Received: 26 October 2020 | Revised: 2 February 2021 | Accepted: 8 February 2021

DOI: 10.1111/bcp.14802

ORIGINAL ARTICLE

Comparison of the EXtracorporeal TReatments In Poisoning (EXTRIP) and Paris criteria for neurotoxicity in lithium poisoned patients

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Aims: Two guidelines for haemodialysis in lithium poisoning, one from the Extracorporeal TReatments in Poisoning (EXTRIP) workgroup and a single centre retrospective one (Paris) differ. We compared outcomes in lithium poisoning based on these criteria with a primary outcome of worsening neurological symptoms in patients for whom EXTRIP and Paris criteria were discordant.

Methods: Poison centre data were queried for lithium poisoned patients for whom haemodialysis was either recommended or performed. Patients were categorized according to EXTRIP and Paris criteria and excluded if the peak lithium concentration was <1.2 mmol/L or if neurological follow-up was unavailable. Comparative analyses were only performed when both criteria could be assessed.

Results: In total, 219 patients were analysed. Paris criteria were met in 70 and EXTRIP criteria in 178. Forty two patients were excluded because Paris criteria could not be evaluated. When Paris and EXTRIP both supported haemodialysis, 50/57 (88%) of patients who received haemodialysis improved, as did all 3 who did not receive haemodialysis. When Paris and EXTRIP did not support haemodialysis, all nondialysed patients did well. Among the 86 patients for whom EXTRIP supported haemodialysis but Paris did not, 4/19 (21%) patients not dialysed deteriorated (P = .02; odds ratio = 8.7, 95% confidence interval = 1.5–51.8), 1 of whom died. All 8 patients for whom Paris criteria supported haemodialysis but EXTRIP did not were dialysed and improved.

Conclusions: When the EXTRIP and Paris criteria are discordant, EXTRIP criteria outperforms the Paris criteria at identifying potentially ill patients who might benefit from haemodialysis.

KEYWORDS
extracorporeal treatment, haemodialysis, lithium, poisoning

All authors have made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; have been involved in drafting the manuscript or revising it critically for important intellectual content; and give final approval of the version to be published.

The authors confirm that the PI for this paper is Dr Robert S. Hoffman. No interventions were performed with human subjects/patients nor were substances administered to human subjects/patients. This study was deemed exempt from comprehensive review by the NYC DOHMH IRB.

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy/ethical restrictions.

1 | INTRODUCTION

Lithium first saw clinical use as a means to reduce uric acid concentrations in patients with gout. The mood-altering effects of lithium led internist Alfred Baring Garrod to erroneously infer the presence of *brain gout* in 1859. In 1871, William Hammond first described the use of lithium for mania, but widespread adoption did not follow until the mid-20th century.[1]

Despite having decades of proof as an effective treatment for bipolar disorders, lithium use is hampered by a narrow therapeutic index, and toxicity is common. The manifestations of toxicity vary based on acuity of exposure, with gastrointestinal manifestations predominating in acute overdose and neurological manifestations in chronic accumulation, either by over medication or reduced elimination. Following lithium toxicity, some patients develop prolonged or permanent neurological sequelae, known as the Syndrome of Irreversible Lithium-Effectuated Neurotoxicity (SILENT), which spans a spectrum of neurological symptoms from mild tremors to debilitating cognitive and motor impairments.[2] While the risks for the development of long-term sequelae are not well characterized, there is an association between the duration of elevated serum lithium concentrations (reflecting a high central nervous system lithium concentration) and an increased likelihood of serious or prolonged symptoms.[3] It follows that expeditious removal of lithium from the body may limit long-term toxicity.

Lithium is well suited for removal by haemodialysis. It is a small molecule, with minimal protein binding and a volume of distribution of 0.7–0.9 L/kg.[4] While it is undisputed that haemodialysis removes lithium, the clinical efficacy of haemodialysis has not been definitively established by well-designed randomized controlled trials. As such, identifying patients likely to benefit from haemodialysis is challenging. The EXtracorporeal TReatments In Poisoning (EXTRIP) Workgroup published a systematic review of the literature in 2015 and established expert consensus guidelines on the use of haemodialysis in lithium poisoning. Despite expert consensus, all suggestions and recommendations were based on very low levels of evidence.[5] The EXTRIP guidelines have never been prospectively externally validated.

Seeking to hone these guidelines with the aim of reducing potentially unnecessary treatments, a retrospective analysis of 128 intensive care unit patients with lithium toxicity identified a lithium concentration ([Li]) ≥5.2 mmol/L or creatinine ≥200 μmol/L as indicators for haemodialysis.[6] On a subsequent analysis, these Paris criteria were applied retrospectively to the same cohort and compared to EXTRIP criteria. For each set of criteria, neurological status at intensive care unit discharge was compared between patients who met the criteria and underwent extracorporeal treatment (ECTR) and those who met the criteria but did not undergo ECTR.[7] The authors concluded that the application of Paris criteria led to a statistical difference in outcome in the primary analysis, and that application of the EXTRIP criteria leads to ECTR in more patients than is necessary. Interpretation of these results is hampered by the inherent circular nature of using the same date to both develop and validate a decision rule, and the fact that the authors modified the EXTRIP criteria.

What is already known about this subject

- The indications for haemodialysis in lithium poisoned patients are not established based on randomized controlled trials. The EXtracorporeal TReatments In Poisoning (EXTRIP) and Paris criteria provide clinically useful guidance but differ in some aspects. Neither have been externally validated.

What this study adds

- When Paris and EXTRIP criteria both support haemodialysis, outcomes were similar in dialysed patients.
- When Paris and EXTRIP criteria both did not support haemodialysis, outcomes were similar in nondialysed patients.
- When haemodialysis was supported by EXTRIP criteria but not Paris criteria and patients were not dialysed, outcomes were worse, including 1 death.

To our knowledge, neither EXTRIP nor Paris criteria have been independently validated or compared. In this study, we applied both EXTRIP and Paris criteria retrospectively to a cohort of patients in a poison centre database to determine if differences in neurological outcomes were significant in cases in which these criteria were discordant. Rather than an independent validation of either set of criteria, we present this comparative analysis on a cohort of patients for whom the criteria are most likely to be applied.

2 | METHODS

The New York City Poison Control Center (PCC) provides toxicology consultation services to a population of approximately 12 million people. It maintains an electronic database of all cases dating back to 1 January 2000. Cases are coded for basic demographics, acuity, clinical effects, the treatments recommended and provided, and medical outcome, all using standardized fields in Toxicall (Computer Automated Systems, Aurora Colorado) and in accordance with case definitions created by the American Association of Poison Control Centers. Case records also include a free-text narrative that describes the clinical course and additional diagnostic studies. By routine, these narratives are updated until the patient's clinical course plateaus, the patient is discharged, or the patient is transferred to psychiatric care. We performed a structured query language search for all cases of human lithium poisoning in which haemodialysis was coded as

recommended and/or *performed*. It is important to note that if the poison centre was consulted regarding the indications for haemodialysis, the decision was made by the on-call consultant. After 2015, the EXTRIP criteria may or may not have been applied by the individual consultants but were never formally adopted as a poison centre protocol.

The study protocol was reviewed by our IRB and deemed exempt from comprehensive review due to absence of potential harm to research subjects. The database was searched from its inception (1 January 2000) to 24 May 2020. Cases were then manually reviewed by 1 of 2 authors (P.D., E.F.), and data were extracted using a predetermined form. Data were collected and managed using REDCap electronic data capture tools.[8,9] The data collection form was piloted and reviewed, coding rules for subjective variables were agreed upon by abstractors a priori. Abstractors were not blinded to study objectives. Cases met inclusion criteria if there was a documented Li concentration >1.2 mmol/L and new neurological symptoms were recorded.

For each case record, the following information was collected: date; age; sex; initial and peak [Li] if multiple concentrations were provided; acuity; coingestions; presence or absence of neurological symptoms, dysrhythmias, seizures, coma, or confusion; creatinine if provided; whether there was a either a documented [Li] >1 mmol/L after 36 hours or a documented [Li] <1 mmol/L before 36 hours; haemodialysis recommendations and additional treatments or gastrointestinal decontamination including intravenous fluids, activated charcoal and whole bowel irrigation; whether or not of haemodialysis was performed; and medical outcome, graded as resolved, improved, unchanged, worsened or not reassessed. Cases were classified as *worsened* for any mention in the narrative of worsening or progressing of confusion/neurological symptoms, or decreased level of consciousness as compared to time of presentation. For cases in which the coded data conflicted with the narrative account, the narrative account was taken as authoritative.

Cases were then evaluated to determine if they met criteria established by the EXTRIP workgroup sufficient to *suggest* or *recommend* haemodialysis and whether or not they met Paris criteria (Table 1). Calculations of the estimated glomerular filtration rate estimated glomerular filtration rate by the Chronic Kidney Disease Epidemiology Collaboration formula were not adjusted for race, as race is not routinely collected in our database. Predicted [Li] at 36 hours after presentation was determined to be a subjective variable not coded or routinely collected in our database, and thus was not used to make determinations of EXTRIP criteria applicability.

2.1 | Statistical analysis

Cases were included in comparative analyses (i.e. analysis of findings when criteria were concordant or discordant) only when data were sufficient to assess both Paris and EXTRIP criteria. Direct comparisons were performed by Fisher's exact test. Odds ratios were calculated for risk of clinical deterioration (death or worsening neurological status) if the patient did *not* undergo haemodialysis.

TABLE 1 The extracorporeal treatments in poisoning (EXTRIP) and Paris criteria for haemodialysis and lithium poisoning

EXTRIP	Paris
Haemodialysis recommended • [Li] >4.0 mmol/L with impaired kidney function ◦ estimated glomerular filtration rate of >45 mL/min/1.73m^2 or ◦ kidney disease improving global outcomes stage 2 or 3 acute kidney injury or ◦ if no known baseline, serum creatinine of ≥177 μmol/L in adults or ≥133 μmol/L in patients aged ≥65 y, or >2× times the upper limit of normal for age and sex in children • decreased consciousness, seizures or dysrhythmias	Extracorporeal treatment indicated if: • [Li] ≥5.2 mmol/L or • serum creatinine ≥200 μmol/L
Haemodialysis suggested • [Li] >5.0 mmol/L • confusion is present • expected time to obtain [Li] <1.0 mmol/L is >36 h	

2.2 | Nomenclature of Targets and Ligands

Key protein targets and ligands in this article are hyperlinked to corresponding entries in. http://www.guidetopharmacology.org, and are permanently archived in the Concise Guide to. PHARMACOLOGY 2019/20.[10]

3 | RESULTS

From over 2 000 000 cases in the database, 3541 lithium cases originated from health-care facilities, 347 had haemodialysis recommended or performed, and 298 recorded both a supratherapeutic [Li] and new neurological symptoms. Following exclusion for incomplete data, 219 patients were analysed (Table 2). The Paris criteria for haemodialysis were met in 70 patients, while 1 or both EXTRIP criteria for haemodialysis were met in 178 patients (78 *recommended*; 146 *suggested*). Forty-two patients were excluded from the comparison because data were insufficient to evaluate the Paris criteria (see Figure 1).

The 70 patients who met PARIS criteria for haemodialysis are shown in Tables 3-5. Three deteriorations (all of whom died) occurred among the 65 patients who had haemodialysis. No deteriorations occurred in the 5 patients who did not have haemodialysis. Statistical analysis was not performed because no events occurred in 1 cell. In total, 107 patients did not meet Paris criteria for haemodialysis. Deteriorations occurred in 2/83 patients (2.4%) dialysed as opposed to 4/24 patients (16.6%) not dialysed (P = .022). The odds ratio (OR) of deterioration for patients who did not meet PARIS criteria for haemodialysis and were not dialysed was 8.1 (95% confidence interval [CI] 1.4–47.4).

TABLE 2 Patient characteristics

	Total	EXTRIP suggests	EXTRIP recommends	Either EXTRIP	Paris recommends
n	219	146	78	178	70
Mean age[a] (y)	47	50	43	48	46
Sex (% female)	60.7	59.6	57.7	61.2	52.9
Mean initial lithium concentration (mmol/L)	3.59	3.82	4.31	3.71	4.51
Mean initial creatinine[a] (μmol/L)	202	216	205	211	337

[a]One or more cases did not include an exact value for the variable, and were therefore excluded from average calculations.
EXTRIP, extracorporeal treatments in poisoning

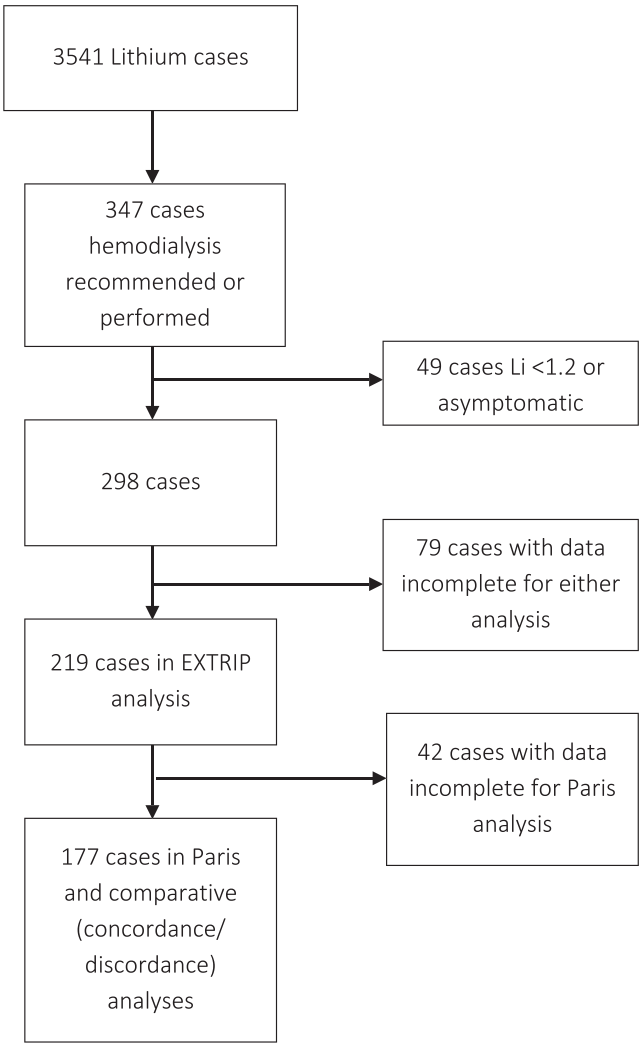

FIGURE 1 Consort diagram

Table 4 shows the data, analysis and comparisons for patients who met the EXTRIP *suggests criteria*. As noted above, many statistical comparisons were not possible because of no events occurring in at least 1 cell. Only 2 analyses reached statistical significance. Among the 107 patients who did not meet the Paris criteria for haemodialysis, 83 underwent the procedure. Neurological deterioration was more likely in the remaining 24 patients who were not dialysed (P = .22; OR 8.10; 95% CI 1.39–47.39). For 81 patients, outcomes could be compared when EXTRIP criteria were met and PARIS criteria were not. Clinical deterioration was more likely in these patients when they did not undergo haemodialysis (P = .01, OR 8.67; 95% CI: 1.42–52.94). When both criteria were met the majority of patients were dialysed and there were no deteriorations. Similarly, when both criteria were not met, the majority of patients were dialysed and there were no deteriorations.

Table 3 shows the data and analysis and comparisons for patients who met the EXTRIP recommend criteria. As noted above, many comparisons were not possible because of no events occurring in at least 1 cell. The comparison between EXTRIP *recommends* and PARIS did not reach statistical significance.

There were 178 patients who met either the *recommended* or *suggested* EXTRIP criteria for haemodialysis. Their analysis is summarized in Table 5. Four of the 26 (15.4%) who did not have haemodialysis deteriorated and 1 patient died as opposed to the 151 patients who underwent haemodialysis, among whom 5 deteriorated (3.3%) and 3 died (P = .031). The OR for deterioration in the patients not dialysed was 5.1 (95% CI 1.3–20.3). In 41 patients, EXTRIP neither *recommended* nor *suggested* haemodialysis. All patients did well, including 5/41 who did not receive haemodialysis. Statistical analysis was not performed because no events occurred in 1 cell. For 62 patients both the PARIS criteria and at least 1 of the EXTRIP criteria for haemodialysis were met. The only 3 deteriorations were among the 57 patients who underwent haemodialysis. Statistical analysis was not performed because no events occurred in 1 cell. There were 21 patients who fulfilled neither criteria for haemodialysis. There were no deteriorations in this group, including the 5 patients who did not receive haemodialysis. Statistical analysis was not performed because no events occurred in 1 cell. There were 86 patients who met at least 1 of the 2 EXTRIP criteria for haemodialysis but did not meet the Paris criteria. Haemodialysis was performed in 67 patients, 2 of whom (3.0%) deteriorated. In contrast, among patients not dialysed 4/19 (21.1%) deteriorated, 1 of whom died (P = .019). The OR for deterioration if dialysis was not performed when EXTRIP was in favour of haemodialysis and Paris was not was 8.7 (95% CI 1.5–51.8). Table S1 provides a more detailed description of all patients who deteriorated. Finally, there were 8 patients for whom Paris was in favour of haemodialysis but neither of the 2 EXTRIP criteria were met. All 8 patients underwent haemodialysis and there

TABLE 3 Comparison of outcomes— extracorporeal treatments in poisoning (EXTRIP) *recommends*

		Haemodialysis							
		Done			Not done				
		Clinically improved	No change	Worsened (death)	Clinically improved	No change	Worsened (death)	Odds of worsening without dialysis (odds ratio)	*P* value
EXTRIP recommends	**Met criteria**	56	6	5 (3)	8	1	2 (1)	2.76 (0.46–16.38)	.13
	Did not meet criteria	103	9	0	15	4	2	ND	ND
PARIS	**Met criteria**	55	7	3 (3)	3	2	0	ND	ND
	Did not meet criteria	75	6	2	18	2	4 (1)	8.10 (1.39–47.39)	.022
Met EXTRIP and Paris		22	2	3 (3)	3	1	0	ND	ND
Did not meet EXTRIP or Paris		50	3	0	14	2	2	ND	ND
Met EXTRIP, but not Paris		25	3	4	4	0	2 (1)	3.50 (0.48–25.72)	0.11
Met Paris, but not EXTRIP		29	5	0	0	1	0	ND	ND

ND = no comparison done because of empty cells.

TABLE 4 Comparison of outcomes— extracorporeal treatments in poisoning (EXTRIP) *suggests*

		Haemodialysis							
		Done			Not done				
		Clinically improved	No change	Worsened (death)	Clinically improved	No change	Worsened (death)	Odds of worsening without dialysis (odds ratio)	*P* value
EXTRIP suggests	**Met criteria**	109	5	5 (3)	14	9	4 (1)	3.97 (.99–15.90)	.026
	Did not meet criteria	57	7	0	9	0	0	ND	ND
PARIS	**Met criteria**	55	7	3 (3)	3	2	0	ND	ND
	Did not meet criteria	75	6	2	18	2	4 (1)	8.10 (1.39–47.39)	.022
Met EXTRIP and Paris		44	3	3 (3)	2	2	0	ND	ND
Did not meet EXTRIP or Paris		27	2	0	8	0	0	ND	ND
Met EXTRIP, but not Paris		48	4	2	10	2	4 (1)	8.67 (1.42–52.94)	.01
Met Paris, but not EXTRIP		11	4	0	1	0	0	ND	ND

ND = no comparison done because of empty cells.

TABLE 5 Comparison of outcomes— extracorporeal treatments in poisoning (EXTRIP) either *suggests* or *recommends*

		Haemodialysis						
		Done			Not done			
		Clinically improved	No change	Worsened (death)	Clinically improved	No change	Worsened (death)	Odd of worsening without dialysis (OR)	*P* value
EXTRIP: Either recommend or suggest	Met criteria	135	11	5 (3)	18	5	4 (1)	5.08 (1.27–20.31)	.031
	Did not meet criteria	31	5	0	5	0	0	ND	ND
PARIS	Met criteria	55	7	3 (3)	3	2	0	ND	ND
	Did not meet criteria	75	6	2	18	2	4 (1)	8.10 (1.39–47.39)	.022
Met EXTRIP and Paris		50	4	3 (3)	3	2	0	ND	ND
Did not meet either EXTRIP or Paris		14	2	0	5	0	0	ND	ND
Met EXTRIP, but not Paris		61	4	2	13	2	4 (1)	8.67 (1.45–51.80)	.019
Met Paris, but not EXTRIP		5	3	0	0	0	0	ND	ND

ND = no comparison done because of empty cells.

were no deteriorations. Statistical analysis was not performed because no events occurred in 1 cell.

4 | DISCUSSION

In this single-centre retrospective analysis of lithium poisoned patients in whom haemodialysis was performed or recommended by our PCC, when the EXTRIP and Paris criteria were both in favour of haemodialysis, dialysed patients generally had favourable outcomes. When the 2 criteria were not in favour of haemodialysis, nondialysed patients also had favourable outcomes. As reported by its creators, application of the Paris guidelines prompts dialysis in fewer patients overall, but when the criteria were discordant, the EXTRIP criteria outperformed the Paris criteria at identifying potentially ill patients who might benefit from haemodialysis. Of the cases of deterioration not identified by the Paris criteria, 2 were not identified by the EXTRIP *recommends* criteria, and all 4 were identified by the EXTRIP *suggests* criteria. EXTRIP criteria were not intended to be merged for comparative analysis, but this comparison is presented here to reflect the merged EXTRIP analysis performed in the original Paris validation study.

Descriptive data are unfortunately limited for these cases. We cannot completely exclude processes unrelated to their lithium toxicity contributing to patients' deterioration or death. This qualification, however, is equally applicable to all cohorts and reflects the typical quality of data from poison control centre databases. Furthermore, poison centre data can be limited by completeness and accuracy for coded clinical effects and treatments.[11,12] There may have been variability between original PCC coders for clinical effects such as *confusion*, *altered mental status* and *other–miscellaneous*. Narrative accounts can be selective in their inclusion/exclusion of relevant data and can terminate in many cases before the outcome of interest is determined in a subsequent retrospective study. Long-term outcomes such as SILENT cannot be extrapolated from poison centre cases, for example, as routine follow up on the order of months or years is seldom performed.

Additionally, our cohort possibly suffers from selection bias. It was not the goal of this study to validate either EXTRIP or Paris as this would be better performed with a prospective trial. Rather the goal was to compare the performance of these 2 criteria in an entirely external data set. Furthermore, we chose not to examine all cases of numerical lithium toxicity (i.e. [Li] >1.2) as many of those patients would be asymptomatic and have no reason to have these criteria applied. There may have been cases in which EXTRIP or Paris criteria were met, but dialysis was neither recommended nor performed. These cases would not have been identified by our search criteria but were unlikely to be significantly ill since most sources prior to EXTRIP suggest more liberal indications for haemodialysis. Our inclusion criteria were designed to select for sicker patients more likely to match those studied in the Paris derivation study and the literature upon which EXTRIP guidelines are based. We recognize that we only reviewed cases reported to 1 regional metropolitan

poison centre in the USA. Since poison centre reporting is largely voluntary, we may have missed cases in our catchment area not reported to our center.[13]

5 | CONCLUSION

In this retrospective data set, application of the Paris guidelines would have resulted in fewer overall cases of haemodialysis for lithium poisoned patients but would have failed to identify a statistically significant number of patients who may have benefited from expedited extracorporeal drug removal. While the EXTRIP criteria result in an increase in the use of haemodialysis, overall patient outcomes were improved, and fewer patients deteriorated. A prospective study is needed to more conclusively determine the relative performance characteristics of both EXTRIP and Paris criteria.

COMPETING INTERESTS

None of the authors have any financial conflicts of interest to declare. Drs Hoffman and Gosselin served on EXTRIP and participated in the development of EXTRIP's lithium guidelines.

CONTRIBUTORS

P.D. conceptualization, investigation, writing, editing; E.F. investigation, writing, editing; M.S. formal analysis, editing; S.G. conceptualization, editing; R.H. conceptualization, writing, editing, supervision.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

How to cite this article: DiSalvo PC, Furlano E, Su MK, Gosselin S, Hoffman RS. Comparison of the EXtracorporeal TReatments In Poisoning (EXTRIP) and Paris criteria for neurotoxicity in lithium poisoned patients. *Brit Jnl Clinical Pharma*. 2021;87(10):3871–3877. https://doi.org/10.1111/bcp.14802