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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

A clinical study of using a phentolamine alcohol wet dressing in the treatment of extravasation after a 20% fat emulsion intravenous infusion – a randomised trial

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SUMMARY

Introduction/Objective The aim of our paper was to investigate the clinical efficacy of using a phentolamine alcohol wet dressing to treat the extravasation of an intravenously administered infusion of milk fat. This study was designed as a randomized trial, and was done at the Hengshui people's Hospital, Hebei Province, China, from June 2019 to June 2020.

Methods In total, 300 patients were randomly divided into two groups. In the experimental group, the patients were treated using a phentolamine alcohol wet dressing, whereas in the control group, the patients were treated using a hydropathic compress with a 50% magnesium sulphate solution. The cure rate, healing time, and patient satisfaction of the two groups were compared and analyzed.

Results The cure rate of intravenous infusion extravasation was 92.67% (139/150) in the experimental group and 70.67% (106/150) in the control group ($p < 0.05$). In the experimental group, there were 66 patients whose cure time was less than 24 hours, 62 patients whose cure time was between 24 and 48 hours, and 22 patients whose cure time was over 48 hours. The cure time of the patients was significantly shorter in the experimental group than the control group. After treatment, in the experimental group, 67 patients were very satisfied, 52 patients were satisfied, 21 patients were generally satisfied, and 10 patients were dissatisfied; in the control group, 32 patients were very satisfied, 40 patients were satisfied, 56 patients were generally satisfied, and 22 patients were dissatisfied. The satisfaction of patients was significantly higher in the experimental group than in the control group.

Conclusion The effect of using a phentolamine alcohol wet dressing to treat the extravasation of an intravenous infusion of milk fat is significantly better than the effect of using a magnesium sulphate solution, and this type of dressing is worthy of clinical application.

Keywords: phentolamine alcohol wet dressing; magnesium sulphate solution; fat emulsion extravasation; cure rate; patient satisfaction

INTRODUCTION

Preface fat emulsion is an intravenously administered nutrition drug, and it is widely used in clinical practice [1, 2]. However, skin damage is common due to its high concentration and high permeability, and extravasation is a common complication that affects drug absorption [3, 4, 5], destroys the integrity of skin and tissue, and causes obvious pain [6, 7]. A detachable hydropathic compress is a new kind of wet compress method, which could effectively dilate blood vessels, improve blood circulation and reduce local pain.

Extravasation of intravenous infusion is relatively common in the clinic, and although the injury site is limited, the skin damage is severe. In recent years, the drug wet dressing method can partially improve the puncture effect because of its full drug action and strong absorbability. However, the traditional wet dressing method is complicated to operate and the steps are cumbersome. In addition, intravenous infusion puncture is affected by the physicochemical properties of the drug, which increases the risk of tissue damage. Phentolamine alcohol wet dressing can restore local blood supply and oxygen as soon as possible, improve microcirculation, reduce the occurrence of skin necrosis and improve the efficiency of wet dressing; reduce the risk of deterioration and failure of the drug during transportation and external environmental changes, prevent the volatilization of the drug and ensure the therapeutic effect [8, 9, 10]. At present, there are few clinical studies concerning the use of a phentolamine alcohol wet dressing to treat extravasation resulting from a milk fat intravenous infusion. Therefore, this study recruited 300 patients with extravasation following an intravenous infusion of milk fat at the Hengshui People's Hospital to investigate the clinical effect of using a hollow detachable hydropathic compress to treat the extravasation.

METHODS

Subjects

Between June 2019 and June 2020, patients with extravasation caused by the intravenous infusion of 20% fat emulsion were recruited for the

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study. The patients were divided into two groups. In the experimental group, patients were treated with a phentolamine alcohol wet dressing. In the control group, the patients were treated with a hydropathic compress with 50% magnesium sulphate solution. The cure rate, cure time, and patient satisfaction in the two groups were compared. All the participants signed informed consent forms, and the study was approved by the ethics committee of Hengshui People's Hospital (No: AF/SC-08/02.0).

Randomization and blinding

The randomization was conducted by an independent person who managed the randomization list, so the investigators and physicians involved in the trial had no access to this list. SPSS Statistics for Windows, Version 19.0 (IBM Corp., Armonk, NY, USA) was used to generate a random allocation sequence, and 300 patients were randomly divided into a control group and a treatment group in a 1:1 ratio, with 150 patients in each group.

The experimental group was treated with a phentolamine alcohol wet dressing, and the control group was treated with a 50% magnesium sulphate solution. It was not possible to blind both the person performing the intervention and the subject during the intervention. However, it was designed to be evaluator-blinded in order to control for bias as much as possible. The participants were evaluated by researchers who had not performed the intervention or randomization.

Inclusion and exclusion criteria

Inclusion criteria: (1) patients with extravasation caused by the intravenous infusion of 20% fat emulsion, and (2) patients older than 18 years.

Exclusion criteria: (1) patients with extravasation caused by the intravenous infusion of other drugs, (2) patients with advanced malignant tumors, and (3) patients with incomplete case data.

Experimental methods

Control group: the gauze was half spread over a kidney basin, and 20 mL of 50% magnesium sulphate was poured on top, infiltrating the gauze. The gauze was then compressed onto the infusion extravasation and squeezed with tweezers until there was no excess water liquid. The site of the extravasation was covered, with care being taken to avoid the puncture point, twice a day, for 20 minutes each time.

Experimental group: the phentolamine alcohol wet dressing consisted of a non-woven fabric drug layer, a waterproof and breathable layer, and a protective layer. The drug layer was soaked with 1 mL phentolamine injection and 5 mL 75% alcohol. The protective layer was the largest and the drug layer the smallest.

The protective layer itself had three layers, comprising an inner film, a thermal insulation layer, and a packaging layer. The thermal insulation layer was between the inner film and the packaging layer, and the edge of the packaging layer was connected to the edge of the inner film by hot pressing. There was an anti-allergic medical tape inside the waterproof and breathable edge, and the phentolamine alcohol wet compress was sterilized using an ethylene oxide sterilizer before use. During use, the protective layer was placed on the affected area and fixed with the anti-allergic medical tape with care being taken to avoid the puncture point. The site of the extravasation was covered twice a day, for 20 minutes each time.

Main outcome measures

The main observation indicators of this study were sex, age, cure rate, healing time, patient satisfaction, and the numeric rating scale (NRS) score for pain, which was used before, in the middle, and at the end of the treatment. Treatment effect categories: wet dressing efficiency, patient satisfaction, patient pain score, and healing time of puncture site.

The treatment effect was observed after six hours of treatment in both groups. (1) The specific criteria for clinical efficacy were as follows: remarkable effect meant that local soft tissue swelling subsided, and redness, swelling, heat and pain completely disappeared; valid meant that local tissue swelling reduced, redness, swelling, pain significantly relieved, and no burning; and invalid meant that local tissue redness, swelling, heat and pain did not subside, skin color did not change, and even blisters and necrosis appeared. The total effective rate was remarkable effect + valid/ remarkable effect + valid + invalid × 100%. (2) The Digital Analog Self-Rating Scale worked as follows: a straight line was divided into 10 equal segments, and the degree of pain was evaluated from 0 to 10 points. A circle was drawn around the number describing the most severe pain in the previous 24-hour period. The total score was 10 points with mild pain scoring 1–3 points, moderate pain 4–6 points, severe pain 7–9 points, and extremely severe pain scoring 10 points. Thus, the lower the score, the milder the pain. (3) The cure time was measured as follows: the starting point was when the intervention measures were begun after the extravasation, and the endpoint was the complete disappearance of the clinical symptoms of intravenous infusion extravasation.

Statistical analysis

SPSS Statistics for Windows, Version 19.0, was used for statistical analysis. Continuous variables of normal distribution were expressed as mean ± standard deviation, and discontinuous variables were expressed as frequency [percentage (%)]. The t-test was used for the group comparisons, and the χ^2 test was used for countable data. A value of $p < 0.05$ was considered statistically significant.

Ethics approval statement

All the participants signed informed consent forms, and the study was approved by the ethics committee of the Hengshui People's Hospital (No: AF/SC-08/02.0).

RESULTS

General information

This study consisted of 155 males and 145 females, aged 18–81 years, who were randomly divided into an experimental group (n = 150) and a control group (n = 150). There were no significant differences in age, sex, weight, body mass index, treatment method, and type of disease between the two groups (both p > 0.05) (Table 1).

Table 1. Demographic characteristics

Index	Experimental group (n = 150)	Control group (n = 150)	p
Age (year, Mean ± SD)	37.1 ± 8.7	36.5 ± 6.8	0.174
Sex [male, n (%)]	71 (47%)	76 (50.6%)	0.094
Weight (kg)	76.8 ± 10.2	79.2 ± 11.1	0.105
Body mass index	23.1	21.7	0.099
Treatment method	0.063		
Surgical treatment	115	107	
Non-surgical treatment	35	43	
Type of disease	0.079		
Chronic intestinal obstruction	69	61	
Mesenteric ischemia	43	50	
Crohn's disease	18	16	
Perioperative nutrition supplement	20	23	

The cure rate of extravasation of an intravenous infusion

The cure rate of extravasation of an intravenous infusion was 98% (147/150) in the experimental group, and this was significantly higher than in the control group 86.7% (130/150) (p < 0.05) (Table 2).

Table 2. The cure rate of two groups

Variables	Experimental group	Control group	X^2/t	p
Cure rate	147 (98%)	130 (86.7%)	1.63124e^{-6}	< 0.05
Remarkable effect	66	59		
Effective	81	71		
Invalid	3	20		

The cure times

In the experimental group, there were 66 patients whose cure time was less than 24 hours, 62 patients whose cure time was 24–48 hours, and 22 patients whose cure time was more than 48 hours. In the control group, the cure time was less than 24 hours in 32 cases, 24–48 hours in 51 cases, and more than 48 hours in 67 cases. The cure time of patients in the experimental group was significantly shorter than it was in the control group (Table 3).

Table 3. The cure time of two groups

Group	< 24 h	24–48 h	> 48 h	Effective rate within 48 hours
Control group	66	62	22	128 (85.3%)
Experimental group	32	51	67	83 (55.3%)
X^2				6.07511e-6
p				< 0.05

Pain

The average NRS of the patients in the experimental group was 3.6 before treatment, 5.9 during treatment, and 7.1 after treatment. In the control group, the mean NRS was 1.1 before treatment, 4.1 during treatment, and 5.2 after treatment. No significant difference in the degree of pain was found between the two groups (Table 4).

Table 4. The numeric rating scale (NRS) score of two groups

Group	NRS score after hydropathic compress
Control group	1.8
Experimental group	4.2
t	7.2922
p	< 0.05

Patient satisfaction

In the experimental group, 67 patients were very satisfied after treatment, 52 patients were satisfied, 21 patients were generally satisfied, and 10 patients were dissatisfied. In the control group after treatment, 32 patients were very satisfied, 40 patients were satisfied, 56 patients were generally satisfied, and 22 patients were dissatisfied. The satisfaction of patients was higher in the experimental group than in the control group (Table 5).

Table 5. The satisfaction of two groups

Group	Very satisfied	Satisfied	Generally satisfied	Dissatisfied	Total satisfaction
Control group	67	52	21	10	140 (93.3%)
Experimental group	32	40	56	22	128 (85.3%)
X^2					0.024806937
p					< 0.05

DISCUSSION

The outcomes showed that the extravasation cure rate of intravenous infusion in the experimental group was significantly higher than that in the control group. The cure time of patients in the experimental group was significantly shorter than that in the control group. The satisfaction of patients increased in the experimental group when compared to the control group.

Phentolamine is a kind of alpha-receptor blocker, which can dilate blood vessels and improve blood circulation [11], while dopamine is a vasoconstrictor. An extravasation of

dopamine can lead to vasoconstriction of extravasated skin tissue and skin tissue necrosis [12, 13]. Phentolamine can antagonize the vasoconstriction of dopamine, dilating the blood vessels of local extravasated skin, improving blood circulation, and relieving pain, which is the only drug approved for vasopressin extravasation [14]. Although phentolamine is considered the standard for extravasation in current treatment protocols, it is often used with greater limitations [15].

Alcohol is a vasodilator, so it can dilate blood vessels in local tissue and improve blood circulation [16, 17]. A hydropathic compress of alcohol has an anesthetic effect on local tissues and nerves, thus reducing the pain suffered by patients. Furthermore, alcohol is a bacteriostatic drug, which can prevent local tissue infection and reduce local reaction [18].

It was found in this study that the hollow design was effective in preventing a skin infection, which can be caused by a hydropathic compress, at the puncture site, and the hollow design also increased the suction and viscosity around the site. The detachable design reduced the amount of labor associated with the daily moving of the wet compress, and the replacement was more convenient. Although the hydropathic compress position was relatively fixed, its effect was improved. The combination of these two methods effectively dilated blood vessels, improved local blood circulation, and reduced the contractile effect of dopamine on blood vessels and the degree of tissue damage. It also effectively reduced the skin pain at the exudation [19, 20], prevented local infection, reduced the healing time, and improved the satisfaction of patients.

Limitations: First, there was no blind method in this study. Second, there was only a small sample size, and so a further trial with a larger sample size is needed. Finally, the specific mechanism of a phentolamine alcohol wet dressing used to treat an extravasation of a milk fat intravenous infusion is still not clear, and, thus, further study is needed.

CONCLUSION

The effect of a phentolamine alcohol wet dressing in the treatment of an extravasation of an intravenous infusion of milk fat is significantly better than that of using a magnesium sulphate solution, and such a dressing is worthy of clinical application.

What this paper adds
What is already known on this subject

An extravasation of an intravenous infusion is a common complication and affects drug absorption. At present, there are few clinical studies concerning the treat extravasation resulting from a milk fat intravenous infusion.

What this study adds

The effect of a phentolamine alcohol wet dressing in the treatment of an extravasation of an intravenous infusion of milk fat is significantly better than that of using a magnesium sulphate solution.

The combination of a hollow design and a detachable design effectively dilated blood vessels and improved local blood circulation.

Clinical registration number: researchregistry6867
https://www.researchregistry.com/browse-the-registry#home/

Conflict of interest: None declared.

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Клиничка студија о коришћењу влажног завоја са фентоламин-алкохолом у лечењу екстравазације после интравенске инфузије са 20% масне емулзије – рандомизовано истраживање

Фу Јуан-Вej, Лиу Џен-Јуан

Народна болница Хенгшуи, Прво одељење рехабилитационе медицине, провинција Хебеј, Кина

САЖЕТАК

Увод/Циљ Циљ рада је био да се испита клиничка ефикасност употребе влажног завоја од фентоламин-алкохола за лечење екстравазације интравенски примењене инфузије млечне масти. Ова студија је осмишљена као рандомизовано испитивање и рађена је у народној болници Хенгшуи, провинција Хебеј, Кина, од јуна 2019. до јуна 2020.

Методе Укупно 300 болесника је насумично подељено у две групе. У експерименталној групи болесници су лечени влажним завојем од фентоламин-алкохола, док су у контролној групи болесници лечени хидропатском облогом са 50% раствором магнезијум-сулфата. Упоређени су и анализирани стопа излечења, време излечења и задовољство болесника из две групе.

Резултати Стопа излечења екстравазације интравенском инфузијом била је 92,67% (139/150) у експерименталној групи и 70,67% (106/150) у контролној групи ($p < 0,05$). У експерименталној групи било је 66 болесника чије је време излечења било мање од 24 сата, 62 болесника чије је време излечења било између 24 и 48 сати и 22 болесника чије је време излечења било дуже од 48 сати. Време излечења болесника било је значајно краће у експерименталној групи него у контролној групи. Након лечења, у експерименталној групи 67 болесника је било веома задовољно, 52 болесника су била задовољна, 21 болесник је био генерално задовољан, а 10 болесника је било незадовољно; у контролној групи 32 болесника су била веома задовољна, 40 болесника је било задовољно, 56 болесника је било генерално задовољно, а 22 болесника су била незадовољна. Задовољство болесника је било значајно веће у експерименталној групи него у контролној групи.

Закључак Ефекат употребе фентоламин-алкохолног влажног завоја за лечење екстравазације интравенске инфузије млечне масти значајно је бољи од ефекта употребе раствора магнезијум-сулфата, а ова врста завоја је вредна клиничке примене.

Кључне речи: фентоламин-алкохолна влажна облога; раствор магнезијум-сулфата; екстравазација масне емулзије; стопа излечења; задовољство болесника