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EFFECTIVENESS OF THERAPEUTIC PLASMA EXCHANGE IN COMPARISON WITH STANDARD OF CARE IN THE TREATMENT OF YELLOW PHOSPHORUS POISONING: AN OBSERVATIONAL STUDY IN SOUTH INDIAN POPULATION

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ABSTRACT

Yellow phosphorus poisoning is commonly seen in India, predominantly due to intentional self-harm. It is known to cause acute liver failure, which is a major contributory factor for its high mortality. Liver transplantation has been the definitive treatment in patients fulfilling the King's College Hospital Criteria for liver transplantation. Therapeutic plasma exchange is an alternative treatment option that has shown promising results with significantly improved outcomes, in various studies.

We conducted a single centre, prospective observational study in a tertiary care hospital in Southern India from August 2022 to March 2024. 46 patients were included in the study, 23 of whom underwent therapeutic plasma exchange. Patients were monitored throughout their hospital admission and were further grouped into those that fulfilled the King's College Hospital criteria and those that did not.

Fulfilment of King's College Hospital criteria was found to be a poor prognostic indicator, with a mortality rate of 84% ($p < 0.001$). Survival rate of 65% was seen in patients who underwent therapeutic plasma exchange ($n=15$), when compared to 57% ($n=13$) in those that did not ($p=0.546$). Among patients who met King's College Hospital criteria, a mortality rate of 100% was seen without therapeutic plasma exchange ($n=8$), which was reduced to 72% ($n=5$) with the usage of therapeutic plasma exchange ($p=0.228$). Survival, among patients who underwent therapeutic plasma exchange, was directly proportional to number of cycles of therapeutic plasma exchange that they underwent ($p=0.007$). Early initiation of therapeutic plasma exchange (within 5 days of yellow phosphorus poisoning) had a survival rate of 73% ($n=8$), when compared to 58% ($n=7$) in those whom therapeutic plasma exchange was initiated after 5 days ($p=0.46$).

Improved survival rates were seen in yellow phosphorus poisoning patients that underwent therapeutic plasma exchange, especially in those that met the King's College Hospital criteria. However, statistical significance could not be established. Larger multicentric randomized controlled trials are needed to further analyse outcomes with the usage of therapeutic plasma exchange.

KEYWORDS: yellow phosphorus poisoning, plasmapheresis, therapeutic plasma exchange, King's College Hospital criteria, acute liver failure

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INTRODUCTION

Yellow phosphorus is a commonly found ingredient in products such as rodenticides, fireworks, fertilizers, etc. Accidental or intentional consumption of such compounds is commonly seen in the Indian subcontinent [Mark K *et al.*, 2021]. Yellow phosphorus poisoning is a challenging menace due to its widespread availability compounded by its toxic effects on the human body. The compound, once it enters the circulation, gets concentrated primarily in the liver, and to a lesser extent in other organs such as kidneys, heart, brain and pancreas [Soni J *et al.*, 2020]. As a result, acute liver failure is the most common manifestation of yellow phosphorus poisoning [Gopalakrishnan S *et al.*, 2020].

Clinical course after consumption of yellow phosphorus can be divided into 3 phases [Mishra A *et al.*, 2017]. Gastrointestinal symptoms predominate usually within the first 24 hours which include perioral burns, nausea, vomiting, loose stools, and abdominal pain. During the second phase which lasts between 1-4 days, the patient may remain asymptomatic. After systemic absorption into the blood, the third phase starts wherein symptoms and signs of organ failure develop after 4-7 days. yellow phosphorus is considered highly toxic. There are scarce epidemiological data regarding the ingestion of yellow phosphorus in the subcontinent. Objectives: This study aimed to identify the clinical profile of rodenticide-poisoned patients and delineate mortality predictors. Design: Prospective observational study. Setting and participants: Study was conducted at the Department of Internal Medicine, Government Villupuram Medical College and Hospital. All adult inpatients with a history of rodenticide poison exposure were eligible participants. A total of 99 patients completed the study protocol. Main outcome: Survival with or without morbidity and death. Results: In all, 90.91% of patients consumed the paste formulation of rodenticide [yellow phosphorus (67.2%These include jaundice, bleeding manifestations due to coagulopathy, renal failure and encephalopathy. Monitoring of lab parameters show leukopenia along with coagulopathy which may be seen as early as 2 days. This is followed by rise in liver enzymes along with increasing bilirubin levels. Serum creatinine concentrations can go up in those cases where significant amounts of yellow

phosphorus have reached the kidneys leading to acute kidney injury.

As there is no antidote available to neutralise the effects of yellow phosphorus in the body, treatment mainly revolves around supportive management in the form of early gastric lavages followed by usage of N-acetyl cysteine which acts as an antioxidant, thus attempting to minimize the toxicity [Bhat S *et al.*, 2015]. As part of standard treatment, N-acetyl cysteine is administered in most centres, using doses similar to that which have been approved for use in paracetamol poisoning, that is, the 21-hour regimen which consists of 3 doses; loading dose of 150 mg/kg infused over 1 hour, then followed by second dose of 50 mg/kg infused over 4 hours. The third dose of 100 mg/kg is then infused over 16 hours.

Outcomes have, however, been very poor as many patients present to the hospital once the signs and symptoms of liver failure have already developed [Fernandez O *et al.*, 1995]. Liver transplantation has been traditionally considered the only definitive treatment option in patients who develop acute fulminant liver failure [Saraf V *et al.*, 2015].

Plasmapheresis or therapeutic plasma exchange is a process, which in principle, involves the removal of unwanted compounds or proteins present in or bound to other proteins in the plasma, by exchanging significant volumes of plasma itself and replacing it with other colloids such as albumin or fresh frozen plasma [Kohli R *et al.*, 2022]. Various centres have attempted using therapeutic plasma exchange for mitigating the effects of yellow phosphorus poisoning, with variable outcomes. Review of literature has shown various studies that have demonstrated significant biochemical improvements after therapeutic plasma exchange when compared with standard treatment, without any major adverse events [Varghese J *et al.*, 2020; Angraje S *et al.*, 2021; Radhakrishnan K *et al.*, 2023; Rohini R, Routray M, 2024]. It has been postulated that one mechanism by which therapeutic plasma exchange can be beneficial in yellow phosphorus poisoning cases is by providing physiologically important compounds that are present in fresh frozen plasma used as a replacement fluid. Another hypothesis suggests that PLEX helps by removing toxic compounds such as Damage Associated Molecular Patterns and other toxins in plasma, and

thus reducing the toxic effects of yellow phosphorus that has already been absorbed in blood with an ongoing pathological response by the body [Varghese J et al., 2020; Angraje S et al., 2021].

In patients that fulfil King's College Hospital criteria for liver transplantation, outcomes are seen to be worse than in those patients that do not meet the criteria [Varghese J et al., 2020; Mathew J et al., 2021; Mohanka R et al., 2021]. However, therapeutic plasma exchange has shown to benefit these patients even without liver transplantation and overall survival benefit is seen. No guidelines have, as of yet, been established for the treatment of acute liver failure due to yellow phosphorus poisoning using plasmapheresis. Our study aims to establish the role of therapeutic plasma exchange in yellow phosphorus poisoning by comparing primary outcome of death in those that underwent therapeutic plasma exchange with those that received standard treatment alone, to help develop concrete guidelines for treatment of yellow phosphorus poisoning and incorporating therapeutic plasma exchange as part of standard care for yellow phosphorus poisoning. Subgroup analysis between those that fulfilled King's College Hospital criteria and those that did not, was also done.

MATERIAL AND METHODS

We conducted a single centre prospective observational study in a tertiary care centre in South India between August 2022 to March 2024. Institutional ethics committee approval was obtained (IEC2:444/2022). Adults >18 years of age who consumed yellow phosphorus were included in the study. Exclusion criteria included those who consumed a mixture of poisons, those who had an underlying chronic liver disease of any aetiology.

With 80% power and mortality difference taken as 20% (based on available studies) and 5% level of significance the sample size calculated was minimum of 23 in each group. It was calculated using PASS software for two independent differences of proportions

The study involved the comparison of standard treatment in yellow phosphorus poisoning with that of therapeutic plasma exchange. Currently, there are no definitive guidelines for treatment of yellow phosphorus poisoning and standard treatment involves supportive care with gastric lavage,

vitamin K supplementation, fresh frozen plasma (if needed) and N-Acetyl Cysteine infusion (regimen given for paracetamol poisoning). All the permissions and clearances were obtained before starting the study. Consent was taken from every participant included in the study. Those 46 participants adhering to the selection criteria were taken for the study and routine lab investigations that were sent as standard of care were observed serially. The treatment protocol that was initiated for every patient was observed. No audio/video recording was involved in this study and the study involved only thorough examination of the patient and routine investigation (Complete Blood Count, Renal Function Test, Liver Function Test, Prothrombin Time/International Normalized Ratio, Ultrasound of Abdomen, Hepatitis B Surface Antigen, Anti-Hepatitis C Virus Antibodies). All the participants who were selected for the study were classified into different groups based on the treatment that they undergo (standard/therapeutic plasma exchange). No additional tests were done. Participants were followed up for up to 90 days, via a phone call, for determining survival.

Data collection was by taking proper clinical details, history, relevant investigations and entering them into predesigned proforma. Data analysis was carried out using SPSS version 29. Mean, median and standard deviation were used for summarizing data with continuous variables while categorical data was analysed using frequencies and percentages. Further contrast and correlation between different groups of participants was done using student's t tests, Pearson's Chi-square tests and Fischer's exact tests, with a p value below 0.05 considered to be statistically significant. The outcome was then compared in the two groups in terms of duration of hospital stay, King's College Hospital criteria, mortality.

RESULTS

A total of 46 participants were part of the study out of which 23 underwent therapeutic plasma exchange and 23 that did not. The youngest patient was 18 years while eldest being 76 years, and with the mean age being 31 ± 13 years. Average duration of hospitalisation was 10.4 ± 7.2 days. Other patient characteristics are mentioned in table 1.

An overall mortality rate of 39% (n=18) was

seen in our study. The mean day of initiation of therapeutic plasma exchange was 5.4 ± 2.2 day. Overall, 65% of participants in the therapeutic plasma exchange group survived ($n=15$), while 57% of participants in the standard treatment group ($n=13$) survived (p value – 0.546), as shown in table 2.

The 73% of participants who were initiated on therapeutic plasma exchange within 5 days survived while only 58% of participants, who were initiated on therapeutic plasma exchange 6th day onwards, survived (p value – 0.469). Average number of cycles of therapeutic plasma exchange done per patient were 3.1 ± 1.5 cycles. Survival rates were directly proportional to the number of cycles of therapeutic plasma exchange that participants underwent (p value – 0.007) (Table 3, Figure).

Out of 46 participants 27 were fulfilling the King's College Hospital criteria for acute liver failure; 84% of participants who fulfilled the criteria died, while only 7.4% of participants who did not meet the criteria died ($p < 0.001$). Among the 19 participants who fulfilled the criteria, mortality was 100% if participants received standard treatment alone (8 out of 8 died). However, 3 out of 8 participants who underwent therapeutic plasma exchange survived (Table 4). Hence mortality rate was reduced to 72% (p -value 0.228).

DISCUSSION

Intentional self-harm with yellow phosphorus poisoning has been reported widely with high incidence among South Indian population due to its easy availability and lethal toxicity. Mortality rates have been high as majority of the population belonging to low socio-economic status can neither afford liver transplantation nor have access to centres that perform it. Therapeutic plasma exchange has thus emerged as a cheaper, and more widely available alternative to liver transplantation in treating patients of acute liver failure.

Our study showed improvement in survival rates among those that underwent therapeutic plasma exchange when compared to those that did not (65% vs. 57%), which was in accordance with previous studies that have shown survival rates of 70-79% in those that undergo therapeutic plasma exchange [Varghese J et al., 2020; Angraje S et al., 2021]. Interplay amongst various factors that

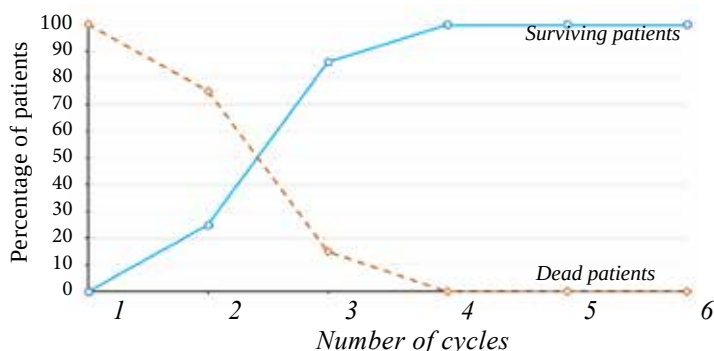


Figure. Survival rate correlation with number of cycles of therapeutic plasma exchange

TABLE 1

Descriptive Characteristics of Study Participants

Characteristics	Groups	
	TPE (N=23)	Standard Treatment (N=23)
Age (years)	33 ± 15	30 ± 10.8
Males - n(%)	15 (65%)	10 (43%)
Females - n(%)	8 (35%)	13 (57%)
Amount of Poison Consumed (grams)	12.5 ± 5.8	10.2 ± 7.6
Duration Before Seeking Medical Help - n(%)	≤1 day	13 (57%)
	1-3 days	7 (30%)
	≥3 days	3 (13%)
Intubated - n (%)	5 (22%)	7 (30%)
Required Haemodialysis - n(%)	3 (13%)	-
No. of Days of Hospital Stay (days)	13.8 ± 7.9	7 ± 4.2
Meeting KCH Criteria - n(%)	Yes	11 (48%)
	No	12 (52%)
Outcome - No. (%)	Survived	15 (65%)
	Died	8 (35%)

NOTES: TPE - Therapeutic plasma exchange, KCH - King's College hospital, N(%) - Total number(непценм) of patients. n(%) - number (percent) of patients in a group.p.

TABLE 2.

Subgroup Analysis of Primary Outcome

Characteristics		Survived (N=28)	Died (N=18)	p-value
Gender	Male	18 (72%)	7 (28%)	0.091
	Female	10 (48%)	11 (52%)	
	No	26 (60%)	17 (40%)	
TPE	Yes	15 (65%)	8 (35%)	0.546
	No	13 (57%)	10 (43%)	
KCH Criteria	Yes	3 (16%)	16 (84%)	<0.001
	No	25 (93%)	2 (7%)	
Day of Initiation of TPE	≤5 days	8 (73%)	3 (27%)	0.469
	>5 days	7 (58%)	5 (42%)	

NOTES: TPE - Therapeutic plasma exchange, KCH - King's College hospital, N(%) - Total number(непценм) of patients. n(%) - number (percent) of patients in a group.

TABLE 3. Comparison of Mean Characteristics Between Participants Who Survived vs. Died

	Survived (M ± SD)	Died (M ± SD)	P-Value
Dose (grams)	10 ± 6	13.9 ± 7	0.054
Duration before seeking help (Days)	1.3 ± 1.6	1.5 ± 1.5	0.746
Day of Initiation of TPE	5.1 ± 2.5	6.1 ± 1.3	0.317
Number of cycles of TPE per patient	3.9 ± 1.1	1.6 ± 0.7	<0.001
Duration of hospital stay (days)	14.2 ± 6.7	4.7 ± 2.9	<0.001

NOTES: TPE - Therapeutic plasma exchange, M - Mean, SD - Standard Deviation

TABLE 4. Survival Benefit with Therapeutic plasma exchange (TPE) in King's College hospital criteria (KCH) Group

KCH Criteria	Outcome	TPE Done	TPE Not Done
Yes	Survived	3 (27%)	0 (0%)
	Died	8 (73%)	8 (100%)
No	Survived	12 (100%)	13 (87%)
	Died	0 (0%)	2 (13%)

may influence the outcome were not independently analysed, such as day of initiation of therapeutic plasma exchange, duration of seeking medical help after consumption of yellow phosphorus, incidence of secondary infections, etc. As therapeutic plasma exchange involves siphoning of blood volume through an extracorporeal device, hypotension is a known complication of the procedure which can be compounded in the presence of sepsis leading to worsening of shock. Effect of this confounding factor and cause of death in these patients was not analysed separately.

Overall mortality rate due to yellow phosphorus poisoning was 39% in our study while mortality rates as high as 76.2% have been seen in previous studies [Appavu V et al., 2019]. Fulfilment of King's College Hospital criteria was found to be an independent poor prognostic factor with a mortality rate of 100% in those who do not undergo therapeutic plasma exchange (p value <0.001), affirming the findings of various previous studies as mentioned in the introduction. However, this was brought down to 72% in the subgroup of participants who underwent therapeutic plasma exchange. This was in line with similar studies conducted previously [Varghese J et al., 2020]. The King's College Hospital criteria includes variables such as prothrombin time, bilirubin levels and time to develop encephalopathy,

which are all individual markers of advanced liver failure. Thus, combining such variables portends a grave prognosis in all patients with acute liver failure, irrespective of the cause.

Survival, among participants who underwent therapeutic plasma exchange, was directly proportional to the number of cycles of therapeutic plasma exchange that they underwent (p value – 0.007). This can be explained by increased removal of plasma cytokines and adhesion molecules, replacement of plasma factors, and immune modulation [Larsen F et al., 2016]. Yet other postulated mechanisms include removal of Von Willebrand factor from the patient's plasma and supplying ADAMTS13 which improves perfusion in the microcirculation of the liver and other vital organs, and promoting functional recovery of these organs [Sardar D et al., 2019]. However, it is prudent to note that correlation between survival and number of cycles of therapeutic plasma exchange in our study can be skewed,

as participants who were admitted in a critically ill state could undergo comparatively lesser cycles of therapeutic plasma exchange before they expired.

Information obtained regarding time of consumption of poison and dose of poison consumed is anecdotal and approximate, as told by either patient themselves or by patient bystanders. This information could not be independently verified and hence analysis done based on this information alone may not be accurate.

There was no statistically significant correlation found between survival and earlier presentation to the hospital (p value – 0.746), as the study was conducted in a tertiary care centre that received referred cases from other primary health centres where many patients had received initial care involving stomach washes and gastric lavages. Effect of such interventions could have thus impacted the outcomes, which was not separately analysed in the current study.

Mean dose of poison consumed was 11.6 ± 6.7 grams. No significant correlation could be found between mortality and the dose of poison consumed (p value – 0.054), as opposed to previous studies [Mohanka R et al., 2021; Angraje S et al., 2021], where they found improved outcomes in those patients that had consumed <10g of yellow phospho-

rus. In our study, dose of poison consumed by participants could not be verified objectively, and was only as estimate claimed by the patients themselves or the bystanders. Thus, expected results such as worsening of outcomes with increasing dose of yellow phosphorus consumed were not seen.

Majority of patients who were intubated in this study were moribund and underwent emergency intubation at a very late stage of the disease/periarrest state. Hence further studies are required to establish intubation as an independent poor prognostic marker for mortality.

CONCLUSION

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