Section: Emergency Medicine

Original Research Article

# EVALUATING THE EFFECTIVENESS OF THE SALEM PROTOCOL IN TREATING PARAQUAT POISONING A MULTI-CENTER STUDY

**Hari Prasad S.[1], C. M. Dhileeban[2], Sentamil Selvan Vijayan[3], V. P. Chandrasekaran[4], K. Rajarajeswaran[5], Sai Sirisha Polinatti[6]**

[1]Assistant Professor, Department of Emergency Medicine, SRM Medical College Hospital and Research Centre, Kattankulathur, India.
[2]Assistant Professor, Department of Emergency Medicine, SRM Medical College Hospital and Research Centre, Kattankulathur, India.
[3]Consultant, Department of Emergency and Critical care Medicine, Ponni hospital - Palladam, Tamilnadu, India
[4]Associate Dean Super Speciality, Department of Emergency Medicine, SRM Medical College Hospital and Research Centre, Kattankulathur, India.
[5]Professor and Head, Department of Emergency Medicine, SRM Medical College Hospital and Research Centre, Kattankulathur, India.
[6]PhD Scholar, SRM College of Nursing, India.

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Corresponding Author:
**Dr. Hari Prasad S.,**
Email: sriramdashariprasad@gmail.com

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## ABSTRACT

**Background:** Paraquat is a widely used herbicide with a high fatality rate (60–80%) due to the absence of a specific antidote. Ingestion leads to severe systemic toxicity and multi-organ failure, with prognosis largely dependent on dose and time to hospital presentation. The Salem protocol, a recently developed multi-modal therapeutic strategy, has been proposed to improve outcomes in paraquat poisoning. The aim is to evaluate the effectiveness of the Salem protocol in treating patients with acute paraquat poisoning. **Materials and Methods:** A prospective, non-randomized, hospital-based experimental study was conducted in the Department of Emergency Medicine at selected centers in Salem, Tamil Nadu, India, between December 2019 and May 2021. Patients of all ages and genders presenting with paraquat poisoning were included, excluding mixed/other poisonings and those leaving against medical advice. The Salem protocol involved saline gastric lavage, multidose activated charcoal, antioxidants, hepatoprotective drugs, glucocorticoids, charcoal hemoperfusion, hemodialysis, and supportive care. Demographic and clinical variables were analyzed using SPSS version 25, with significance set at $p < 0.05$. **Result:** A total of 26 patients were included; most were aged 16–25 years (65%), and females comprised 62.5%. The majority (57.6%) consumed 11–50 ml of paraquat. Mean time to hospital arrival was 2.1 hours in survivors and 4.85 hours in non-survivors. Survival was achieved in 6 patients (23%), with statistically significant association between outcome and time of arrival ($p = 0.00044$). Survivors had consumed significantly smaller volumes of paraquat (21.6 ± 17.7 ml vs. 48.05 ± 22 ml) and underwent more cycles of charcoal hemoperfusion and dialysis (4.83 ± 0.37 vs. 1.3 ± 0.71). **Conclusion:** The Salem protocol demonstrated promising effectiveness in improving survival among paraquat-poisoned patients, particularly in younger individuals presenting early with smaller ingested doses. Extended charcoal hemoperfusion and dialysis significantly contributed to improved prognosis. Broader multi-center trials are needed to validate and refine this protocol.

## INTRODUCTION

Paraquat (1, 1'– dimethyl-4, 4'-bipyridinium) a nitrogenous herbicide widely used in agriculture as contact herbicide & is a highly toxic compound and the fatality rate of Paraquat ranges between 60 and 80% due to the lack of specific antidote to inhibit toxicity.[1] A dose of 30 mg/kg may be fatal, which is equivalent to 8–10 ml of the 20% solution available commercially.[2] However prompt action and rapid assessment is critical step in the treatment of paraquat poisoned patients, it completely depends upon the plasma paraquat concentration.

Paraquat is a severe local irritant with devastating systemic toxins. Its acts as fast absorbent on oral ingestion causing severe lethal effects especially


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when taken in empty stomach. Myocardial injury and necrosis of the adrenal glands also may occur. A lethal oral dose of the 20% concentrate solution is about 10 to 20 mL in an adult and 4 to 5 ml in a child.[3]

Several researches has been taking place in the recent times to develop a standard guidelines and protocol treatment for paraquat poisoning, on referencing with the systemic review and meta- analysis from various resources,[4] studying the efficacy of the treatment modalities a new protocol has been developed called as Salem protocol which includes saline gastric lavage, multidose activated charcoal, antioxidants, hepato protective drugs, glucocorticoid therapy , charcoal hemoperfusion.[5-7] Present study was aimed to evaluate the effectiveness of the Salem protocol in treating paraquat poisoning.

## MATERIALS AND METHODS

Present study was prospective, non-randomized, hospital experimental study. conducted in department of Emergency Medicine, at Sri Gokulam Hospital, and Sri Gokulam Specialty Hospital, Salem, Tamil Nadu, India. Study period was from December 2019 to May 2021. Study was approved by institutional ethical committee.

**Inclusion criteria**

- Patients of all age group & either gender, who are admitting with Paraquat poisoning in selected hospitals, who are affordable for the treatment with Salem protocol & given written consent and willing to participate in the study

**Exclusion criteria**

- The study excludes mixed / other poisons.
- Excludes patients who left against medical advice

Study was explained to participants in local language & written informed consent was taken.

Patient initial vital parameters and condition at the time of admission are assessed and recorded using a tool developed by the researcher and required lab investigations are been sent and recorded. Implementation of the new treatment protocol with supportive measures with concerned guidelines was done. Ongoing assessment and monitoring of the patients vital parameters and stability was done. Combined approach includes N - Acetyl Cysteine, Glutathione, Methyl Prednisolone, Charcoal Lavage, Peglec, Charcoal Hemoperfusion, Hemodialysis, Vitamin E, Vitamin C, supportive management and care.

Statistical analysis carried out by using the Statistical Package for Social Sciences version SPSS IBM,25 for windows, (SSS Inc.,, Chicago, Illinois, USA). Continuous variables will be expressed as Mean, Standard Deviation and categorical variables as frequencies and percentages. The relationships between demographic variables with clinical variables will be assessed by multiple logistic regression analysis. A P (probability) value < 0.05 will be considered as significant.

## RESULTS

The study included totally 26 subjects selected on the basis of the inclusion criteria of them, the majority subjects belong to 16 to 25 years age group (65%), followed by age group of 45 and above (12 %) and there is only 3% of subjects with less than 15 years of age group. Majority 62.5% of the female subjects consumed paraquat poison compared to males subjects which is only 38.5%

**Table 1: General characteristics**

| Characteristics | No. of subjects | Percentage |
|---|---|---|
| Age group (in years) | | |
| < 15 | 1 | 3 |
| 16- 25 | 17 | 65 |
| 26- 35 | 3 | 12 |
| 36-45 | 2 | 8 |
| >45 | 3 | 12 |
| Gender | | |
| Females | 16 | 62.5 |
| Males | 10 | 38.5 |

Majority 15(57.6%) subjects consumed around 11 to 50ml of paraquat as per the information given by the attendant and subjects.

**Table 2: Distribution on Basis of Amount of Poison Consumed N=26**

| Amount of poison consumed in ml | Total in number | Percentage(%) |
|---|---|---|
| Less than 10 | 7 | 27 |
| 11 to 50ml | 15 | 57.6 |
| 51- 100 ml | 3 | 11.4 |
| 101 and above | 1 | 4 |

Mean duration of 2.1 hours has been taken by the recovered subjects to reach the setting and a mean duration of 4.35 hours has been taken the paraquat succumbed subjects.


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**Table 3: Distribution of Mean time of arrival to the setting**

| All the subjects to the setting | Survivors | Non survivors |
|---|---|---|
| 4.03 hrs. | 2.1 hours | 4.35 hrs. |

New developed Salem protocol showed its effectiveness on the survival of the total 6 paraquat poisoned patients among 26 patients.

**Table 4: Distribution of Prognosis (Treatment outcome) N=26**

| Survived | Non-survived | Chi square value | df | P value |
|---|---|---|---|---|
| 6 (23%) | 20 (77%) | 16.68 | 1 | 0.00044* |

*significant

Mean age group of survivors is 26 ±10.8 which is comparatively low with the standard deviation of the non-survivor group and also the mean time of arrival to the setting is comparatively low compared to the non-survival group of subjects. There is a huge difference between the amount of poison consumed by the survivors and non survivors, in aspect of treatment charcoal hemoperfusion and the dialysis 4.83 ±0.37 cycles were performed which is comparatively higher than the non survivors.

**Table 5: Comparative characteristics of Survivors and Non Survivors**

| Characteristic | Survivors | Non survivors |
|---|---|---|
| | Mean ± SD | Mean ± SD |
| Age in years | 26 ± 10.8 | 25 ± 13.4 |
| Mean time of arrival to the setting in hours | 2 ± 1 | 4.85 ± 1.44 |
| Amount of poison consumed in ml | 21.6 ± 17.7 | 48.05 ± 22 |
| Charcoal hemoperfusion and dialysis in days * | 4.83 ± 0.37 | 1.3 ± 0.71 |

*rest of the treatment given as per the protocol

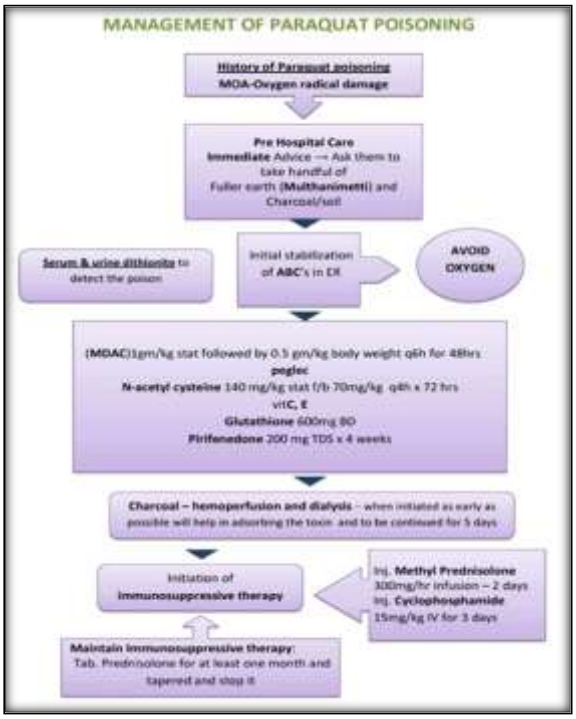


**Figure 1: The New Developed Salem Protocol**

## DISCUSSION

Paraquat is been banned in 32 countries in view to the serious concerns over increasing suicides. In India, only the state of Kerala has banned Paraquat but in other states as it a major herbicide available, its use in regulation. The Government of India is yet to take measures to arrest the counterfeit sale.[3,4] The burden of the problem is still in existence and Till then there is a need to study the effective measures in the treatment of the Paraquat poisoned patients.

Majority of the paraquat intoxicated patients belong to the age group of 16 – 25 years (65%) and having a median age of 26±10.8 And also researcher surprised to see the youngest subject of 14 years/ male during the process. There is a need of in depth studies for these observations.

Mohammad delirrad et al,[8] also noted that the mean age of paraquat poisoned patients belong to the age group of 21-30 years in his study, the review has shown that the major age group fall in this category which is a huge lose to the nation. The present study supported with this review. The study also revealed that the majority of the subjects were females 16(62.5%) but recovery rate was low comparative to males

There is significant difference between the mean time of arrival of the patients who have survived and non-survived. Sabzghabaee AM et al,[9] noted that there will be good prognosis of the patient if they are at young age, exposure to less poison and on early arrival to the hospital. In our study the survivors, shown the mean time of arrival to the setting as 2 ±1 hour which is comparatively lower than the non survivors. It's almost more than the double time of 4.85±1.44 hour for the non survivors.

The severity and outcome of paraquat poisoning are determined primarily by the amount of poison ingested we rely on the information given by the patient attender/relative and rarely by the patient, sometimes patient brings the bottle and shows how much he/she ingested. In the present study the mean of 21.6±17.7 was the amount consumed by the survivors and a mean volume of 48.05±22 ml was the amount consumed by the non survivors. the mean


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volume of consumption of poison is low by the survivors and almost the value doubled in the non survivors. overall from the data available from the study the least amount of poison consumed is 2ml and the highest is 200ml of 24% commercially available paraquat.

There were cases who were not affordable to the treatment and left against the medical advice during the period of my thesis. As the treatment protocol uses all the combined methods for the treatment of the paraquat with the strong review available, the treatment found to be effective, the present study showed the positive result for 6(23%) of the subjects and couldn't be effective for the 20(77%) of the subjects.

Initially for almost half of the cases charcoal hemoperfusion and dialysis were performed for a single day according to the availability of charcoal filter and affordability of the patient, where the results were not so promising. This is the time where we have got the thought of extending the charcoal hemoperfusion and dialysis to 5 days, where the results were promising and are statistically significant.

They were multiple factors affecting the outcome of the patient the clinical parameters all though not included in the study; the researcher observed that the respiratory failure, metabolic acidosis and multi organ dysfunction as the major causes for the non-survived patients.

The duration of the hospital stay for the subjects who survived is around 25 – 32 days. A multi-disciplinary approach by the medical, nursing, dietary, physiotherapy was implemented for all the survivors during the stay of the setting. Counseling has been provided by the psychiatry department on their discharge, the patients were reviewed after 4 days initially and later after 10 days to analyze post paraquat sequalae.

The study is limited only to the outcome of the patient based on survived or non-survived & only to the 60 – 90 days survival patients.

## CONCLUSION

The Salem protocol for paraquat poisoning demonstrated effective outcomes, particularly in younger patients without comorbidities who present early to the hospital. Its effectiveness is further enhanced in centers equipped with the expertise and resources to manage paraquat toxicity.

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