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Original Article

Paediatrics Section

Efficacy and Safety of High-dose versus Standard-dose Prazosin in Paediatric Scorpion Envenomation: A Single-blinded Randomised Controlled Study

APOORVA GAYATRI ABBADI[1], HIDAYTULLAH R BIJAPURE[2], CHANDRIKA R DODDIHAL[3], BHAVANA B LAKHKAR[4], Y ROHITH[5], VJ PRAKASH[6], KUMAR BM PRASANNA[7], MALLANAGOUDA PATIL[8]

ABSTRACT

Introduction: Scorpion sting is a serious health problem in the world, especially in developing countries like India. It is often associated with serious clinical manifestations. As children have a small body surface area, they are prone to more serious cardiac, respiratory and neurological complications. Prazosin, an alpha-blocker, is the drug of choice for the treatment of scorpion envenomation. With the increasing incidence of paediatric scorpion envenomation in rural India, there is a need to optimise prazosin dosing protocols to improve outcomes and reduce hospital stays.

Aim: To evaluate and compare the efficacy and safety of standard-dose versus high-dose prazosin protocols in managing paediatric scorpion envenomation in a tertiary care hospital in North Karnataka, India.

Materials and Methods: A single-blinded randomised controlled study was conducted in Paediatric Intensive Care Unit (PICU) at BLDE DU Shri BM Patil Medical College Hospital and Research Centre, Vijayapur, Karnataka, India, from January 2017 to December 2022. Children below 18 years of age admitted to the hospital with history of scorpion sting with severity grades II and III were enrolled. Children were randomised into three groups: Group A: 30 µg/kg every three hours; Group B: 60 µg/kg initially, followed by 30 µg/kg every three hours; and Group C: 90 µg/kg initially, followed by 30 µg/kg every three hours. They were monitored for sweating, cold or warm extremities, the appearance and disappearance of pain, vital parameters and priapism (in male children) hourly until stabilised, then every third hourly for 24 hours and then sixth hourly til discharged from the PICU. After the patient was haemodynamically stable for 24 hours shifted to a high-dependency unit. The time interval between sting and treatment, various vital parameters, duration of the PICU stay and hospital stay were noted. Categorical variables were compared using the Chi-square test and continuous variables were analysed using the Student's t-test.

Results: A total of 86 children were recruited. The standard protocol (Group A) had 26, Group B had 29 and Group C had 31 children. Forty-eight (56%) of the children were over five years old (12, 21 and 15 were in Groups A, B and C, respectively). The male-to-female ratio of 1.8:1, 2.6:1 and 1.8:1 in Groups A, B and C, respectively. The sting-to-symptom interval, priapism, duration of hypertension and duration of hospital stay were higher in Group B compared to Group A. The duration of hypertension, cardiac involvement and priapism were higher in Group C, whereas a shorter sting-to-symptom interval and symptom-to-prazosin initiation were noted in Group C compared to Group A.

Conclusion: High-dose prazosin is a safe and effective treatment for scorpion envenomation in children, offering a potential advantage over the standard dosing protocol.

Keywords: Autonomic storm management, Indian red scorpion, Neurological complications, Paediatric priapism, Scorpion sting

INTRODUCTION

Scorpion envenomation is common in rural areas, with high morbidity and mortality. A large number of scorpion species are harmless; out of the 1,500 known, 30 are important to us [1]. In India, the red scorpion (*Mesobuthus tamulus*) is the most common harmful species. Antivenin, prazosin and dobutamine are the mainstays of management [1]. Cardiovascular collapse and pulmonary oedema are the main causes of mortality. Most cases in India occur in rural, remote areas where medical facilities may not be available, which significantly contributes to mortality [1,2].

Prazosin is called an antidote to scorpion venom physiologically and pharmacologically antidote to scorpion venom. This is cheap, easy to swallow and effective for autonomic storm caused by scorpion venom. Once this fact was known, prazosin became popular. In a study by Bawaskar HS and Bawaskar PH, antivenin was compared to prazosin and found useful in Indian scenario [3]. The cost, toxicity and non availability of antivenin in rural areas are the main hindrances [4]. Moreover, the time elapsed from sting to treatment is an important factor in determining mortality. It is usual for a patient with scorpion stings to need at least 5-6 hours to reach a suitable facility in rural areas [4]. Prazosin has also been made available in primary health centres. Even rural doctors carry it with them and it has been reported that even some local shopkeepers stock a few tablets. This widespread availability has reduced mortality rates [5]. However, it was observed in few instances where parents accidentally administered double or triple doses of prazosin, or local practitioners mistakenly prescribed higher doses before the patients arrived in a tertiary care hospital facility. These patients received 60 to 90 µg/kg within 20-30 minutes, leading to a better response, which was previously documented [2].

The absence of suitable prazosin formulations for children has frequently led to dosing inaccuracies and potential overdose risks. The study hypothesised that high-dose prazosin will result in quicker stabilisation and shorter PICU stay compared to standard dosing, without additional safety concerns. Hence, present study was undertaken to evaluate and compare the efficacy and safety

of standard-dose versus high-dose prazosin protocols in managing paediatric scorpion envenomation.

MATERIALS AND METHODS

This single-blinded, randomised controlled study was conducted in a PICU at the BLDE DU Shri BM Patil Medical College Hospital and Research Centre in Vijayapur, North Karnataka, India from January 2017 to December 2022. Study approval was obtained from the Institutional Ethics Committee of BLDE University, Vijayapur, India (IEC No. 189/2016-17). Written informed consent was obtained from the guardian of patients enrolled in the study.

Inclusion criteria: Children below 18 years, presenting with a history of scorpion sting with grades II and III [6], were included in the study.

Categorisation of severity of scorpion stings envenomation was done as follows:

Grade I: Local pain/paresthesia at sting site, no systemic manifestations.

Grade II: Pain/paresthesia that has traveled from sting site with or without tachycardia, but without cardiovascular involvement.

Grade III: Peripheral circulatory failure, with cardiovascular or respiratory manifestations.

Grade IV: Central Nervous System (CNS) and/or multisystem involvement.

Exclusion criteria: Children with known systemic diseases, major or multiple anomalies like cardiac defects, renal anomalies, or neurological disorders that could impact the outcomes of the study, who received prazosin before admission to our hospital and those who refused to give consent were excluded from the study.

Sample size: Assuming a pooled standard deviation of five units, the study required a sample size of 25 participants per group (a total of 75 participants, assuming equal group sizes) to achieve 80% power and a 5% level of significance (two-sided) for detecting a true difference of four units in the means between the test and reference groups. This means that, with a random sample of 25 from each population, if the difference in means is four units and the pooled standard deviation is five units, the study would have 80% power to detect a significant difference, indicated by a two-sided p-value <0.05 [2].

The formula used for sample size calculation was:

$n= f(\alpha/2, \beta)\times 2\sigma^2/(\mu 1-\mu 2)^2$

Where:

n= sample size

(μ1-μ2) difference between two means wished to detect

σ^2- Variance

α=1.96

β= 0.8

Randomisation was done via a computerised randomisation chart obtained from www.randomiser.org [7]. A computer-generated random table was used to randomise participants into three groups:

- Group A: Standard protocol with 30 μg/kg every three hours, up to a maximum of five doses.
- Group B: High initial dose of 60 μg/kg, followed by 30 μg/kg every three hours, up to a maximum of five doses.
- Group C: Higher initial dose of 90 μg/kg, followed by 30 μg/kg every three hours, up to a maximum of five doses.

Data collection: Vital parameters, including pulse, respiratory rate and blood pressure, were monitored hourly along with symptoms such as sweating, cold or warm extremities, pain onset or relief and priapism (in male children) until the patient stabilised. After stabilisation, monitoring was conducted every three hours for the next 24 hours, followed by every six hours until discharge from the PICU. Prazosin was administered every three hours until the extremities were warm. Once the patient remained haemodynamically stable for 24 hours, they were transferred to a high-dependency unit. Age-appropriate normal values for pulse rate, respiratory rate and blood pressure were used as reference standards [8]. Patients with complications continued to be monitored in the general ward until complete recovery.

Patients enrolled in the study underwent several diagnostic tests, including a Complete Blood Count (CBC), urine analysis, blood sugar evaluation, serum electrolytes, renal function tests, liver function tests and cardiac marker assessments. Electrocardiograms (ECGs) were performed upon admission, six hours later and at discharge. A chest X-ray was conducted if respiratory distress was present. Echocardiography was completed within 24 hours of admission and repeated before discharge if abnormalities were detected. In cases where CNS symptoms appeared, an Electroencephalogram (EEG) and Magnetic Resonance Imaging (MRI) were also performed. All tests were conducted strictly for diagnostic purposes only, as part of standard care.

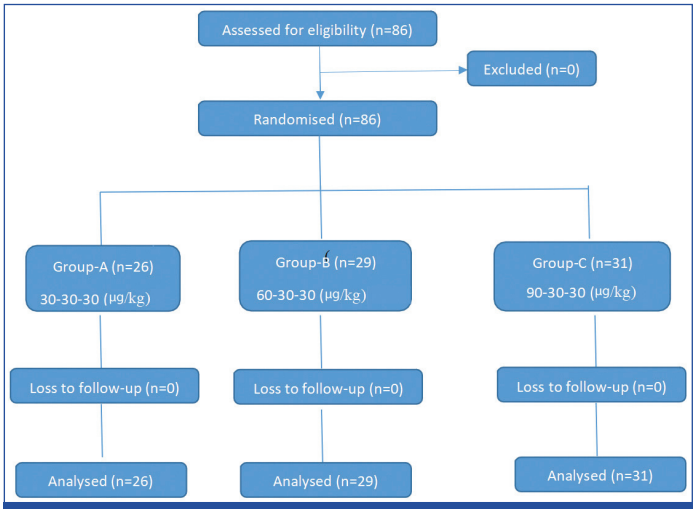
Outcome measures: The primary outcome of the study was to measure the time to stabilisation, the incidence of complications and recovery time. The secondary outcome measures included the duration of PICU stay, total hospital stay and mortality rate. Key time intervals—between the sting and onset of symptoms and between symptom onset and treatment initiation—were also documented.

STATISTICAL ANALYSIS

All data were collected, entered into Microsoft Excel sheet and analysed using computer software Statistical Package for the Social Sciences (SPSS) version 20.0 (IBM Corp, Armonk, NY). The mean duration of symptoms and signs, along with range, was calculated and statistical differences among the three groups were noted. The mean duration of PICU stay and hospital stay, along with range, was calculated and compared. Categorical variables were compared using the Chi-square test and continuous variables were compared using the Student's t-test. The p-value of <0.05 was considered significant. The Cochrane RoB 2 (Risk of Bias 2) tool was used to ensure that all elements of study design, including blinding and randomisation, were properly assessed and reported.

RESULTS

A total of 86 children were recruited for the study. Group A consisted of 26 children, Group B had 29 children and Group C included 31 children [Table/Fig-1].



[Table/Fig-1]: Consort flow diagram.

There were unequal numbers of patients enrolled in each group due to the natural variation in flow of patients with severity grades II and III during the enrollment period. Among the children enrolled, 48

children (56%) were over five years old, with 12 in Group A, 21 in Group B and 15 in Group C. The male-to-female ratios were 1.8:1 in Group A, 2.6:1 in Group B and 1.8:1 in Group C, indicating a predominance of male participants.

The mean weight of the children was 15.5 kg (range 9.5 to 25 kg) in Group A, 17.6 kg (range 6 to 35 kg) in Group B and 15.4 kg (range 9.5 to 25 kg) in Group C. The extremities were the most common site for stings, accounting for 66 (77%) of cases. In rest of the children below five years of age, stings predominantly affected the head and neck region. The delay in medication initiation for Group B was due to logistical challenges at the hospital, including availability of staff and medications or the time needed to confirm severity grading in newly admitted patients. This delayed the administration of the high-dose prazosin protocol despite symptoms presenting early.

None (0%) out of 86 children enrolled were deteriorated or died after admission. There was only one child who had hypotension and that was at admission [Table/Fig-2].

Variables	Group A (Standard Protocol)	Group B (60-30-30)	Group C (90-30-30)	p-value
Age range (years)	3-16	4-15	2–14	-
Number of children >5 years	12	21	15	0.086
<5 years	14	8	16	
Male	17 (65.4%)	21 (72.4%)	20 (64.5%)	0.780
Female	9 (34.6%)	8 (27.6%)	11 (35.5%)	
Male: Female	1.8:1	2.6:1	1.8:1	-
Weight (Mean) (kg)	15.5	17.6	15.4	0.038
Weight (Median) (kg)	15	15	14	
Weight (Range) (kg)	9.5-25	6-35	9.5-25	
#Mean interval between sting and symptom in hours (Range)	2.5 (0.3-3.5)	3.1 (0.5-5)	1.8 (0.25-3.30)	AB-0.002* AC-0001*
#Mean interval between sting and Prazosin administration in hours (Range)	4.25 (0.5-23)	8.3 (0.5-15)	3.5 (1-8)	AB-0.0017* AC-0.034*
#Number (%) of children with sweating at admission	21 (80%)	21 (72%)	25 (80%)	AB-0.554 AC-0.177
#Number (%) of children with cold extremities at admission	20 (76%)	26 (89%)	26 (83%)	AB-0.487 AC-0.124
#Number (%) of children pain at sting site	25 (96%)	25 (86%)	27 (87%)	AB-0.065 AC-0.134

[Table/Fig-2]: Baseline characteristic of the study participants.
*Statistically significant (p<0.05); #All the parameters have been compared with Group A (Standard protocol); Risk of bias assessment tool used- Cochrane RoB 2

The interval between the sting and the onset of symptoms, as well as the time from symptom onset to the first dose of prazosin, was longer in Group B compared to Group A. Group B experienced a shorter duration of PICU stay but a longer total hospital stay compared to Group A [Table/Fig-3].

Clinical parameters	Group A (n=26)	Group B (n=29)	p-value
Number (%) of children with abnormal pulse rate	6 (23%)	12 (41%)	0.952
Mean duration of abnormal pulse rate in Hours (range)	3.3 (0.5-7.5)	1.13 (1-16)	
Number (%) of children with hypertension	5 (19%)	6 (21%)	0.0291*
Mean duration of hypertension in hours (range)	1.9 (1-3.5)	4.2 (1-16)	
Number (%) of children with priapism	7 (26%)	14 (48%)	0.0917
Mean duration of priapism in hours (range)	6 (1-16)	4.6 (1-8)	
Number (%) of children with pulmonary involvement	4 (15%)	5 (17%)	0.2341
Number (%) of children with cardiac involvement	12 (46%)	19 (65%)	0.1602
Number of children with CNS involvement	0	4 (3 lethargy,1 irritable)	
Mean duration of PICU stay in days (range)	2.9 (1-4)	1.8 (1-4)	0.0009*
Mean duration of hospital stay in days (range)	1.16 (1-3)	3.5 (2-10)	0.0082*

[Table/Fig-3]: Comparison of clinical parameters (Group A vs Group B).
CNS: Central nervous system; PICU: Paediatric intensive care unit; *Statistically significant (p<0.05); Risk of bias assessment tool used- Cochrane RoB 2

The interval between the sting and the onset of symptoms was shorter in Group C compared to Group A. However, the time between the onset of symptoms and the first dose of prazosin was longer in Group C. Additionally, Group C had a longer duration of hypertension and a higher incidence of cardiac involvement compared to Group A [Table/Fig-4].

Clinical parameters	Group A (n=26)	Group C (n=31)	p-value
Number (%) of children with abnormal pulse rate	6 (23%)	10 (32%)	0.3213
Mean duration of abnormal pulse rate in Hours (range)	3.3 (0.5-7.5)	3.5 (1.5-16)	0.787
Number (%) of children with hypertension	5 (19%)	9 (33%)	0.0109*
Mean duration of Hypertension in hours (range)	1.9 (1-3.5)	4.6 (1-16) 1 hypotension	0.00041
Number (%) of children with priaprism	7 (26%)	16 (51%)	0.0967
Mean duration of priapism in hours (range)	6 (1-16)	5 (1-12)	0.265
Number (%) of children with pulmonary involvement	4 (15%)	6 (19%)	0.2531
Number (%) of children with cardiac involvement	12 (46%)	20 (64%)	0.1767
Number (%) of children with CNS involvement	0	0	
Mean duration of PICU stay in days (range)	2.9 (1-4)	1.3 (1-2)	<0.0001*
Mean duration of hospital stay in days (range)	1.16 (1-3)	2.2 (1-4)	0.0016*

[Table/Fig-4]: Comparison of clinical parameters (Group A vs Group C).
CNS: Central nervous system; PICU: Paediatric intensive care unit; * Statistically significant (p<0.05); Risk of bias assessment tool used; -Cochrane RoB 2

In present study, mean duration of abnormal pulse rate, the number (%) of children with priapism, mean duration of hospital stay, number (%) of children with cardiac involvement and the number of children with CNS involvement were found to be significant when comparing Group B and Group C [Table/Fig-5].

The children were monitored at regular intervals: at 30 minutes, one hour, one hour and 30 minutes, two hours, four hours, eight hours, 12 hours and 16 hours. Pulse rate, respiratory rate and blood pressure were measured to assess their status. It was noted that tachycardia, tachypnoea and hypertension were resolved earlier in Group C (90-30-30) children comparison to children of Group A (30-30-30) and Group B (60-30-30) [Table/Fig-6a-c].

DISCUSSION

Prazosin, dobutamine and Anti-Scorpion Venom (ASV) are the main ingredients in the treatment of scorpion sting envenomation.

Clinical parameters	Group B (n=29)	Group C (n=31)	p-value
Number (%) of children with abnormal pulse rate	12 (41%)	10 (32%)	0.642
Mean duration of abnormal pulse rate in hours (range)	1.13 (1-16)	3.5 (1.5-16)	0.00016
Number (%) of children with hypertension	6 (21%)	9 (33%)	0.655
Mean duration of hypertension in hours (range)	4.2 (1-16)	4.6 (1-16) 1 hypotension	0.498
Number (%) of children with priapism	14 (48%)	16 (51%)	0.00019
Mean duration of priapism in hours (range)	4.6 (1-8)	5 (1-12)	0.498
Number (%) of children with pulmonary involvement	5 (17%)	6 (19%)	0.051
Number (%) of children with cardiac involvement	19 (65%)	20 (64%)	0.000077
Number of children with CNS involvement	4 (3 lethargy, 1 irritable)	0	0.00018
Mean duration of PICU stay in days (range)	1.8 (1-4)	1.3 (1-2)	0.058
Mean duration of hospital stay in days (range)	3.5 (2-10)	2.2 (1-4)	0.015

[Table/Fig-5]: Comparison of clinical parameters (Group B vs Group C).
CNS: Central nervous system; PICU: Paediatric intensive care unit; * Statistically significant (p<0.05); Risk of Bias Assessment Tool Used- Cochrane RoB2

	30 min*	1 h	1.30 h**	2.0 h**	4 h**	8 h**	12 h**	16 h**
Group A (30-30-30) (N)								
Normal	19	19	22	23	22	23	23	23
Bradycardia	1	0	0	0	0	0	1	1
Tachycardia	6	7	4	3	4	3	2	2
Group B (60-30-30) (N)								
Normal	16	19	21	21	21	22	22	22
Bradycardia	2	1	1	1	1	1	1	1
Tachycardia	11	9	7	7	7	6	6	6
Group C (90-30-30) (N)								
Normal	22	22	24	24	29	29	30	31
Bradycardia	6	6	5	5	1	0	1	0
Tachycardia	3	3	2	2	1	2	0	0

[Table/Fig-6a]: Pulse rate of participants at different time intervals in the course of management between three groups.
*Minutes; **hours

	30 min*	1 h	1.30 h**	2 h**	4 h**	8 h**	12 h**	16 h**
Group A (30-30-30) (N)								
Normal	21	24	24	25	25	26	26	26
Tachypnea	5	2	2	1	1	0	0	0
Group B (60-30-30) (N)								
Normal	22	23	24	29	29	29	29	28
Tachypnea	7	6	5	0	0	0	0	1
Group C (90-30-30) (N)								
Normal	30	30	30	30	30	31	31	31
Tachypnea	1	1	1	1	1	0	0	0

[Table/Fig-6b]: Respiratory rate of participants at different time intervals in the course of management between three groups.
*Minutes; **hours

	30 min*	1 h**	1.30 h**	2 h**	4 h**	8 h**	12 h**	16 h**
Group A (30-30-30) (N)								
Normal	20	21	22	24	25	25	26	26
Hypertension	5	4	4	2	1	1	0	0
Hypotension	1	1	0	0	0	0	0	0
Group B (60-30-30) (N)								
Normal	23	23	24	25	28	29	29	29
Hypertension	6	6	5	4	1	0	0	0
Hypotension	0	0	0	0	0	0	0	0
Group C (90-30-30) (N)								
Normal	21	25	26	28	29	30	31	31
Hypertension	9	5	5	3	2	1	0	0
Hypotension	1	1	0	0	0	0	0	0

[Table/Fig-6c]: Blood pressure of participants at different time intervals in the course of management between three groups.
*Minutes; **hours

Bawaskar HS and Bawaskar PH compared the six-hour prazosin regimen with the 3-hour regimen (standard protocol) and reported better, uneventful recovery in the standard protocol group (94% vs. 53%). They also reported the prevention of pulmonary oedema by a standardised protocol [9]. In a previous study, it was observed that patients who received a higher dose of prazosin—either due to accidental administration of double or triple doses by caregivers or incorrect higher dosing prescribed by local practitioners—showed better outcomes [2]. Gupta BD et al., compared prazosin with dobutamine and found that prazosin was better at reducing recovery time and hospital stay [10]. Patil SN observed that if there was prazosin-resistant cardiotoxicity, dobutamine was lifesaving [11].

Bawaskar HS and Bawaskar PH compared the use of prazosin alone with prazosin with ASV serum and found that the ASV group did better [3]. Though theoretically and physiologically, ASV should be the mainstay of management, it may not be available in rural settings and in other places, the cost may be prohibitive. So, the present study compared the high dosage with the standard prazosin dosage to see whether doses can be escalated based on the severity of envenomation. Drug toxicity with high doses was a concern. Prazosin is known for its first-dose phenomenon, even at 30 µg/kg [12]. Hence, this was a major concern necessitating hourly monitoring of blood pressure and other vital parameters. There were only two children who had hypotension and that was at admission. It shows none of our children receiving standard or high doses had the first-dose phenomenon. Postural hypotension is one of the main manifestations of the first-dose phenomenon. However, since most children were lying down, they may not have exhibited symptoms.

The study had more children over five years old (56%) with male preponderance; the same was observed by other authors as well [11,12]. Survival was better in children over five years old [13]. Most stings occurred in the extremities in present study (70%). Head and neck involvement was rare and was predominantly observed in children below five years of age. Baseer KA and Naser MAA also reported head and neck involvement in only 2.6% of non survivors [13].

In present study, cases with a sting in the head or neck also had severe envenomation. They responded to high-dose Prazosin, even in children under five years old, without any toxicity. Neurological manifestations, which are a hallmark of severe toxicity, were observed in only four children in Group B. This group received Prazosin late, with a mean sting-to-Prazosin interval of eight hours, which likely contributing to the neurological manifestations. However, they responded well to an initial 60 µg/kg dose.

Ananda Kumar PM et al., noted that cardiac involvement was greater with a sting treatment interval of more than four hours and in those who presented with hypotension [14]. In this study, the sting treatment interval was longest in Group B and shortest in Group C; the difference from the A group was statistically significant. Cardiac involvement was seen more in the B and C groups than in Group A (64%, 65% and 46%, respectively), this was not statistically significant (p-value >0.05). Severe envenomation in Group B can be explained on the basis of a delay in treatment and a better outcome may be because of the high first dose.

The sting symptom interval was the shortest in Group C, indicating a high potency of toxin, but the sting treatment interval was the shortest and it may be that a high dose was useful Bawaskar HS and Bawaskar PH also reported that patients show a better response when treatment is administered early [15]. In a study by Natu VS et al., it was found that ASV serum resulted in better recovery compared to prazosin alone. However, in present study, it was observed that administering a high dose of prazosin led to early recovery, eliminating the need for additional ASV treatment [16].

In present study, none of the patients died, whereas mortality rates reported by various authors range from 1% to 10% [17,18]. These observations suggest that high-dose prazosin is effective in treating scorpion sting envenomation and is safe for use in children.

Limitation(s)

The limitations of this study are: small sample size (findings are not generalisable); potential examiner bias may occur since this was a single-blinded randomised study; and the study was not registered with the Clinical Trials Registry - India (CTRI).

CONCLUSION(S)

High-dose prazosin is effective in achieving quicker stabilisation and reducing the duration of PICU stay in paediatric scorpion envenomation cases compared to standard dosing. The incidence of complications such as hypertension and priapism was slightly higher with higher doses; however, no significant adverse events or mortality were observed, indicating the safety of escalated prazosin dosing. Early administration of prazosin, especially at higher doses, improves clinical outcomes, supporting its use as a primary intervention in severe envenomation cases. Future studies with larger sample sizes and a double-blinded design, with assessments for the long-term safety and efficacy of prazosin hydrochloride, are needed.

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PARTICULARS OF CONTRIBUTORS:

1. Junior Resident, Department of Paediatric, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.
2. Associate Professor, Department of Paediatric, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.
3. Associate Professor, Department of Community Medicine, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.
4. Professor, Department of Paediatric, Datta Meghe Institute of Higher Education and Research (DMIHER), Meghe, Sawangi, Wardha, Maharashtra, India.
5. Junior Resident, Department of Paediatric, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.
6. Assistant Professor, Department of Paediatric, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.
7. Assistant Professor, Department of Health Informatics, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.
8. Professor, Department of Paediatric, BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura, Karnataka, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Mallanagouda Patil,
BLDE (Deemed to be University), Shri B M Patil Medical College Hospital and Research Centre, Vijayapura-586103, Karnataka, India.
E-mail: mm.patil@bldedu.ac.in

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