We conducted a separate sensitivity analysis in which the constituent variables of serum creatinine concentration, age, and sex are replaced by eGFR (Supplemental Table 1) and found that as with the main analysis presented in Table 2, patients taking a thiazide, an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, patients with a higher lithium concentration, and patients with higher sodium concentrations all achieved a lithium concentration <1 mEq/L at a slower rate. In contrast to the main analysis, when constituent variables were replaced by eGFR, patients who had undergone whole bowel irrigation achieved a lithium concentration <1 mEq/L at a faster rate. Thus, we consider the evidence with respect to whole

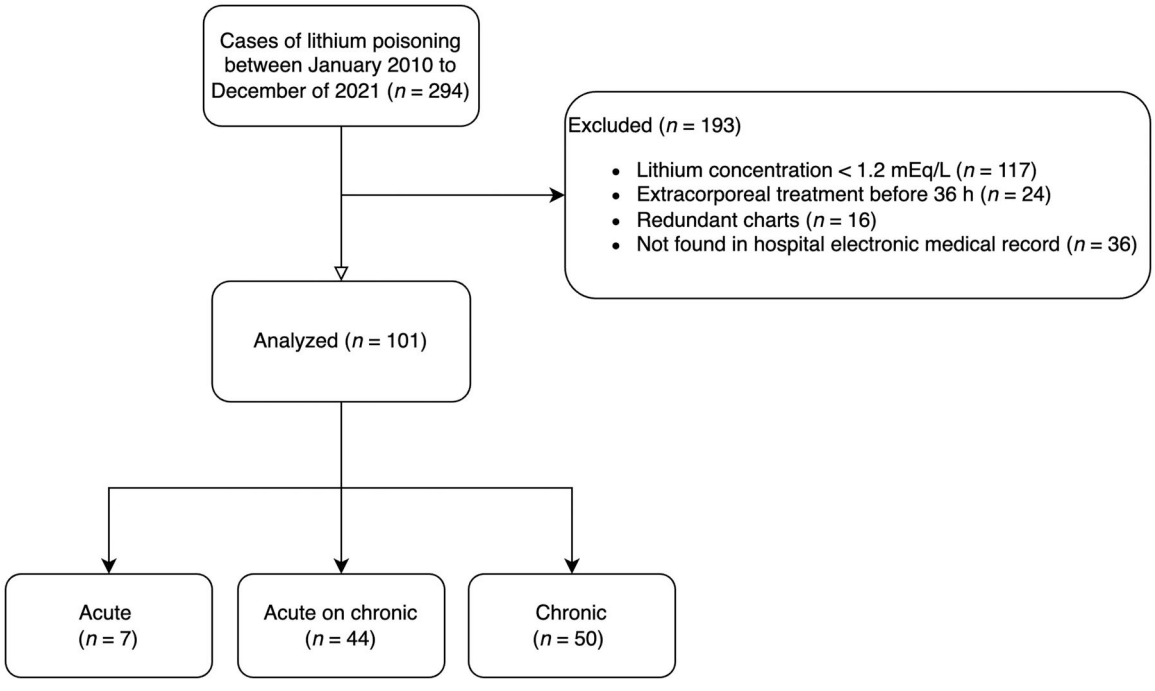

Figure 1. Flowchart for study inclusion and exclusion.

Table 1. Baseline characteristics of 101 patients meeting inclusion criteria.

Characteristic	Result
Total	
Age (years), median (IQR)	37 (17 – 52.5)
Gender, *n* (%)	
Male	31 (30.7)
Female	70 (69.3)
Weight (kg), median (IQR)	78.1 (65.0 – 90.5)
Initial lithium concentration (mEq/L), median (IQR)	2.1 (1.8 – 2.7)
Initial creatinine concentration (mg/dL), median (IQR)	0.92 (0.76 – 1.3)
Initial creatinine concentration (μmol/L), median (IQR)	81.3 (67.2 – 114.9)
Initial sodium concentration (mEq/L), median (IQR)	137 (135–139)
Thiazide, *n* (%)	9 (9)
Nonsteroidal anti-inflammatory drug, *n* (%)	11 (10.9)
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, *n* (%)	18 (17.8)
Multiple substances, *n* (%)	44 (43.6)
Formulation, *n* (%)	
Immediate release	61 (50.4)
Sustained release	40 (39.6)
Chronicity, *n* (%)	
Acute	7 (6.9)
Acute-on-chronic	44 (43.6)
Chronic	50 (49.5)
Estimated glomerular filtration rate (eGFR) (mL/min/m^2), median (IQR)	91.5 (57.5 – 119.3)
Whole bowel irrigation, *n* (%)	6 (5.9)
Clinical outcome, *n* (%)	
Admitted to medical floor	65 (64.4)
Left against medical advice	2 (2)
Discharged	9 (8.9)
Admitted to intensive care unit	23 (22.8)
Observation	2 (2)

IQR: interquartile range.

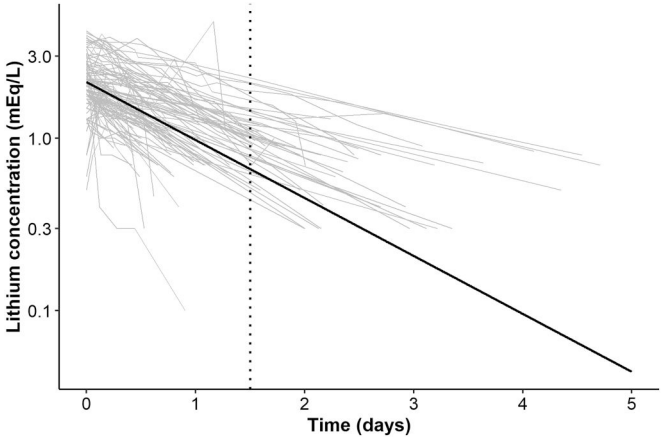

Figure 2. Spaghetti plot depicting the change in lithium concentration over time. The grey lines depict individual patients; the black line depicts the average rate of decrease from the model. The vertical black dotted line is placed at 36 h. The *y*-axis is logarithmic.

bowel irrigation equivocal and in need of additional research. With respect to eGFR, higher eGFR values were associated with achieving a lithium concentration <1 mEq/L at a faster rate.

Evaluation of the nomogram

The nomograms for the full sample, as well as stratified by exposure type, are presented in Figure 4. Nomogram results for chronic patients are presented in Table 3. Five chronic patients were correctly identified as having lithium concentrations ≥1 mEq/L at 36 h and 18 patients were correctly identified as having lithium concentrations <1 mEq/L at 36 h. Thus, the sensitivity and specificity values were 83.3% and 40.9%, respectively. The positive and negative predictive values were 16.1% and 94.7%, respectively.

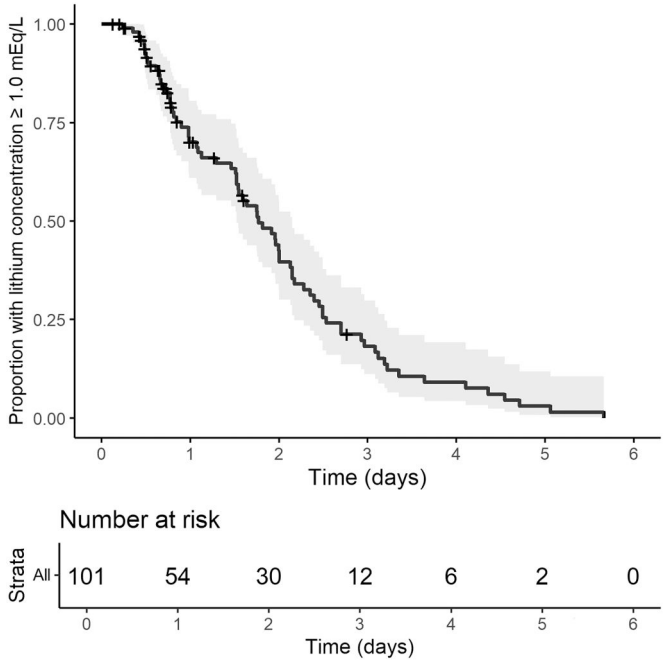

Figure 3. Kaplan-Meier Curve depicting the rate of reaching 1 mEq/L over time. The grey shaded area is the 95% confidence interval.

Additional details and results, including those for acute and acute-on-chronic exposures, are included in the supplemental materials.

Incidence of long-term neurological sequelae

Chart review for SILENT was limited because the majority of patients (57 patients, 56%) did not have any documented

Table 2. Cox regression results.

Predictor	Hazard ratio	95% CI	*P* Value
Age (years)	0.96	0.94 – 0.98	<0.001
Gender			
Male	Reference	–	–
Female	1.49	0.79 – 2.81	0.22
Weight (kg)	0.99	0.98 – 1.01	0.70
Multiple substances	0.83	0.48 – 1.45	0.52
Thiazide	0.32	0.12 – 0.86	0.024
Nonsteroidal anti-inflammatory drug	3.62	1.22 – 10.80	0.021
Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker	0.34	0.13 – 0.88	0.027
Chronicity			
Acute	Reference	–	–
Acute-on-chronic	2.07	0.48 – 8.92	0.33
Chronic	1.17	0.57 – 2.41	0.67
Formulation			
Immediate release	Reference	–	–
Sustained release	0.65	0.33 – 1.28	0.21
Initial lithium concentration (mEq/L)	0.59	0.40 – 0.85	0.004
Initial sodium (mEq/L)	0.87	0.77 – 0.98	0.026
Whole bowel irrigation	2.13	0.74 – 6.16	0.16
Initial creatinine concentration (mg/dL)	0.79	0.59 – 1.04	0.09
Initial creatinine concentration (μmol/L)	69.8	52.2 – 91.9	0.09

follow-up visits. We identified one patient who possibly developed SILENT, a man in his 50s with chronic lithium toxicity. His initial lithium concentration was 2.2 mEq/L and his last supratherapeutic lithium concentration was 1.3 mEq/L approximately 24 h after the first lithium concentration was drawn. He had an acute kidney injury with a serum creatinine concentration of 1.8 mg/dL (159.1 μmol/L) from a baseline creatinine of 1.1 mg/dL (97.2 μmol/L); he received intravenous fluids. At an outpatient follow-up visit 4 months after discharge, he had persistent ataxia and dizziness that started after his hospitalization.

Discussion

Our analysis of a retrospective sample of patients with elevated lithium concentration who did not receive extracorporeal treatment within 36 h shows that older patients, patients taking a thiazide, an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and patients with higher sodium concentrations all achieve lithium concentration <1 mEq/L at a slower rate. Our data demonstrate that patients with a higher initial lithium concentration achieve a lithium concentrations <1 mEq/L at a slower rate. While increased age and a higher initial lithium concentration are rather intuitive and well understood risk factors for lithium toxicity, this does provide new data for incorporating concurrent medications into clinical decision making as there was an independent effect observed outside of acute kidney injury.

Therefore, we suggest that identifying higher serum sodium concentration, use of angiotensin-converting enzyme inhibitors or angiotensin receptor blockers, and thiazides as predictors of an increased time to reach a therapeutic lithium concentration may help identify patients who would most benefit from prompt extracorporeal treatment.

Interestingly patients taking nonsteroidal anti-inflammatory drugs reached a lithium concentration <1 mEq/L at a faster rate. This finding is rather counterintuitive as medications such as nonsteroidal anti-inflammatory drugs cause constriction of the afferent arteriole, which should cause a slower rate to reach a therapeutic lithium concentration. With only 11 patients out of 101 recorded as taking a nonsteroidal anti-inflammatory drug, there is a wide confidence interval associated with this finding (HR 3.62, 95% CI 1.22–10.80).

Our data showed findings consistent with Sam and colleagues [8] and others when using our data to assess the performance of the nomogram by Buckley and colleagues [3]. Sensitivity was highest in patients with chronic lithium toxicity (83.3%) as opposed to acute-on-chronic cases (20%). However, the specificity and positive predictive value continue to be relatively poor across all groups (54.5% and 16.7% respectively for the full sample). This suggests that the nomogram has an important but limited role in identifying low-risk patients, but that it may not be the appropriate tool to identify patients who will have a higher lithium concentration at 36 h, and therefore may benefit from receiving prompt extracorporeal treatment.

We recognize that in addition to not being the first to validate the nomogram developed by Buckley and colleagues [3], we are also not the first to add to the validation study performed by Sam and colleagues [8]. In a letter to the editor, Mahonski and colleagues [13] pooled their retrospective data with data from Sam and colleagues [8] which showed a cumulative sensitivity of 80%, specificity of 54%, negative predictive value of 75% and positive predictive value of 61%. These trends are similar to our chronic toxicity group as shown in Table 3. We have included a contingency table in the supplemental materials which compiles our data for our chronic toxicity patients with pool data from Mahonksi and colleagues [13] (Supplemental Table 6).

Limitations

Outside of the inherent limitations in a retrospective chart review [14], we want to highlight several important limitations in our study. Our study is limited with respect to chart review methodology because our reviewers (SA, ZI) were unblinded and each chart was only abstracted individually. However, a crossover sample was performed to test

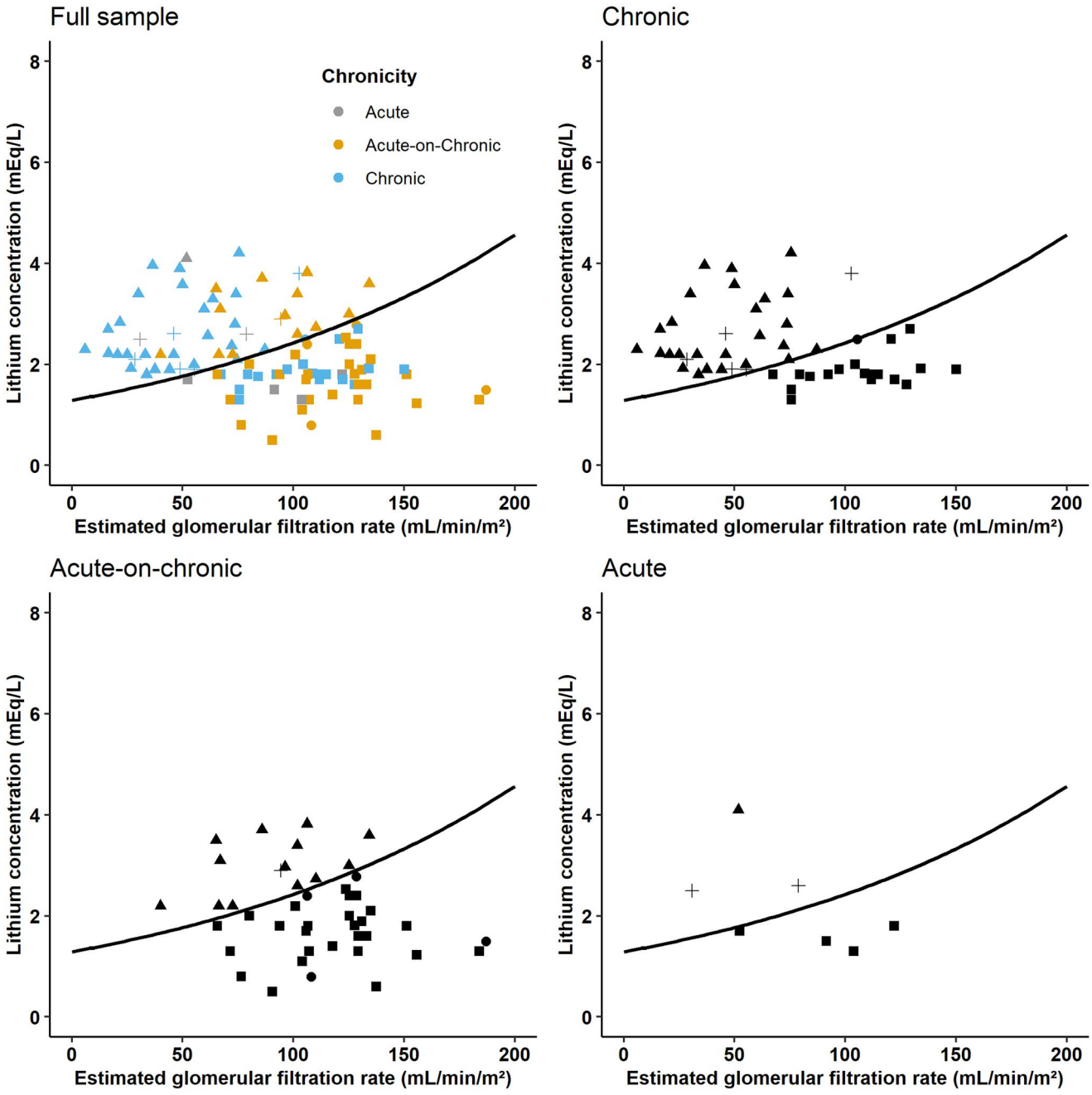

Figure 4. Nomograms stratified by the type of exposure. Legend: ●: false negative, ▲: false positive, ■: true negative, + true positive.

Table 3. Contingency table for nomogram predictions: chronic patients.

	Actual 36 h lithium concentration ≥1 mEq/L	Actual 36 h lithium concentration <1 mEq/L	
Predicted 36 h lithium concentration ≥1 mEq/L	5	26	PPV: 16.1 (95% CI: 7.1–32.6)
Predicted 36 h lithium concentration <1 mEq/L	1	18	NPV: 94.7 (95% CI: 75.4–99.1)
	Sensitivity: 83.3 (95% CI: 43.6–97.0)	Specificity: 40.9 (95% CI: 27.7–55.6)	

PPV: positive predictive value; NPV: negative predictive value.

interrater reliability using Krippendorff's alpha and the mean and median interrater reliability for the main study variables were 0.80 and 0.97, respectively.

We excluded patients who received any kind of extracorporeal treatment before 36 h had elapsed. Twenty-four patients were excluded out of the initial 294 charts for receiving extracorporeal treatment before 36 h. However, in our remaining 101 patients, none of them received extracorporeal treatment after 36 h. This limits our ability to make recommendations on which patients would most benefit from this therapy.

With respect to abstracting concurrently prescribed medications (thiazides, nonsteroidal anti-inflammatory drugs, angiotensin-converting enzyme inhibitors, and angiotensin

receptor blockers) the reviewers relied only on documented outpatient medications during the patient encounter and did not obtain objective biologic specimens (i.e., drug concentrations) or patients' subjective reports to confirm the patient was taking the medication as prescribed.

We were limited in our ability to identify SILENT because of a general lack of follow-up data, identifying only one suspect case. It remains challenging to provide further data retrospectively on which patients are most at risk of SILENT and would benefit most from extracorporeal treatment as there are a lack of robust data in the existing literature

Finally, regarding our attempt to validate the nomogram by Buckley and colleagues [3] and compare it to similar validation studies such as the one by Sam and colleagues [8], we used the 2021 Chronic Kidney Disease Epidemiology Collaboration formula for calculating eGFR, which does not include patient race [11]. We also included pediatric patients (age <18 years) using a different formula for eGFR that incorporates height [12]. Twenty-seven out of the 101 patients included were in this pediatric age group.

Conclusions

In this retrospective chart review of patients with supratherapeutic lithium concentrations, several risk factors for prolonged supratherapeutic lithium concentrations were identified. Older patients, patients taking a thiazide, patients taking an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, patients with a higher initial lithium concentration, and patients with higher sodium concentrations all achieved a lithium concentration <1 mEq/L at a slower rate. The estimated mean and median times to achieving lithium concentration goals exceeded 36 h. Finally, the nomogram proposed by Buckley and colleagues [3] performed best with regards to negative predictive value and sensitivity in the overall group and had relatively better performance in patients with chronic lithium toxicity as opposed to acute-on-chronic overdoses in a manner consistent with prior validation studies.

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Data availability statement

The data that support the findings of this study are available from the corresponding author, (SA), upon reasonable request.

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