

Review Article

Polygeline: a comprehensive review of its role as a plasma volume expander in clinical practice

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ABSTRACT

Plasma volume expanders (PVEs) play a crucial role in emergency situations, such as trauma, shock, and major surgery, where rapid restoration of blood volume is essential. The choice between crystalloids and colloids as PVEs depends on various factors, including their pharmacokinetic properties. This review focuses on Polygeline, a synthetic colloid, and aims to discuss its development, physico-chemical properties, pharmacokinetics, clinical efficacy in different scenarios, safety profile, and its place in therapy. The development of polygeline dates to World War I, and its composition involves urea-linked gelatin, sodium chloride, and potassium chloride. The physico-chemical properties of polygeline, such as its average molecular weight, osmolality, and colloidal oncotic pressure, contribute to its unique characteristics, including prolonged intravascular presence and isotonicity with plasma. Compared to crystalloids like normal saline and Ringer's Lactate (RL), polygeline demonstrates a longer duration of action and higher maximum volume expansion, making it a valuable option in various clinical scenarios. The literature review includes studies on polygeline's clinical efficacy in critically ill patients, trauma cases, intra-operative use, haemodialysis, and large-volume paracentesis. Notable findings include its effectiveness in improving hemodynamic stability, especially in trauma patients, and its safe use in haemodialysis to lower catheter-related complications. The safety profile of polygeline appears favourable, with low incidences of anaphylactoid reactions and its safe administration in critically ill patients. In comparison to hydroxyethyl starch (HES), another synthetic colloid, Polygeline seems to have advantages in terms of safety, especially in patients with renal or hepatic impairment.

Keywords: Polygeline, Plasma volume expander, Colloids

INTRODUCTION

Plasma volume expanders (PVE) have proved to be lifesaving drug therapy in emergency situations including trauma, shock and major surgery. Trauma remains a leading cause of death worldwide, with approximately half of these attributed to haemorrhage. Annually, 60,000 people in the US and 1.9 million people in the world lose their lives due to haemorrhage and its consequences. Out of them, 1.5 million people die of physical trauma around the world each year.¹ India has one of the highest numbers of fatalities due to road accidents. In India, nearly 0.15

million people died in road traffic accidents in 2016.² A UK based trauma centre reported 62.2% of massive transfusions were required in the trauma division of the emergency department (ED). The other departments requiring blood products are cardiovascular surgery, critical care, cardiology, obstetrics, and general surgery.^{3,4} Critically ill people may lose fluid because of serious conditions, infections (e.g. sepsis), trauma, or burns, and need additional fluids urgently to prevent dehydration or kidney failure. Accidental trauma leads to hypovolemic shock, reduced intravascular volume and impaired tissue perfusion.²

PVEs increase the osmotic pressure of the intravascular compartment, which leads to the influx of the interstitial fluids through the capillary pore which, in turn, leads to the increase in the blood volume.⁵ PVEs are categorized as crystalloids or colloids. Crystalloids consist of solutions such as normal saline (NS), LR, normal plasma, glucose 5%, glucose 25%, and 3% saline. Colloids are grouped as synthetic, semi-synthetic or natural. Examples of synthetic colloids are HES, dextrans, gelatins [large polypeptides obtained by hydrolysis of collagen, with either succinylated (gelofusine) or urea cross-linked polypeptides. Human albumin and fresh frozen plasma (FFP) and types of naturally occurring colloids.⁶ These colloid solutions have different pharmacokinetic properties that may affect plasma expansion in different ways. All colloids have a larger molecular weight than crystalloids and do not cross the endothelium into the interstitial fluid easily. In summary, colloidal fluids stay in the intervacular space for longer than crystalloids, provide the benefit of rapid plasma expansion, and can correct colloidal osmotic pressure.⁷

Choice of plasma volume expander is usually based on the patient profile, efficacy, safety and clinical judgement. Despite the absence of clear recommendations for any particular fluid therapy, there is plentiful debate about the relative merits of crystalloid or colloid, and even about different types of colloids. The objective of this review article is not to compare colloid vs crystalloid but to review the current status of knowledge for one type of synthetic colloid, namely polygeline with a particular focus on its clinical efficacy and safety in different clinical scenarios. There have been more clinical studies including real world

studies on polygeline over recent years, and this review sheds a light on them.

DEVELOPMENT OF POLYGELINE: FROM WORLD WAR I TO CURRENT SCENARIO

Polygeline is a type of intravenous colloid that contains degraded gelatin used in the prevention or treatment of hypovolaemic shock associated with a reduction in adequate circulating blood volume due to haemorrhage, loss of plasma (burns, peritonitis, pancreatitis, crush injuries), or loss of water and electrolytes from persistent vomiting and diarrhoea.⁸ It can be used in extracorporeal circulation and as a carrier insulin solution during heart surgery. Although it is very effective as the sole volume expander, it is usually used in conjunction with a crystalloid, which has been shown both experimentally and clinically to increase its benefits.⁹

Composition

Polygeline is a modified gelatin solution prepared from cattle bone gelatin, thermally homogenised and crossed linked with hexamethylene diisocyanate (i.e. urea-linked gelatin).¹⁰ Polygeline is constituted of polygeline (35 g in 1,000 ml), sodium chloride (4.25 g in 500 ml) and potassium chloride (0.20 g in 500 ml). It has mean molecular weight of 30,000 Dalton.¹⁰

History

The history of polygeline goes back to World War I. Figure 1 depicts the journey of polygeline.

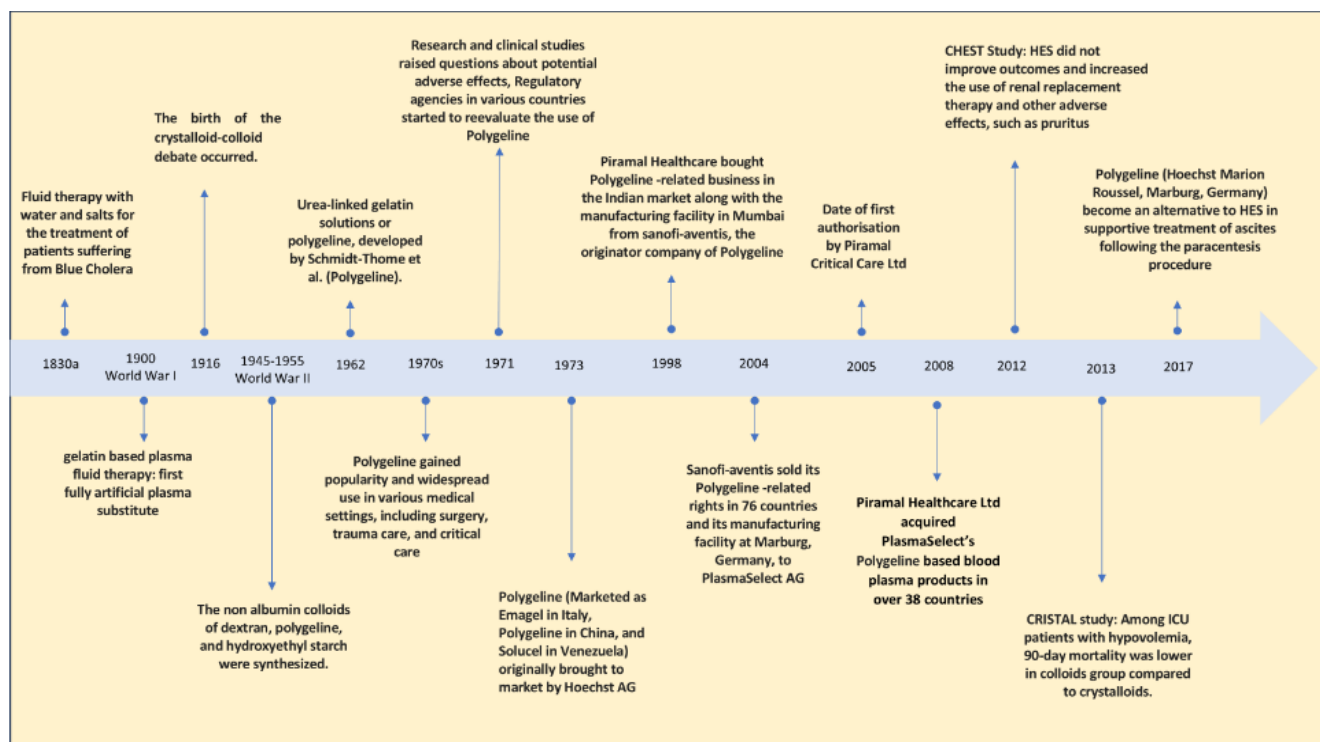


Figure 1: History of polygeline.¹¹⁻¹⁷

Physico-chemical properties

Polygeline has an average molecular weight of 35 kD, which is very low compared to HES (70-450 kD) which contributes to less side effects compared to HES. Compared to normal saline and RL, polygeline stays for a longer time in the intravascular compartment and has less chances of tissue oedema. With an osmolality of 300-350 and colloidal oncotic pressure of 25-42, polygeline is isotonic and iso-oncotic with plasma. Polygeline has a pH ~7.3 (similar to plasma), thus maintaining acid base balance, whereas the pH of HES (5.5) is less than the pH of plasma.

Pharmacokinetics

Polygeline is administered through intravenous infusion to facilitate its absorption. Upon administration, it undergoes metabolism, wherein proteolytic enzymes like trypsin, plasmin, or cathepsin break it down into smaller peptides and amino acids. The distribution and excretion of polygeline involve a mean half-life ($t_{1/2}$) of 5 hours, with approximately 74% excreted through the kidneys within four days of administration. Polygeline has a longer duration of action (4-6 hours) and plasma half-life (~2-9 hours) compared to NS and RL (duration=1-4 hours, $t_{1/2}$ =30 min). The elimination half-life of polygeline may be prolonged in individuals of advanced age and those with severely impaired renal function. Furthermore, the excretion process tends to be slower in patients experiencing blood loss compared to normal volunteers. This intricate interplay of absorption, metabolism, distribution, and elimination factors underscores the complex pharmacokinetics of polygeline in the human body.¹⁷ Maximum volume of expansion is highest with polygeline (70-80%), compared to both crystalloids NS and RL (both 20-25%) indicating less amount of Polygeline required compared to crystalloids. In patients with renal or hepatic impairment, polygeline can be safely used since it does not worsen renal or hepatic function. On the other hand, HES can worsen renal impairment in critically ill with existing renal impairment and can cause or worsen hepatic dysfunction.

METHODOLOGY OF LITERATURE REVIEW

A PubMed literature search was made of all the meta-analysis, clinical trials, observational studies and case reports using the following key words: gelatin-based colloid, polygeline, urea-linked gelatin, polygeline AND critically ill, resuscitation, shock, severe sepsis, septic shock, trauma, major surgery, kidney, renal, mortality, complication, anaphylactoid reactions, adverse, illness, renal replacement therapy. The review includes the use of polygeline in the following clinical scenarios: resuscitation phase of the adult critical patient with hypotension; maintenance fluid therapy; management of haemorrhagic shock; trauma patients. The literature search was limited to articles published in English, with no restrictions regarding

the time period covered. The full texts of most of the selected articles were retrieved.

CLINICAL EFFICACY IN CRITICALLY ILL/SHOCK

In 2009, Pohan et al reported an open, non-comparative clinical trial concluded polygeline colloid to be a safe and effective initial fluid treatment option for maintaining adequate fluid balance in adults with stage I-II dengue haemorrhagic fever (DHF).¹⁸ Haematocrit significantly reduced from baseline during the first 6 hours of fluid treatment, and this reduction was sustained over the 48-hour observation period. Another study involved patients undergoing intravenous fluid in restoration of circulating volume in children with septic shock.²⁹ The prospective, randomized, open-label trial showed that normal saline and gelatin polymer solutions were equally effective as resuscitation fluids in restoring plasma volume and achieving hemodynamic stability. In 1992, Stockwell et al showed no significant variations between the polygeline and 3.5% albumin group in the occurrences of pulmonary oedema or renal failure.²⁰

CLINICAL EFFICACY IN TRAUMA

In 2017, Singh et al presented retrospective analysis to study the effectiveness and safety of polygeline in adult patients with hypovolemia due to traumatic injury.²¹ It was a nonrandomized, noncomparative, retrospective data analysis. In results, the mean total polygeline administered was 1025.0±464.18 ml and blood transfusion were required in 3.33% of patients. Diastolic, systolic, and mean arterial blood pressure and pulse rate significantly increased after 1 h of polygeline administration ($p<0.0001$). The improvement in vital parameters was consistent at 6, 14, and 18 h after administration of polygeline. Arterial pH significantly increased from 7.2±0.12 to 7.3±0.11 after 1 h of administration ($p<0.0001$) and was consistent till 24 h ($p=0.035$). Blood lactate decreased after 1 h ($p<0.0001$). After a mean duration hospital stay of 10.5±4.63 days, all the patients were discharged without any clinically significant abnormality or adverse event. In conclusion, polygeline improved hemodynamic stability in patients with hypovolemia due to traumatic injury. The improvement was seen within 1 h (golden hour) of polygeline administration and maintained consistently. Polygeline can be safely administered to patients with traumatic injury to improve hemodynamic parameters and achieve stability.

In another prospective, multicentric, safety study given by Shah et al, polygeline was found to be safe and effective in improving hemodynamic stability in patients with hypovolemia due to accidental trauma.² Polygeline significantly improved all vital parameters (blood pressure and pulse rate), urine output and central venous oxygen saturation; reduced arterial pH and mean blood lactate levels.

In 2016, Singh et al evaluated effectiveness and safety of polygeline in adult patients with hypovolemia following traumatic injury.²² Overall improvement (reduction in HR and increase in BP) was seen in 97.92% patients. Symptomatic improvement in pallor, dry tongue, and skin changes at six and 24 hours was observed majority of the patients ($p < 0.0001$). Use of polygeline resulted in early and significant improvement in hemodynamic parameters.

INTRA-OPERATIVE USE

In 1998, Zhu et al assessed the impact of incorporating polygeline into the cardiopulmonary bypass solution during paediatric cardiac surgery.²³ In the polygeline group ($n=20$), no patients experienced allergic reactions or coagulation disorders, even when substantial amounts of polygeline (45 ml/kg) were used. This study demonstrated that polygeline could be employed as a component of the primary solution in place of plasma to maintain the desired plasma colloid oncotic pressure, potentially reducing the risk of infections associated with blood product transfusions and lowering costs for patients. In another study, explained by Davies involving 32 patients undergoing major vascular surgery, intra-operative haemodilution and autotransfusion were performed.²⁴ Polygeline was employed as the diluent and demonstrated effectiveness for this purpose.

In 2011, Kunwar et al presented a prospective comparative study to evaluate the efficacy of equal volume of RL versus 3.5% polymer of degraded gelatine solution as preloading fluid for prevention of hypotension after spinal anaesthesia for lower segment caesarean section.²⁵ In which patients were randomly allocated into group A and group B. Group A patients were preloaded with RL 10 ml/kg body weight and group B were preloaded with polygeline 10 ml/kg body weight within a period of 5-10 minutes before spinal anaesthesia. After giving the block, blood pressure (systolic, diastolic, and mean) was recorded after every 2.5 minutes for the initial 20 minutes and every 5 minutes during the rest of the period of surgery. Onset of hypotension, along with another parameter were recorded and analysed. In results, the episodes of hypotension were higher in patients who received RL as preloading fluid than those who received polygeline as preloading fluid (42% versus 24%). Hence, preloading with polygeline gives better hemodynamic stability and lesser incidence of hypotension than that of RL.

PLASMA EXPANDER FOR HAEMODIALYSIS

Polygeline has been employed as a plasma expander in haemodialysis for end-stage renal disease patients. A study by Buturović et al compared the effects of filling haemodialysis catheters with heparin, citrate, or Polygeline during interdialytic periods. During clinical trial, thirty end-stage renal disease (ESRD) patients with subclavian or jugular single lumen catheters as temporary vascular access for haemodialysis were enrolled. Patients treated with polygeline had lower catheter occlusion, clot

volume, infection, and fibrin sheath formation rates compared to patients treated with heparin or citrate.²⁶

FOR LARGE-VOLUME PARACENTESIS

Polygeline has been a useful plasma expander in patients with cirrhosis and ascites undergoing large-volume paracentesis (LVP). Polygeline helps mitigate paracentesis-induced circulatory dysfunction (PICD), which can cause BP drops, renal impairment, and hyponatremia.²⁷ A Cochrane study by Ginés et al demonstrated that polygeline is comparable to albumin, the standard plasma expander, in terms of hemodynamic effects, renal function, and mortality in LVP patients.²⁸ Similarly, Khan et al conducted a study comparing Polygeline to human albumin for plasma expansion during paracentesis in cirrhotic patients with ascites ($n=50$). The study found both solutions equally effective in maintaining blood pressure and kidney function, suggesting polygeline as a cost-effective alternative to albumin.²⁹

SAFETY PROFILE

The oldest safety data on polygeline can be dated back to 30-40 years. Although previous studies raised questions about potential adverse effect, this review highlights the most recent safety data of polygeline and advantage over other colloids and crystalloid solutions. The advantage of polygeline is its safe administration in critically ill patients, whereas, as per European medicine agency HES is contraindicated in critically ill patients and in patients with renal impairment, burns, and sepsis.³⁰ Furthermore, polygeline does not cause any pruritus as it does not get accumulated in the body or skin tissues, whereas HES is known to cause pruritus delayed in onset.

Polygeline can be used for maintaining fluid adequacy in critically ill patients stage I-II of DHF. All subjects tolerated Intravenous fluid treatment according to study protocol and no subject experienced life-threatening side effect or fluid overload (needed diuretics treatment) during observation. Out of 43 patients, 5 (10%) experienced sinus bradycardia and 2 subjects (4%) experienced sinus tachycardia. All these subjects were asymptomatic, stable and didn't need any special treatment. D-dimer was significantly increased, but there were no clinical symptoms observed.³¹

Other PVEs like hypertonic saline are contraindicated in all clinical settings except in patients with severe hyponatremia and neurologic sequelae. Rapid correction of hyponatremia may cause central pontine myelinolysis, a devastating neurologic condition. Crystalloids containing potassium (RL solution, Hartman's solution, etc.) are relatively contraindicated in patients with hyperkalaemia since these may exacerbate their condition, which in turn can lead to ventricular dysrhythmias whereas, crystalloids containing dextrose (D5%W, D10%W, D5% 0.45% NS, etc.) in patients with hyperglycaemia.³²

Anaphylactic reactions

The incidence of anaphylactoid reactions with polygeline is 0.03% (Blood transfusion: 0.2 -2%, penicillin's: 1-5%). HES leads to higher incidence of anaphylactoid reactions as compared to other synthetic colloids as well as albumin. Due to the observed improvement in the product, general premedication with histamine H1-and H2-receptor antagonists is not deemed necessary prior to administering polygeline to patients. However, for safety reasons, it is recommended for at-risk patients, including those with carcinoma, a history of allergic diathesis, or prior reactions to plasma substitutes.³³

Polygeline: effects on renal function

In patients with renal impairment, gelatines, such as polygeline, are safer alternatives for volume replacement, as they are excreted by the kidneys and induce osmotic diuresis without adverse effects. Thus, HES is not preferred in such cases since it can worsen renal dysfunction or cause transient acute renal failure, especially in patients with or at risk of kidney impairment.^{34,35} The 2001 Lancet study concluded that HES as a plasma-volume expander is an independent risk factor for ARF (odds ratio=2.32, 95% CI 1.02-5.34, p=0.028) in patients with severe sepsis or septic shock.³⁶

Polygeline: effects on hepatic function

Polygeline is not reported to cause hepatic dysfunction, whereas HES is known to cause or worsen hepatic dysfunction.^{35,36}

Polygeline: effects on coagulation and platelet function

Out of twenty patients, who were admitted for reduction mammoplasty and underwent a standardised anaesthesia protocol, ten patients received 500 ml polygeline (colloid) and 10 controls received 1,500 ml RL (crystalloid). The solutions were administered intravenously during surgery over a period of 30-40 minutes. Prothrombin time (PT), activated partial thromboplastin time (aPTT), thrombin time (TT) and platelet aggregation in response to adenosine diphosphate (ADP) and collagen were not affected by the plasma volume expander given. Arachidonic acid-induced aggregation decreased significantly after RL was given but did not change when polygeline was given. The bleeding time was prolonged slightly, but not significantly, from 7.4±1.6 minutes to 8.8±1.6 minutes with RL and from 6.9±2.0 to 9.7±3.7 minutes with polygeline.³⁷

Based on safety studies, polygeline does not influence coagulation and has no interference with blood group typing/cross-matching, while HES and dextran adversely affect coagulation and elevate risk of bleeding while also interfering with blood group typing and cross-matching.^{15,20,38}

Polygeline: effects on tissue deposition

Polygeline is excreted by kidneys and can be used without fear of any tissue deposition. HES is deposited in a variety of tissues, including skin, liver, muscle, spleen, intestine, trophoblast, placental stroma and reticuloendothelial system.^{36,48}

PLACE IN THERAPY

In critically ill patients, patients who experienced shock and those in hypovolemic shock, polygeline can be used for volume replacement.^{30,39} In trauma patients, polygeline as a resuscitative fluid can be used along with the other modalities for the management of hemodynamic instability in patients with hypovolemia due to traumatic injury.^{2,21,22} Improvement can be seen within 1 h (golden hour) of polygeline administration and maintained consistently. Intraoperatively, polygeline can be used as part of the cardiopulmonary bypass solution in cardiac surgery; intra-operative haemodilution for major vascular surgery; fluid resuscitation following coronary artery bypass grafting; intravenous fluids for body fluid management during abdominal aortic surgery.⁴⁰⁻⁴³ During anaesthesia, polygeline is used for prevention of hypotension after spinal anaesthesia for lower segment caesarean section; co-loading/pre-loading for prevention of hypotension after spinal anaesthesia; Isovolemic haemodilution in extensive head and neck surgery.^{25,44,45} For haemodialysis, use polygeline as a plasma expander in haemodialysis for ESRD. Polygeline demonstrates lower catheter occlusion, infection, and fibrin sheath formation rates compared to heparin or citrate.⁴⁶ For paracentesis procedures, polygeline is used as a plasma expander in patients with cirrhosis and ascites undergoing LVP.²⁷⁻²⁹

Polygeline should be administered intravenously in a volume approximately equal to the estimated blood loss. Normally, 500 ml will be infused in not <60 min but in emergencies, polygeline can be rapidly infused. Losses of up to 25% of blood volume can be replaced by polygeline alone. Polygeline has no upper limit of volume to be administered whereas a maximum of 1500 ml of HES can be administered (20 ml/kg). Furthermore, HES is not recommended to be administered for >24 hours.⁴⁷

Table 1: Indication-wise posology of polygeline.¹⁷

Indications	Posology
Hypovolaemic shock	Initially infuse 500-1,000 ml of polygeline up to 1,500 ml of blood loss can be replaced entirely by polygeline. Blood loss 1,500 ml-4,000 ml: fluid replacement should be with equal volumes of polygeline, and blood should be given separately. Blood loss >4,000 ml, the separate infusion should be in the ratio of 2 parts blood to one-part polygeline. The haematocrit should not be allowed to fall below 25%.

Continued.

Indications	Posology
Burns	At least 1 ml of polygeline be infused per kg of body weight, multiplied by the % of body surface burned for each 24 hours for two days. Additional crystalloid solutions should be given to cover the normal fluid loss, i.e., about 2,000 ml per 24 hours. In severe burns, additional protein and vitamin therapy may be required.
Plasma exchange	Polygeline should be given either alone or in combination with other replacement fluids in a volume adequate to replace the plasma removed. Up to 2 litres have been given as sole replacement fluid.

CONCLUSION

In conclusion, polygeline emerges as a synthetic colloid with promising clinical efficacy and a favourable safety profile. Its unique physico-chemical properties contribute to its sustained intravascular presence, making it a valuable option for plasma volume expansion. The physico-chemical properties of polygeline, such as its average molecular weight, osmolality, and colloidal oncotic pressure, contribute to its unique characteristics, including prolonged intravascular presence and isotonicity with plasma.

The reviewed literature supports its use in various clinical scenarios, including critically ill, hypovolemic shock, trauma, haemodialysis, and large-volume paracentesis. Polygeline's versatility in improving hemodynamic stability, along with its safety, positions it as a viable choice in fluid resuscitation strategies. The safety profile of polygeline appears favourable, with low incidences of anaphylactoid reactions and its administration is relatively safer for critically ill patients. In comparison to HES, another synthetic colloid, polygeline seems to have advantages in terms of safety, especially in patients with renal or hepatic impairment.

The comprehensive insights provided in this review aim to contribute to the current understanding of polygeline and encourage continued exploration of its clinical applications.

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