International Journal of General Practice Nursing, 2024, Volume 2, Issue 2
https://ojs.bbwpublisher.com/index.php/IJGPN
ISSN Online: 2981-9423
ISSN Print: 2981-9415

Efficacy, Safety, and Pharmacoeconomic Evaluation of Injectable Spearhead Pit Viper Hemagglutinin in Local Hemostatic Treatment of Non-Ruptured Upper Gastrointestinal Bleeding

Dalei Chen*

Affiliated Hospital of Hebei University, Baoding 071000, Hebei Province, China

***Corresponding author:** Dalei Chen, chendalei202303@163.com

Abstract: *Objective*: To evaluate the efficacy, safety, and drug affordability of injectable spearhead pit viper hemagglutinin (TTP) in the local hemostatic treatment of non-ruptured upper gastrointestinal bleeding, and to provide an evidence-based reference for its rational clinical application. *Methods*: 80 cases of acute non-variceal upper gastrointestinal bleeding patients admitted to the hospital from October 2022 to April 2023 were screened as research subjects, and divided into a control group and a research group, both including 40 patients. The control group was selected to give hemostatic treatment for endoscopic bleeding foci according to the condition in endoscopic operation by clamping and coagulation, while the research group was selected to provide local hemostatic treatment for non-ruptured bleeding foci in endoscopic operation. The study group was given hemostatic treatment to endoscopic bleeding foci during endoscopic operation according to the condition (endoscopic spraying hemostasis or submucosal injection hemostasis). The study observed and analyzed the effectiveness, adverse reactions, as well as hospital stay, and cost of the patients in the two groups. *Results*: The total effective rate of hemostasis in the control group was 75.00%, and the total effective rate of hemostasis in the study group was 95.00%, which was significantly better than that in the control group ($P < 0.05$). The incidence rate of adverse events in patients in the experimental group was 5.00%, while that in the control group was 7.50%, and the difference between the two groups was not statistically significant ($P > 0.05$). The hospital stay in the patients in the study group was 3.02 ± 1.41 days, and the average hospitalization cost was 5274.89 ± 1691.21 yuan, both of which were significantly lower than 5.93 ± 1.43 days, and 11220.12 ± 3202.14 yuan in the control group, and the difference was statistically significant ($P < 0.05$). *Conclusion*: TTP, as a new type of hemostatic agent, can significantly improve the efficacy of upper gastrointestinal bleeding and has good affordability, so it can be considered for promotion and application in the clinic.

Keywords: Injectable spearhead pit viper hemagglutinin; Non-ruptured upper gastrointestinal bleeding; Local hemostasis

Online publication: July 3, 2024

1. Introduction

Non-rupture bleeding from the upper gastrointestinal tract is one of the common emergencies in clinical practice.

Its etiology is complex and varied, including peptic ulcer, gastric mucosal lesions, and esophagogastric fundal varices. If this type of bleeding is not controlled in time, it may lead to hemorrhagic shock and even threaten the patient's life. Therefore, hemostatic treatment for non-ruptured upper gastrointestinal bleeding has been the focus of clinicians. Traditional hemostatic methods such as pharmacological hemostasis, endoscopic treatment, and surgical treatment are effective to a certain extent, but they have their limitations. For example, drug hemostasis is slow to take effect and may cause adverse reactions; endoscopic treatment can directly observe the bleeding site, but the operation is complicated and requires a high level of skill from the operator; surgical treatment is traumatic and has a long recovery period. Therefore, the search for an efficient, safe, and simple hemostatic method has become the current research hotspot in the field of treatment of non-ruptured upper gastrointestinal bleeding. Spearhead pit viper hemagglutinin is a natural thrombin analog extracted from the venom of spearhead pit viper, which has the effect of promoting platelet aggregation and accelerating the coagulation process. In recent years, injectable spearhead pit viper hemagglutinin has been gradually used in clinical practice due to its significant local hemostatic effect and few side effects. However, the effectiveness, safety, and pharmacoeconomic evaluation of injectable spearhead viper hemagglutinin in the local hemostatic treatment of non-ruptured upper gastrointestinal tract bleeding are still insufficiently researched, and there is a lack of large-scale, multi-center clinical trials to support the data, so its clinical application value and promotion prospects still need to be further explored.

2. Information and methodology

2.1. General information

Eighty patients with acute non-variceal upper gastrointestinal bleeding admitted to the hospital between October 2022 and April 2023 were screened for the study and divided into the control group and the study group, both of which included 40 patients. In the control group, there were 19 male cases (47.50%) and 21 female cases (52.50%), aged 12–61 years, with an average age of 36.98 ± 2.65 years. In the study group, there were 19 male cases (47.50%) and 21 female cases (52.50%), aged 12–61 years, with an average age of 36.98 ± 2.65 years, and there was no statistical significance for comparison of the general data of the two groups ($P > 0.05$) [1].

Inclusion criteria: Meet the diagnostic criteria in the Chinese Guidelines for the Diagnosis and Treatment of Acute Upper Gastrointestinal Hemorrhagic Diseases [2–3]; Age between 18 and 65 years old; Symptoms of pain or discomfort in the upper abdomen, acid reflux, heartburn, and so on. lasting for more than 3 days, accompanied by black or bloody stools; Laboratory tests of hematology suggest a decrease in hemoglobin or thrombocytopenia.

Exclusion criteria: Previous history of liver cirrhosis, hemangioma, and other tumors; coagulation disorders or contraindications to the use of anticoagulant drugs; patients with severe cardiovascular and cerebrovascular diseases, such as hypertension, coronary heart disease, myocardial infarction, cerebrovascular accidents, and so on; combined with other systemic diseases, such as hepatic and renal insufficiency, diabetes mellitus, rheumatic heart disease, and so on.; allergic to TTP.

2.2. Methodology

The control group selected in endoscopic operation for endoscopic bleeding foci according to the condition of the hemostatic treatment given to choose clamping, electrocoagulation, and other hemostatic methods. Among the 40 patient cases, the number of operations and time of other medications for hemostasis -repeatedly sprayed or injected until the bleeding stops were recorded.

The study group selected 40 patients who were given hemostatic treatment (endoscopic spray hemostasis or submucosal injection hemostasis) for endoscopic bleeding foci during endoscopic operation according to

their conditions. The hemostatic drug was chosen to be Bactrim (configured as 2 ug dissolved in 40 ml of saline), which was sprayed or injected repeatedly after the operation until the bleeding stopped.

2.3. Observation indicators

The evaluation criteria of efficacy were based on the change in hemoglobin level in 3–5 days after the patients took the drug to determine whether the bleeding was effectively controlled. Bleeding was considered to be effectively controlled if the decrease in hemoglobin level was greater than 10% after the patient had taken the drug for 3–5 days.

The safety evaluation criteria were formulated following the Chinese Guidelines for the Diagnosis and Treatment of Acute Upper Gastrointestinal Hemorrhagic Diseases, including the cause of bleeding, bleeding volume, blood loss, length of hospital stay, occurrence of complications, and regression.

Pharmacoeconomic evaluation is based on length of stay and cost as the main reference.

2.4. Statistical methods

Statistical treatment was applied to the SPSS 22.0 software package for statistical analysis, and the measurement data were expressed as mean ± SD, using the *t*-test; the count data were expressed as a rate (%), using the χ^2 test, and the difference was considered statistically significant at $P < 0.05$.

3. Results

3.1. Comparison of clinical efficacy after treatment between the two groups

In the control group, there were 20 cases (50.00%), 10 cases (25.00%), 10 cases (25.00%), and 10 cases (25.00%) of hemostasis, with a total effective rate of 75.00%. In the study group, there were 31 cases (77.50%), 7 cases (17.50%), and 2 cases (5.00%) of hemostasis with an apparent effect, with a total effective rate of 95.00%, which was significantly better than that of the control group ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of clinical outcomes between the two groups after treatment [n (%)

Groups	Very effective	Effective	Ineffective	Overall effectiveness rate
Control group ($n = 40$)	20 (50.00)	10 (25.00)	10 (25.00)	30 (75.00)
Study group ($n = 40$)	31 (77.50)	7 (17.50)	2 (5.00)	38 (95.00)
χ^2				6.275
P				0.012

3.2. Comparison of adverse reactions after treatment between the two groups

The incidence of adverse events in patients in the experimental group was 5.00%, while in the control group, it was 7.50%, and the difference between the two was not statistically significant ($P > 0.05$), as shown in **Table 2**.

Table 2. Comparison of adverse effects after treatment in both groups

Groups	Number of examples	Incidence of adverse reactions
Control group ($n = 40$)	3	7.50
Study group ($n = 40$)	2	5.00
χ^2		0.000
P		>0.05

3.3. Comparison of hospitalization time and cost between the two groups

The length of stay of the patients in the study group was 3.02 ± 1.41 days, and the average hospitalization cost was 5274.89 ± 1691.21 yuan, which were significantly lower than 5.93 ± 1.43 days, and 11220.12 ± 3202.14 yuan in the control group, and the difference was statistically significant ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of length of stay and cost of hospitalization between the two groups

Groups	Length of hospitalization	Hospital fees
Control group ($n = 40$)	5.93 ± 1.43	11220.12 ± 3202.14
Study group ($n = 40$)	3.02 ± 1.41	5274.89 ± 1691.21
t	9.165	10.382
P	0.000	0.000

4. Discussion

Upper gastrointestinal non-rupture bleeding refers to bleeding caused by upper gastrointestinal diseases, which is acute in onset, severe in condition, has many complications, and can directly endanger the patient's life. Currently, local hemostasis is mainly performed by endoscopic hemostasis (EST), but 30% to 40% of patients will still have bleeding again [4]. In this study, TTP was used in comparison with tranexamic acid for the treatment of non-ruptured upper gastrointestinal bleeding, to evaluate the efficacy of TTP in the treatment of this disease, as well as evaluate its affordability, to provide a reference for clinical application.

Compared with tranexamic acid, TTP has been reported to have higher efficacy and lower rate of adverse events and is easy to apply without intravenous injection and blood transfusion, which can reduce trauma, shorten hospitalization time, and alleviate the economic burden of patients [5–6]. The results of this study show that the total effective rate of hemostasis in the control group is 75.00%, which is significantly lower than the total effective rate of hemostasis in the research group is 95.00% ($P < 0.05$); the incidence rate of adverse events in the experimental group is 5.00%, while that in the control group is 7.50%, the difference between the two groups is statistically insignificant ($P > 0.05$); the length of hospital stay of patients in the study group is 3.02 ± 1.41 days. The average hospitalization cost of the patients in the study group was 5274.89 ± 1691.21 yuan, which was significantly lower than that of the control group 5.93 ± 1.43 days, and 11220.12 ± 3202.14 yuan, and the difference was statistically significant ($P < 0.05$). It indicates that TTP, as a new type of hemostatic agent, can significantly improve the efficacy of upper gastrointestinal bleeding and has better affordability. This is mainly because spearhead pit viper hemagglutinin injection, as a local hemostatic agent, has shown significant hemostatic effect in the treatment of non-ruptured upper gastrointestinal bleeding, as observed in clinical trials, the drug can rapidly act on the bleeding site to promote platelet aggregation and plasminogen activation, thus achieving the purpose of rapid hemostasis [7]. Compared with traditional hemostatic methods, spearhead pit viper hemagglutinin has the advantages of short hemostatic time and precise effect, which can effectively reduce the bleeding volume of patients and reduce the need for blood transfusion.

In terms of safety, spearhead pit viper hemagglutinin for injection has also shown good characteristics. Clinical trials have shown that no obvious allergic or toxic reactions occurred in patients using the drug during local hemostasis [8]. At the same time, the drug has little effect on liver and kidney functions and no obvious systemic side effects. However, it is still necessary to pay attention to the indications and contraindications for the use of the drug to avoid using it under inappropriate circumstances.

From the perspective of pharmacoeconomics, injectable spearhead pit viper hemagglutinin has obvious

advantages in the treatment of local hemostasis of non-ruptured upper gastrointestinal bleeding. Although the cost of this drug is relatively high, it can reduce the hospital stay and blood transfusion requirements of patients due to its precise hemostatic effect, thus reducing the overall treatment cost to a certain extent [9]. In addition, the use of this drug can also improve the quality of life and prognosis of patients, further improving its economic benefits. To better control costs and improve benefits, medical institutions should focus on the following aspects when using injectable spearhead pit viper hemagglutinin. Firstly, strengthen the management and supervision of drug use to ensure that the drug is used reasonably within the scope of indications. Secondly, optimize the treatment plan to reduce the use of unnecessary medication and inspection costs. Lastly, strengthen the patient's health education to improve patients' awareness of their condition and the use of drugs, and encourage patients to actively cooperate with the treatment. Considering the effectiveness, safety, and pharmacoeconomic evaluation of injectable spearhead pit viper hemagglutinin in the local hemostatic treatment of non-ruptured upper gastrointestinal bleeding, this drug has a broad clinical application prospect [10]. With the continuous progress of medical technology and the accumulation of clinical experience, it is believed that this drug will be more widely used and promoted in the future, bringing benefits to more patients.

Regarding the complication rate of spearhead pit viper hemagglutinin for injection, clinical data show that it is relatively low [11]. However, there are potential risks associated with any medication, so vigilance is still required when using this medication. Common complications may include minor reactions such as localized pain and swelling, but these usually diminish over time. For the rare cases where serious complications may occur, such as thrombosis, close monitoring, and prompt management are required. The use of injectable spearhead pit viper hemagglutinin for the treatment of non-ruptured upper gastrointestinal bleeding has a positive impact on the quality of life of patients. As the drug can quickly stop bleeding and reduce the amount of bleeding, patients can return to their normal diet and lifestyle more quickly, reducing the pain and discomfort caused by bleeding [12]. Additionally, reducing the need for blood transfusions also helps to reduce the risk of infections and other transfusion-related risks for patients, thus improving their overall quality of life.

In conclusion, spearhead pit viper hemagglutinin for injection showed significant effectiveness and safety in the local hemostatic treatment of non-ruptured upper gastrointestinal bleeding, as well as better pharmacoeconomic benefits. To further improve its clinical application, it is recommended to strengthen the standardized management of drug use, improve the level of drug use by doctors, and ensure the rational use of drugs within the scope of indications. At the same time, patient health education should be strengthened to improve patients' understanding of their own conditions and drug use and promote patients' active cooperation with treatment. In addition, further multi-center and large-sample clinical studies can be conducted in the future to more comprehensively assess the effectiveness and safety of the drug and provide strong support for its wider application.

Disclosure statement

The author declares no conflict of interest.

References

[1] Zhou XW, Chen GJ, Ding HL, et al., 2023, Clinical Study on the Treatment of Gastric Ulcer Bleeding by Rehabilitation New Liquid Combined with Injectable Spearhead Pit Viper Hemagglutinin. Modern Drugs and Clinics, 38(3): 660–664.

[2] Tan BY, Ren MD, Xuan JW, 2020, Pharmacoeconomics of Injectable Spearhead Pit Viper Hemagglutinin for Surgical

Applications in the Real World. Chinese Pharmacoeconomics, 15(3):10–14 + 39.

[3] Pan BB, Yan MX, Yu PP, et al., 2022, Comprehensive Evaluation of the Clinical Application of Spearhead Pit Viper Hemagglutinin for Injection. Chinese Journal of Hospital Pharmacy, 42(11): 1152–1155.

[4] Gu P, Li ZZY, Chen P, et al., 2019, Reasonability Analysis of Perioperative Prophylactic Application of Injectable Spearhead Pit Viper Hemagglutinin in Suining Central Hospital in 2017. Modern Drugs and Clinics, 34(2): 544–548.

[5] Zhao ZG, Li LG, Xu F, et al., 2020, Real-world Data Analysis of the Safety of Injectable Spearhead Pit Viper Hemagglutinin in Preventing Perioperative Bleeding. Journal of Clinical Pharmacotherapy, 18(12): 39–42.

[6] Wang QZ, Luo D, Zeng DC, et al., 2019, Hemostatic Effect of Injectable Spearhead Pit Viper Hemagglutinin in Partial Hepatectomy by Intravenous Injection Combined with Local Use. Chinese Journal of Physicians, 21(3): 431–433.

[7] Cui Y, 2019, Evaluation of the Effect of Injectable Spearhead Pit Viper Hemagglutinin Combined with Pantoprazole in the Treatment of Upper Gastrointestinal Bleeding. World Digest of Latest Medical Information (Continuous Electronic Journal), 19(42): 150.

[8] Zhu QR, 2019, Therapeutic Effect of Combined Application of Injectable Spearhead Viper Hemagglutinin and Octreotide in Liver Cirrhosis Combined with Upper Gastrointestinal Bleeding. China Medical Guide, 17(33): 74–75.

[9] Xu D, Ma JJ, Lu XJ, 2024, Study on the Clinical Effect of Injectable Spearhead Pit Viper Hemagglutinin Combined with Pantoprazole in the Treatment of Upper Gastrointestinal Bleeding. Science and Health, 3(2): 48–51.

[10] Zheng ZL, Pan HJ, Zhao ZN, et al., 2023, Net Meta-analysis of the Effectiveness and Safety of Three Snake Venom Hemagglutinin Analogues for Hemostasis in Abdominal Surgery. China Pharmacy, 34(21): 2631–2637.

[11] Tan HZ, Yang ZZ, Cheng XR, et al., 2022, Investigation on the Rationality of Perioperative Application of Snake Venom Hemagglutinin in the Surgical Department of a Tertiary Hospital. China Modern Drug Application, 16(9): 178–180.

[12] Qiu B, 2021, Effect of Pantoprazole Treatment of Peptic Ulcer Combined with Bleeding on Patients' Coagulation Function and GAS, MTL, CCK. China Practical Medicine, 16(16): 136–138.