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Original Research Article

The clinico-epidemiological profile and safety and effectiveness of polygeline in Indian patients presenting with hypovolemia: results from a prospective, multicentre, single-arm and open-label post-marketing observational study

Sanjay Shah[1], Ajai Singh[2], Krishnamurty[3], Sarang Vyawahare[4], Vijay Khandale[5], Kiran Chowan[6]*, Milind Bhole[6], Shivani Acharya[7], Rhutuja Rane[7]

[1]Apollo International Hospitals, GIDC Bhat Estate, Gandhinagar, Gujarat, India
[2]All India Institute of Medical Sciences, Bhopal, Madhya Pradesh, India
[3]Subharti Medical College and Hospital, Meerut, Subhartipuram, Meerut, Uttar Pradesh, India
[4]Ishwar Institute of Health Care, Padegaon, Aurangabad, Rajasthan, India
[5]Maeers Vishwaraj Hospital, Loni Kalbhor, Pune, Maharashtra, India
[6]Department of Medical Affairs, Abbott, Bandra (E), Mumbai, Maharashtra, India
[7]Department of Clinical Development and Operations, Abbott, Andheri East, Mumbai, Maharashtra, India

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***Correspondence:**
Dr. Kiran Chowan,
E-mail: kiran.chowan@abbott.com

ABSTRACT

Background: Severe trauma and acute fluid loss are major causes of hypovolemia, linked to high morbidity and mortality if untreated. Intravenous fluid resuscitation, including plasma volume expanders (PVEs), is essential for restoring intravascular volume and perfusion. Polygeline, a gelatine-based colloid, is widely used; however, Indian real-world safety and effectiveness data remain limited. Objectives were to describe the demographic and clinico-epidemiological profile of Indian patients with hypovolemia and to evaluate the effectiveness and safety of Polygeline 3.5% intravenous infusion in routine clinical practice.
Methods: This prospective, multicentre, open-label, post-marketing observational study enrolled 154 patients aged 18-65 years who received polygeline 3.5% IV infusion. Demographic and clinical characteristics were documented. Effectiveness was assessed by changes in hemodynamic parameters, urine output, respiratory rate, metabolic markers, pallor, and skin condition over 24 hours. Safety and tolerability were monitored throughout the study.
Results: Hypovolemia was equally attributed to traumatic and non-traumatic causes. Among traumatic cases, 46% were classified as class II hypovolemia and 4.7% as class III, while non-traumatic cases showed fewer moderate to severe presentations. Over 24 hours, significant improvements were observed in hemodynamic parameters: mean systolic blood pressure increased from 99.99 to 119.11 mmHg, diastolic pressure from 61.68 to 74.43 mmHg, pulse rate declined from 104.60 to 85.53 bpm, respiratory rate from 21.57 to 18.82 breaths/min, and urine output increased from 21.08 to 218.90 mL ($p<0.0001$). One non-serious adverse drug reaction (0.6%) was reported and resolved without intervention.
Conclusions: Polygeline 3.5% IV infusion demonstrated effective hemodynamic stabilization with a favourable safety profile in patients with hypovolemia of traumatic and non-traumatic origin.

Keywords: Hypovolemia, Polygeline, Plasma volume expander, Fluid resuscitation, Hemodynamic stabilization, Post-marketing observational study

INTRODUCTION

Severe traumatic injury represents a major global public health concern, accounting for more than 5 million deaths worldwide, with haemorrhage responsible for nearly half of these fatalities.[1] In India, physical trauma contributes to approximately 1.5 million deaths each year, with road traffic accidents accounting for the highest proportion, resulting in nearly 0.2 million deaths annually.[2,3] Trauma-related mortality is most frequently observed among individuals aged 15-30 years.[4] Accidental trauma commonly leads to hypovolemic shock through acute intravascular volume loss, resulting in compromised tissue perfusion and subsequent organ dysfunction.[2]

Intraperitoneal and intrathoracic bleeding represent major contributors to the development of hypovolemic shock, followed by substantial blood loss from long-bone fractures.[3] Hypovolemic shock is a potentially life-threatening condition, thus prompt identification and timely intervention are essential.[5] The condition arises from a circulatory failure due to heavy intravascular volume loss, resulting in tissue hypoperfusion and tissue hypoxia.[5] Without appropriate treatment, sustained hypoperfusion can progress to ischemic damage of vital organs and ultimately lead to multiorgan failure.[5] Intravenous (IV) fluid infusion therapy remains a cornerstone intervention for management of hypovolemia or haemorrhagic shock, since it primarily stabilizes the hemodynamic condition and prevents the coagulopathy.[6] PVEs are widely used in such emergency situations, including hypovolemia, haemorrhagic shock, and major surgery, due to their ability to restore circulating volume rapidly.[7] PVEs increase intravascular osmotic pressure, drawing interstitial fluid into the vascular compartment and thereby expanding blood volume.[8]

PVEs are classified as crystalloids or colloids.[7] Usually, isotonic crystallids are used in resuscitation of hypovolemic shock, like normal saline, Lactated Ringer's or balanced electrolyte solutions, and hypertonic saline like 3% saline in patients with head injuries, while colloids can be synthetic, semi-synthetic/natural, include hydroxyethyl starches (HES), dextrans, gelatine-based polypeptides, human albumin, and fresh frozen plasma.[7,9] Due to their high molecular weight, colloids largely remain within the intravascular compartment, generating oncotic pressure and providing more sustained plasma expansion compared with crystalloids.[10] This property allows colloids to correct colloid osmotic pressure effectively and makes them useful in volume replacement in intensive care, surgical patients, and following procedures such as coronary artery bypass grafting.[11-13]

Polygeline, a new age colloid, has been reported as an effective and well-tolerated option for correcting hypovolemia by a Cochrane review.[14] It is a modified gelatine preparation that is rapidly excreted in the urine due to its short half-life and hence has reduced toxicity.[15,16] However, the use of polygeline IV infusion in hypovolemic patients in real-world practices and data on its efficacy and safety specifically in hypovolemic shock remain limited.[10] Hence, a prospective, multicentre, open-label, non-comparative, post-marketing observational study was conducted to evaluate the efficacy and safety of polygeline 3.5% IV infusion in the management of hypovolemia in patients aged 18 years and above.

METHODS

Study design

This prospective, multicentre, single-arm, open-label, post-marketing surveillance study (CTRI/2025/01/078960; registered on January 17, 2025) evaluated the demographic and clinico-epidemiological profile of Indian patients with hypovolemia and assessed the safety and effectiveness of polygeline in its management. The study was conducted from January to August 2025 at five sites across diverse geographic regions in India.

The study was carried out in compliance with the International Council for Harmonization guidelines on Good Clinical Practice (ICH-GCP), applicable local regulatory standards, and the ethical principles of the Declaration of Helsinki. It also adhered to the New Drugs and clinical trials rules, 2019, established by the Ministry of Health and Family Welfare, Government of India, as well as relevant institutional standard operating procedures. Before study initiation, the protocol, informed consent documents, and any amendments were reviewed and approved by the appropriate ethics committee.

Patients

The inclusion criteria comprised patients aged 18 to 65 years presenting with class II or III hypovolemia secondary to haemorrhage (as per advanced trauma life support criteria for acute haemorrhage), prescribed IV polygeline at the investigator's discretion, and were willing to provide written informed consent, either personally or through a legally acceptable representative (LAR).

Patients were excluded if they had a known hypersensitivity to polygeline or any of its constituents; were pregnant or breastfeeding; had concomitant asthma; were unconscious; or were considered critically ill at the investigator's discretion. Patients who had received hydroxyethyl starch (HES), albumin, other gelatine-based products (such as gelofusine), or any other synthetic colloid were also excluded.

Study endpoints

This study aimed to evaluate the demographic and clinico-epidemiological profile of Indian patients with

hypovolemia, and to assess the safety and effectiveness of polygeline in its management.

The primary endpoint of the study was the assessment of clinico-epidemiological characteristics of the enrolled population (safety set), including demographics (age, sex, education, occupation) and clinical presentation, such as hypovolemia classification, volume of blood loss, and cause of hypovolemia.

The secondary (effectiveness) endpoints included mean changes from baseline in systolic blood pressure (SBP), diastolic blood pressure (DBP), respiratory rate, pulse rate, urine output, and pallor and skin condition at 6, 10, 14, 18, and 24 hours. Additional effectiveness endpoints included mean changes in arterial pH, bicarbonate levels, blood lactate, and anion gap at 12 and 24 hours compared to the baseline.

The exploratory endpoints included assessing the percentage of patients who received 500, 1000, 1500, 2000, or more than 2000 mL of polygeline; the percentage of patients who received crystalloids and the mean volume administered during polygeline treatment; the percentage of patients who were transfused with whole blood along with the mean volume transfused during polygeline therapy; and the distribution of patients with trauma versus non-trauma who received polygeline.

Safety outcomes encompassed the occurrence of adverse drug reactions (ADRs), other pharmacovigilance-relevant information (OPRI), serious ADRs and OPRI, as well as ADRs resulting in treatment discontinuation during the treatment with the polygeline 3.5% IV infusion.

Statistical analysis

As the primary objective of the study was descriptive-evaluating the clinico-epidemiological profile of patients with hypovolemia-no formal sample size calculation was performed. The study was conducted in 150 eligible patients. Based on prior studies of polygeline in hypovolemic patients, this sample size was considered adequate to achieve the study's primary objective.[2,3,10] To account for potential dropouts, a total of 154 subjects were enrolled.

All patients who received polygeline 3.5% IV infusion were included in the safety population. Patients in the safety population who completed at least one follow-up assessment were included in the intention-to-treat (ITT) population. The per-protocol (PP) population comprised patients in the ITT population who had data available up to 24 hours of follow-up and completed the study without major protocol deviations; this population was used for the effectiveness analysis.

Continuous variables for the primary, secondary, and exploratory endpoints were summarized using mean and standard deviation (SD). Categorical variables for the primary and exploratory endpoints were presented as counts and percentages (n [%]). Safety parameters were summarized using descriptive statistics (frequency [n] and percentage [%]). Changes in continuous outcomes (secondary endpoints) from baseline to follow-ups were analysed using paired t-tests at a 5% level of significance (two-sided). Mean, SD, and mean change were rounded to one decimal place. All statistical analyses were performed using SAS® Software (release 9.4).

RESULTS

Demographics and baseline characteristics

Patients disposition

A total of 154 hypovolemic patients were enrolled in the study. All enrolled patients received a baseline IV infusion of 3.5% polygeline, with the dose and infusion volume tailored to the estimated blood loss and overall clinical status. All patients completed at least one follow-up assessment; therefore, both the safety population and the ITT population consisted of 154 patients. Four patients withdrew consent and discontinued participation, resulting in a per-protocol (PP) analysis population of 150 patients.

Primary endpoint

The study enrolled 154 patients (male: female=115:39) with a mean (SD) age of 37.5 (12.8) years. Regarding educational status, 31.1% had completed secondary education, 26.7% were primary school pass-outs, and 19.3% were graduates. The most common occupation category was salaried employment (31.3%), followed by other occupations (20.0%) and manual workers (18.7%). The causes of hypovolemia were evenly distributed, with 77 patients (50.0%) each presenting with traumatic and non-traumatic aetiologies.

The causes of hypovolemia were evenly distributed, with traumatic and non-traumatic aetiologies each accounting for 50% of cases. Among traumatic cases, the majority were classified as class II hypovolemia, whereas non-traumatic cases showed fewer instances of moderate to severe hypovolemia. Traumatic causes were diverse, with polytrauma contributing the largest share (28 patients; 36.4%), followed by accident- and road-traffic-related injuries (17 patients; 22.1%) and traumatic brain injuries (12 patients; 15.6%). The remaining traumatic cases involved a wide range of limb, thoracoabdominal, pelvic, burn, crush, and mixed-injury presentations, each representing about 1.3% of the cohort. Among non-traumatic aetiologies, gastrointestinal fluid losses predominated-especially diarrhoea (42 patients; 54.5%) and diarrhoea with vomiting (10 patients; 13.0%)-with the rest attributed to sepsis, shock, metabolic derangements, and other isolated conditions. The demographic and clinico-epidemiological characteristics of the study population are summarized in Table 1.

Secondary effectiveness outcomes

Significant progressive improvement was observed across key hemodynamic parameters over 24 hours following baseline polygeline 3.5% IV infusion in patients with hypovolemia.

Compared to the baseline mean (SD) SBP level of 99.8 (26.8), the SBP levels increased significantly ($p<0.0001$) to 107.8 (21.5), 112.3 (16.8), 113.0 (14.0), 116.5 (13.2), and 119.1 (11.4) at 6, 10, 14, 18, and 24 hours, respectively (Figure 1). Similarly, compared to the baseline mean (SD) DBP level of 61.7 (17.01), the DBP levels increased significantly ($p<0.0001$) to 68.0 (13.6), 70.2 (11.8), 71.4 (9.5), 72.7 (9.7) and 74.4 (8.4) at 6, 10, 14, 18, and 24 hours, respectively (Figure 1).

The effect of polygeline 3.5% IV therapy was also evident in other vital parameters. Pulse rate declined steadily and significantly ($p<0.0001$) from a baseline mean (SD) of 104.8 (19.0) beats per minute (bpm) to 95.9 (14.7) bpm at 6 hours, and further to 85.5 (11.3) bpm at 24 hours, indicating a reduction in compensatory tachycardia. Respiratory rate demonstrated a modest but significant decrease ($p<0.0001$), declining from a baseline mean (SD) of 21.6 (3.1) breaths per minute to 20.4 (2.7) at 6 hours, and to 18.8 (2.9) breaths per minute at 24 hours, suggesting improved respiratory stability. Additionally, a significant improvement ($p<0.0001$) in renal perfusion and fluid balance was observed. Urine output increased markedly from a baseline mean (SD) of 21.4 (55.2) mL to 68.5 (56.8) mL at 6 hours, and further to 218.9 (174.8) mL at 24 hours (Table 2).

A similar pattern of improvement was observed in metabolic parameters, with progressive changes evident as early as 12 hours post-treatment. Arterial pH increased significantly ($p<0.0001$) from a baseline mean (SD) of 7.3 (0.1) to 7.4 (0.1) at 24 hours. Bicarbonate levels rose markedly ($p<0.0001$), increasing from a mean (SD) of 19.0 (4.1) mmol/L at baseline to 23.8 (3.8) mmol/L at 24 hours, indicating improved buffering capacity. Blood lactate levels, a key marker of tissue hypoperfusion, declined substantially ($p<0.0001$) from a baseline mean (SD) of 3.5 (2.4) mmol/L to 1.7 (1.4) mmol/L at 24 hours, reflecting enhanced oxygen delivery and reduced anaerobic metabolism. Likewise, the mean (SD) anion gap decreased significantly ($p<0.0001$) from 15.0 (6.8) mmol/L at baseline to 10.5 (4.7) mmol/L at 24 hours, consistent with resolution of metabolic acidosis (Table 2).

Over 24 hour observation period following administration of polygeline 3.5% IV, a progressive improvement in pallor grading was noted among 150 patients. At baseline, most patients classified as grade 1 (66%), while 31.3% were grade 0, and only a small proportion fell into grades 2 and 3. By 6 hours, proportion of patients with grade 0 pallor increased to 33.3%, rising further to 65.3% at 24 hours. Correspondingly, grade 1 pallor decreased from 66% at baseline to 32.7% at 24 hours. Grade 2 remained consistently low at 2% throughout the assessment period, and grade 3, initially observed in one patient at baseline, was no longer present after 1st hour of treatment (Figure 2).

A gradual improvement in skin condition was observed following administration of polygeline 3.5% IV. At baseline, most patients presented with cold skin (68.7%), while 16.7% had clammy skin and 14.7% had warm skin. These proportions remained relatively stable during the first 6 hours. However, from 10 hours onward, a clear shift was noted: the proportion of patients with clammy skin decreased from 16.7% to 4% at 24 hours, and cold skin declined from 68.7% to 52%. Concurrently, the percentage of patients with normal or warm skin increased, with normal skin rising from none at baseline to 1.3% at 6 hours and to 27.3% at 24 hours (Figure 3).

Exploratory outcome

Mean (SD) volume of polygeline administered was 647.7 (232.5) mL. The most commonly administered dose of Polygeline 3.5% IV was 500 mL, received by 103 patients (68.7%). A higher volume of 1000 mL was given to 45 patients (30.0%), reflecting its use in cases requiring greater volume expansion. Lower doses of 250 mL and 400 mL were administered to one patient (0.7%) each. Among the 150 patients treated with Polygeline 3.5% IV, 13 (8.7%) also received crystalloid therapy, with a mean (SD) crystalloid volume of 442.5 (122.8) mL. Additionally, only one patient (0.7%) required a blood transfusion as a supplementary intervention.

Safety and tolerability

Safety was assessed by monitoring and recording all ADRs and OPRIs and any events leading to discontinuation of treatment. A total of 1 ADR (0.6%) was reported during the study-anxiety, which was mild, non-serious, and assessed as having a probable/likely relationship with the study drug. No treatment was required, and the event resolved spontaneously during the study period. This ADR did not lead to discontinuation of the study drug. Overall, polygeline administration was found to be well-tolerated amongst Indian patients with hypovolemia.

Table 1: Clinico epidemiological profile and baseline characteristics of patients-safety population, (n=154).

Parameters	N (%)
Sex	
Male	115 (74.7)
Females	39 (25.3)

Continued.

Parameters	N (%)
Age (in years), mean (SD)	37.5 (12.8)
Height (cm), mean (SD)	166.4 (6.4)
Weight (Kgs), mean (SD)	65.0 (10.0)
BMI (Kg/m^2), mean (SD)	23.5 (3.3)
Volume of blood loss (ml), mean (SD)	19.8 (6.7)
Cause of hypovolemia	
Traumatic (T=77)	
Class II	70 (90.9)[#]
Class III	7 (9.1)[#]
Non-traumatic (NT=77)	
Class II	6 (7.8)[$]
Class III	2 (2.6)[$]
Education	
No formal education	2 (1.3)
Master degree	6 (4.0)
Not reported	26 (17.3)
Undergraduate university degree	29 (19.3)
Primary school	40 (26.7)
Secondary school	47 (31.3)
Occupation	
Business	4 (2.7)
Farmer	10 (6.7)
Worker	28 (18.7)
Other	30 (20.0)
Not reported	31 (20.7)
Job	47 (31.3)

*N=Number of patients in safety set, n=Number of patients with data available, T=Number of patients with traumatic aetiology, NT=Number of patients with non-traumatic etiology, percentages are calculated using 'N' as the denominator. #Percentages are calculated using 'T' as the denominator. $Percentages are calculated using 'NT' as the denominator, BMI-body mass index; SD-standard deviation.

Table 2: Mean (SD) vital and metabolic parameters over 24 hours, following polygeline administration-(PP set, n=150).

Time point-statistics	Pulse rate	Respirat-ory rate	Urine output	Arterial pH	Bi-carbonate levels	Blood lactate	Anion gap
Baseline (Day 0)-mean (SD)	104.8 (19.0)	21.6 (3.1)	21.4 (55.2)	7.3 (0.1)	19.0 (4.1)	3.5 (2.4)	15.0 (6.8)
6 hours after treatment-mean (SD)	95.9 (14.7)	20.4 (2.7)	68.5 (56.8)				
Mean (SD) change from baseline at 6 hours	-8.9 (14.2)	-1.2 (3.2)	47.1 (80.5)				
P value	<0.0001	<0.0001	<0.0001				
10 hours after treatment-mean (SD)	92.(13.2)	19.6 (2.7)	115.5 (66.8)				
Mean (SD) change from baseline at 10 hours	-11.9 (15.1)	-2.0 (3.3)	94.0 (97.6)				
P value	<0.0001	<0.0001	<0.0001				
12 hours after treatment-mean (SD)				7.4 (0.1)	22.2 (3.5)	2.1 (1.5)	12.3 (5.2)
Mean (SD) change from baseline at 12 hours				0.1 (0.1)	3.2 (3.6)	-1.4 (1.6)	-2.7 (4.9)
P value				<0.0001	<0.0001	<0.0001	<0.0001
14 hours after treatment-mean (SD)	90.0 (12.2)	19.4 (2.7)	140.6 (92.5)				
Mean (SD) change from baseline at 14 hours	-14.8 (16.9)	-2.2 (3.4)	119.2 (118.6)				
P value	<0.0001	<0.0001	<0.0001				
18 hours after treatment-mean (SD)	88.7 (11.9)	19.1 (2.7)	163.7 (116.3)				
Mean (SD) change from baseline at 18 hr	-16.1 (18.9)	-2.5 (3.7)	142.3 (140.6)				
P value	<0.0001	<0.0001	<0.0001				
24 hours after treatment-mean (SD)	85.5 (11.3)	18.8 (2.9)	218.9 (174.8)	7.4 (0.1)	23.8 (3.8)	1.7 (1.4)	10.5 (4.7)
Mean (SD) change from baseline at 24 hours	-19.2 (20.2)	-2.7 (4.0)	197.5 (198.0)	0.1 (0.1)	4.8 (4.3)	-1.8 (1.9)	-4.5 (6.2)
P value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

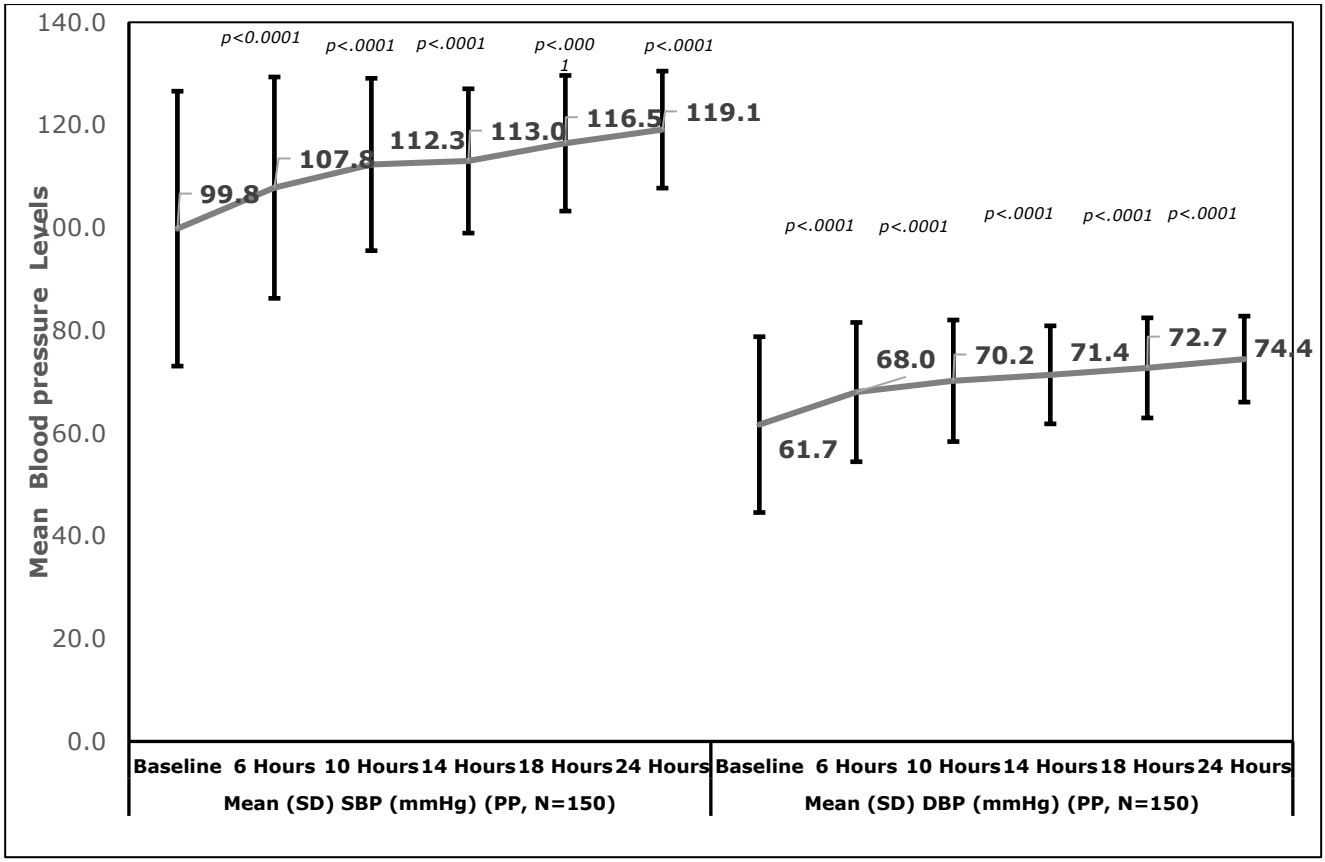

Figure 1: Mean (SD) blood pressure (Systolic and diastolic) levels over 24 hours, following polygeline administration-(PP set, n=150).

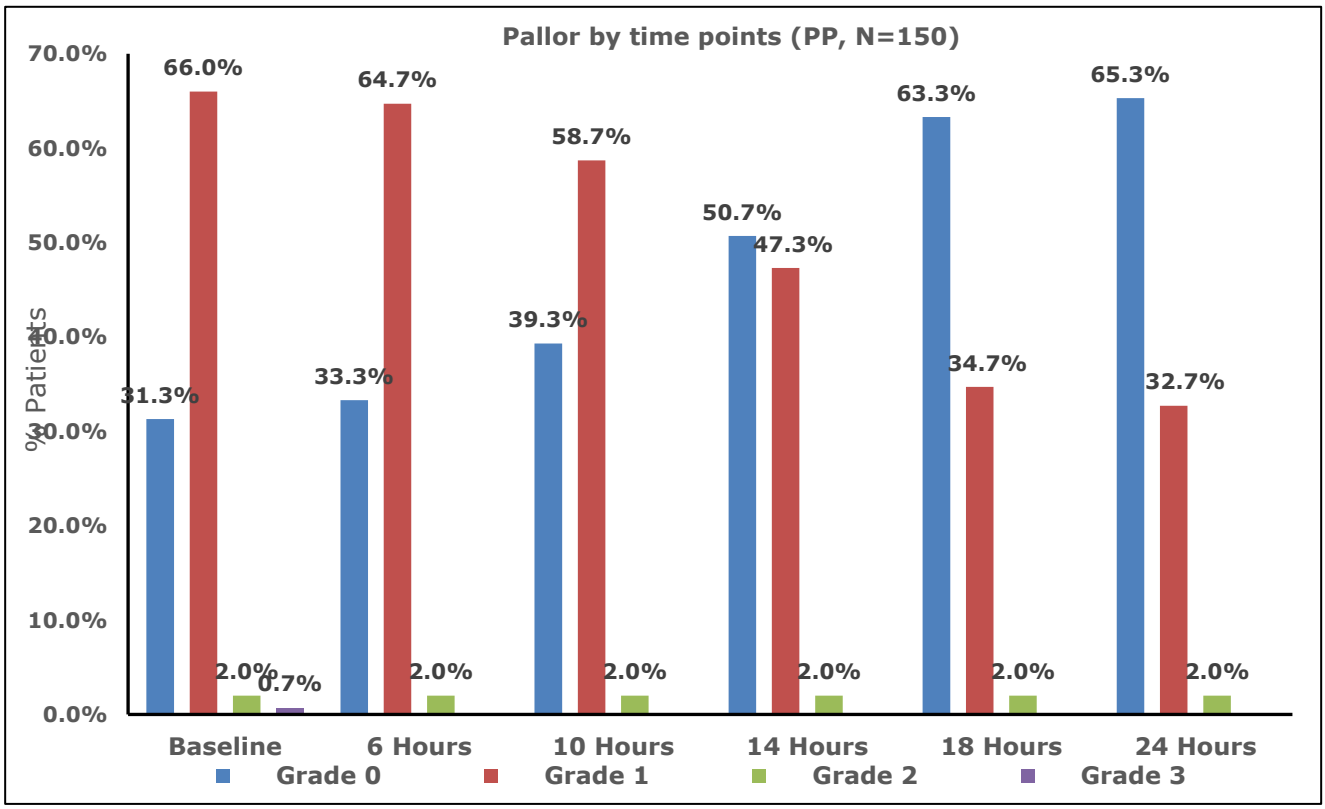

Figure 2: Clinical grading of pallor over 24 hours following polygeline administration-(PP set, n=150).

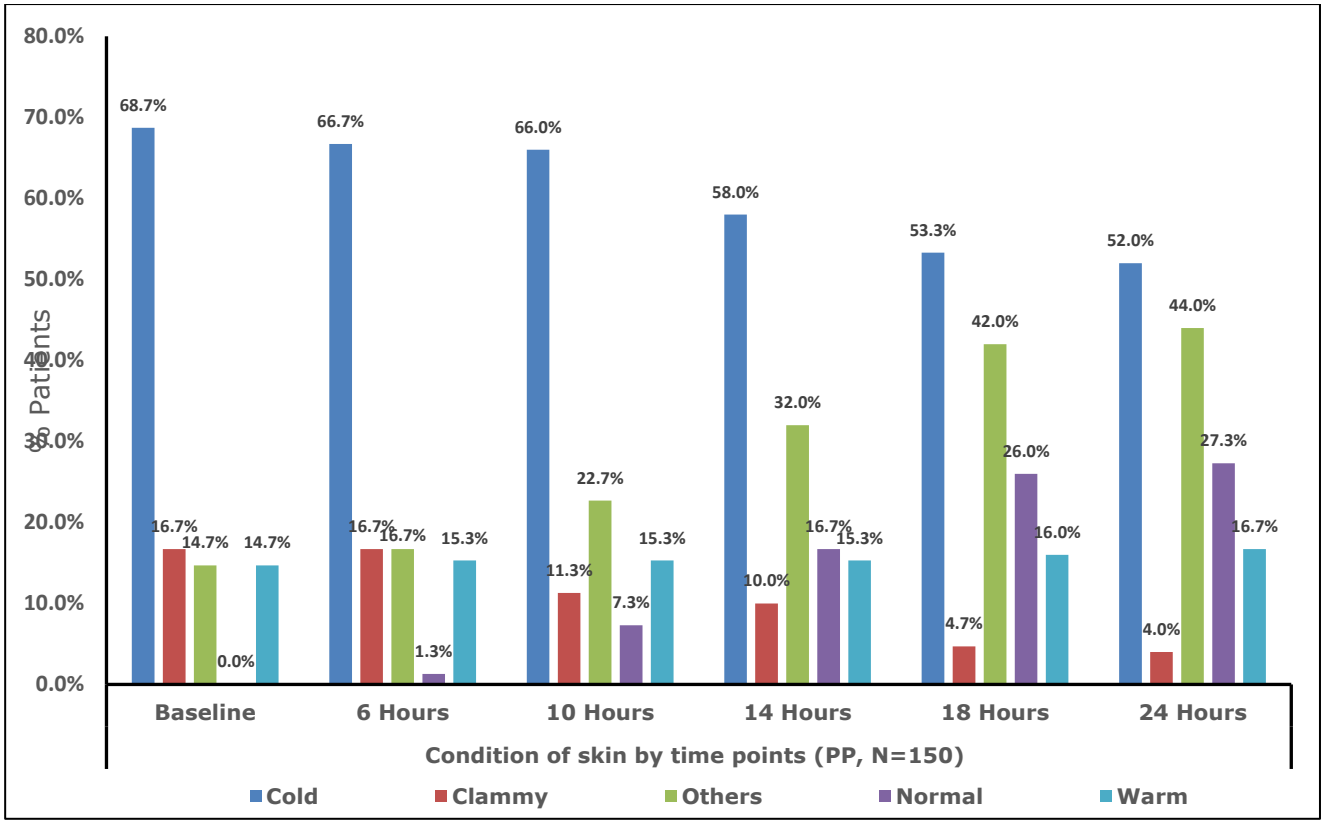

Figure 3: Condition of skin over 24 hours following polygeline administration-(PP set, n=150).

DISCUSSION

Traumatic injury remains a frequent occurrence in routine clinical practice, and severe trauma complicated by hypovolemia necessitates prompt medical intervention to prevent adverse outcomes.[10,17] In this context, fluid resuscitation constitutes a fundamental component of early management aimed at restoring intravascular volume and maintaining tissue perfusion.[10,17] Therefore, the present study aimed at investigating the effectiveness and safety profile of polygeline in Indian patients of hypovolemic shock aged 18 years or above.

The study population predominantly comprised young to middle-aged adults with a marked male preponderance. Hypovolemia was equally attributable to traumatic and non-traumatic etiologies. Traumatic hypovolemia was largely due to polytrauma and road-traffic injuries and was more frequently of moderate severity (Class II), whereas non-traumatic cases were mainly related to gastrointestinal fluid losses, particularly diarrhoea, and generally presented with milder severity.

The present study demonstrated a clinically meaningful improvement in hemodynamic parameters within 24 hours of polygeline 3.5% intravenous infusion in patients with hypovolemia. Systolic blood pressure increased from a low baseline mean of 99.8 mmHg to a near-normal value of 119.1 mmHg at 24 hours, with corresponding rise in DBP from 61.7-74.4 mmHg, indicating effective intravascular volume restoration. This improvement was accompanied by a progressive reduction in pulse rate from 104.8 bpm at baseline to 85.5 bpm at 24 hours, reflecting attenuation of compensatory tachycardia and stabilization of circulatory status. The findings are consistent with the earlier investigations reporting that polygeline administration leads to significant improvements in SBP, DBP, and mean arterial pressure, with pulse rate showing progressive stabilization over 6, 14, and 18 hours of treatment.[2,3,10]

Additional physiological stabilization was reflected by a significant reduction in respiratory rate from a baseline mean (SD) of 21.6 (3.1) breaths per minute to 20.4 (2.7) at 6 hours and 18.8 (2.9) at 24 hours. Improvement in renal perfusion and fluid balance was also evident, as urine output increased markedly from a baseline mean (SD) of 21.4 (55.2) mL to 68.5 (56.8) mL at 6 hours and further to 218.9 (174.8) mL at 24 hours. The results align with earlier reports showing a rapid improvement in respiratory rate within 1 hour of polygeline administration, with the effect maintained over 24 hours, along with an early and sustained increase in urine output following IV polygeline infusion.[10]

Metabolic parameters showed steady improvement beginning as early as 12 hours after treatment. Arterial pH increased significantly from a baseline mean (SD) of 7.3 (0.1) to 7.4 (0.1), while bicarbonate levels rose from 19.0 (4.1) mmol/L at baseline to 23.8 (3.8) mmol/L at 24 hours, indicating improved buffering capacity. Blood lactate levels declined markedly from a baseline mean

(SD) of 3.5 (2.4) mmol/L to 1.7 (1.4) mmol/L at 24 hours, reflecting improved tissue oxygenation and reduced anaerobic metabolism. In parallel, the mean (SD) anion gap decreased significantly from 15.0 (6.8) mmol/L at baseline to 10.5 (4.7) mmol/L at 24 hours, consistent with resolution of metabolic acidosis. Similar trends, including early increases in arterial pH within 1 hour and sustained reductions in blood lactate up to 24 hours, have been reported in previous studies.[10]

During the 24-hour observation period following polygeline 3.5% IV administration, a gradual and clinically relevant improvement in pallor grading was observed among the 150 patients. At baseline, the majority were categorized as grade 1 (66%), followed by grade 0 (31.3%), and the remaining patients in grades 2 and 3. The proportion of patients with Grade 0 pallor increased to 33.3% at 6 hours and further to 65.3% at 24 hours, accompanied by a corresponding reduction in grade 1 pallor to 32.7% at 24 hours. Grade 2 pallor remained low at 2% throughout the assessment period, while grade 3 pallor, observed in one patient at baseline, resolved within the first hour of treatment. An improvement in peripheral perfusion was also evident over the 24 hours, since the percentage of patients with clammy skin declined from 16.7% at baseline to 4% at 24 hours, while those with cold skin decreased from 68.7% at baseline to 52% at 24 hours, indicating progressive restoration of skin perfusion. The findings are consistent with previous investigations that demonstrated similar improvement in pallor, dehydration, and skin changes 6- and 24-hour post-treatment with polygeline blood transfusion.[3]

From a safety perspective, the findings reinforce the favourable tolerability profile of polygeline 3.5% IV in hypovolemic patients. A single ADR (0.6%)-anxiety, was observed, which was mild, non-serious, self-limiting, and did not necessitate treatment interruption or discontinuation. The observations are in line with earlier studies reporting good tolerability of IV infusion of polygeline, thereby strengthening existing evidence of its favourable safety profile in the management of hypovolemia among Indian patients.[10]

CONCLUSION

In conclusion, the findings of this study demonstrate that polygeline 3.5% IV infusion is effective in achieving hemodynamic stabilization within the first hour and maintaining it for up to 24 hours in patients with hypovolemia of both traumatic and non-traumatic origin. Treatment was associated with significant improvements in blood pressure, pulse rate, respiratory rate, urine output, and metabolic parameters, reflecting restoration of intravascular volume, improved tissue perfusion, and correction of metabolic derangements within 24 hours of administration. The observed improvements in clinical signs such as pallor and peripheral skin perfusion further support the overall physiological recovery following treatment. Importantly, polygeline was well tolerated, with only a single mild and self-limiting adverse drug reaction reported, and no treatment discontinuations. Taken together, these results reinforce the role of polygeline 3.5% as a plasma volume expander with a favourable safety and effectiveness profile for the management of hypovolemia in routine clinical practice, consistent with previously published evidence.

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