

# Effect of Diosmin Tablets Combined with Mayinglong Shexiang Hemorrhoid Ointment on Wound Healing, Edema and Anal Function after Mixed Hemorrhoid Surgery

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## Sun: Diosmin Tablets with Mayinglong Shexiang Hemorrhoid Ointment for Hemorrhoid Surgery

The objective of the study is to explore the effect of diosmin tablets combined with Mayinglong Shexiang hemorrhoid ointment on wound healing, edema and anal function after mixed hemorrhoid surgery. 98 patients were divided into 2 groups single and compound medication group, each of 49. Single group used diosmin tablets while the compound group used diosmin tablets combined with Mayinglong Shexiang hemorrhoid ointment. The total effective rate of medication, visual analogue scale score, wound healing, edema score, anal function and adverse drug reactions were compared between the two groups. The total effective rate (93.88 %) in the compound group was significantly higher than 79.59 % in the single group ( $p < 0.05$ ). The visual analogue scale score, bleeding score, wound healing time, and edema score was lower in the compound group than that in the single group ( $p < 0.05$ ). The anorectal pressure in the composite group was higher than that in the single group, and the Wexner score was lower than that in the single group ( $p < 0.05$ ). There was no significant difference in the adverse drug reaction rate between the two groups ( $p > 0.05$ ). Diosmin tablets combined with Mayinglong Shexiang hemorrhoid ointment has a good effect on postoperative recovery of mixed haemorrhoids which can effectively improve edema, relieve pain, and also has good effect on improving anal function of patients. The drug is safe and worthy.

**Key words:** Diosmin tablets, Mayinglong Shexiang hemorrhoid ointment, drug safety

Mixed hemorrhoids refer to a hemorrhoid disease in which internal hemorrhoids and external hemorrhoids coexist. Its clinical symptoms include anal pain, anal itching, painful stools and bleeding. The pathogenesis of mixed hemorrhoids is relatively complicated, mainly including long-term constipation causing anal varicose veins, hemorrhoids formation and sedentary inactivity which causes perianal muscle relaxation thereby increasing the risk of anal varicose veins and haemorrhoids. Improper diet increases the pressure around the anus and the risk of hemorrhoids, Pregnancy leads to hemorrhoids, congenital inheritance, obesity, etc.,<sup>[1]</sup>. The incidence of mixed hemorrhoids is usually higher than that of young people due to the influence of multiple factors such as decreased intestinal function, body tissue relaxation, and hormones in the elderly<sup>[2]</sup>. Pregnant women are also prone to mixed hemorrhoids because of the hormone secretion in

the body and the compression of blood vessels around the anus by the enlarged fetus. Surgical treatment is usually the main treatment method for more serious mixed hemorrhoids. Although surgery can effectively solve the condition of hemorrhoids, postoperative treatment is also very important. At present, postoperative treatment of mixed hemorrhoids is mainly through drug therapy. Postoperative medication for mixed hemorrhoids is mainly divided into Chinese and Western medicine. This study combines Chinese and Western medicine, which is more innovative than other studies. Most studies mainly assess two aspects, pain and edema. This study includes anal function as an observation indicator, which is innovative. Since pain and edema are symptoms, and anal function can truly reflect the effect of drugs, in this study Western medicine and traditional Chinese medicine were compared to reveal which medicine is more effective, that has a

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guiding significance for clinical medication. Drugs of postoperative treatment of mixed hemorrhoids include painkillers, analgesics, antibiotics, wound healing drugs, hemorrhoid drugs, drug sitz baths, etc. In this study, diosmin tablets and Mayinglong Shexiang hemorrhoid ointment, which are commonly used in clinical practice, were selected as research drugs. Diosmin tablet is an active drug for blood vessels, which can strengthen the venous and lymphatic return and improve microcirculation by promoting the function of the local venous vessel wall. In the treatment of hemorrhoids, diosmin tablets promote the reflux of the hemorrhoid veins, achieve the purpose of shrinking the hemorrhoids, and also reduce the bleeding of internal hemorrhoids. After mixed hemorrhoid surgery, the surgical wound and the preserved skin bridge are prone to edema, which can lead to wound pain and unnatural contraction of the anus. Therefore, diosmin tablets are often the first choice. Mayinglong Shexiang hemorrhoids ointment belongs to external medicine. Its main ingredients include musk, sulfur, burnet, borneol, gallnut, gentian, *flavescens*, peppermint oil and other Chinese herbal medicines. After mixed hemorrhoid surgery, due to surgical trauma and hemorrhoids, the anus can easily cause swelling, pain, itching and other problems. So, Mayinglong Musk hemorrhoid ointment is often used clinically. Both diosmin tablets and Mayinglong Shexiang hemorrhoids ointment have different pharmacological mechanisms and different effects. Therefore, the comparative study of both the drugs as a compound and a single drug can provide a reference for clinical medication.

## MATERIALS AND METHODS

### Research data:

98 patients were selected for this study from the

mixed hemorrhoid surgery patients who were admitted to the General Hospital of Shaoxing Second Hospital from January 2020 to January 2023. According to the type of medication, all the patients were divided into compound medication group (referred to as compound group) and single medication group (abbreviated as single group), with 49 patients in each group. The single medication group was given 3 tablets, twice a day after breakfast and dinner<sup>[3]</sup> while the compound group was given diosmin tablets along with Mayinglong Shexiang hemorrhoid ointment 2 times daily, for 7 d<sup>[4]</sup>. There was no significant difference in basic information such as average age, disease, and clinical stage of the two groups of research subjects ( $p>0.05$ ) (Table 1).

### Inclusion criteria:

Patients with mixed hemorrhoids who underwent surgical treatment in our hospital; patients having normal anal structure and basic functioning; patients with no allergic reactions; good tolerance to diosmin tablets and Mayinglong Shexiang hemorrhoid ointment and patients who were familiar with the purpose of this study and signed informed consent were included in this study.

### Exclusion criteria:

Patients having other anorectal, heart, liver, kidney diseases and other functional diseases; patients with mental illness; AIDS patients and pregnant or lactating patients were excluded in this study.

### Medication method:

**Single group:** Oral diosmin tablets (Nanjing Zhengda Tianqing Pharmaceutical Co., Ltd., production batch number: H20058471, 0.45 g×24 tablets/box) were given to this group. Usage and dosage included 3 tablets, twice a day after breakfast and dinner.

**TABLE 1: COMPARISON OF BASIC DATA BETWEEN THE TWO GROUPS ( $\bar{x}\pm s$ )**

Group (n=49)	Average age (y)	Average duration of disease (y)	Clinical stage (number of cases)	
			III	II
Compound	47.26±1.25	5.02±0.31	29	20
Single	47.32±1.26	5.01±0.31	30	19
$\chi^2$	0.0892	0.0813	0.0836	0.0812
p	>0.05	>0.05	>0.05	>0.05

**Compound group:** Mayinglong Musk hemorrhoid ointment (produced by Mayinglong Pharmaceutical Group Co., Ltd., production batch number: Z42021920; production specification: 4 g×8 sticks/box) was applied on the basis of single group. Usage and dosage included 2 times daily, for 7 d. Patients were directed to squeeze out an appropriate amount of ointment and apply it around the anal wound, fix and cover the wound with sterile gauze and adhesive tape; the sterile gauze should be soaked with magnesium sulphate.

#### Research indicators and evaluation criteria:

**Drug effectiveness:** The drug effect is divided into 4 levels, which included cure, markedly effective, effective, and ineffective level. Cure level implied disappearance of pain, edema, hemorrhoids, etc., completely and wound heals completely. Significantly effective level indicated shrinking of the hemorrhoids by >75 % with no pain, edema and the wound basically heals. In effective level, pain symptoms are relieved, edema disappears and the hemorrhoids shrink by 50 %-75 %, and the wound is partially healed. While in ineffective level, pain, edema, hemorrhoids and other symptoms are not effectively improved, and the wound healing is not ideal or ulcerated.

Drug effective rate =  $\frac{\text{cure rate} + \text{marked rate} + \text{effective rate}}{\text{total}}$

**Wound condition:** Pain assessment of the wound was studied using the Visual Analogue Scale (VAS) scale. Higher pain scores indicated greater pain severity.

**Bleeding score:** Bleeding score standard design included range of 0-10 points. Where, 0 points indicated no bleeding; 1 point indicated very little bleeding from the wound; 2 points indicated <10 drops of blood during defecation and 3 points implies >10 drops of blood during defecation or jet bleeding.

**Wound healing:** Two indicators namely, wound healing time and granulation growth time were observed. The shorter the wound healing time and the shorter the granulation growth time, the better is the wound healing.

**Edema score:** The severity of hemorrhoidal edema was divided into 4 grades. Grade 1 means no edema; grade 2 means mild, edema which is <0.5 cm from the surgical incision and <0.5 cm to the skin; grade 3 means moderate, edema is

0.5 cm-1 cm from the surgical incision and <1 cm higher than the skin; grade 4 is severe, >1 cm from the surgical cut surface, and >1 cm above the skin. The edema scoring standard is set as 0 points for grade 1; 1 point for grade 2; 2 points for grade 3 and 3 points for grade 4.

**Anal function:** Anal function mainly examines two indicators, one is anorectal pressure, and the other is scoring anal function using the Wexner scale. The anorectal pressure is measured by the digestive tract pressure detector and the solid-state pressure sensor catheter to measure the Maximum Systolic Pressure of the Anal Canal (MSPAC), the Diastolic Pressure of the Anal Canal (DPAC), the Resting Pressure of the Anal Canal (RPAC) and the Length of the High Pressure Zone of the Anal Canal (LHPZAC). The greater the three pressure values and the shorter the length of the anal canal high pressure zone, the better the anal function; the lower the Wexner score, the better is the anal function.

#### Statistical analysis:

The statistics and analysis of the data in this study used Statistical Package for the Social Sciences (SPSS) 22.0 software, and  $p < 0.05$  was considered statistically significant.

## RESULTS AND DISCUSSION

The drug effective rate of the compound group was studied which was found to be 93.88 %. It was significantly higher than that of the single group (79.59 %) ( $p < 0.05$ ) (Table 2).

Wound condition was studied, which included pain score, bleeding score, wound healing, edema score and anal function.

Pain score was studied using VAS score of the composite group and it was significantly lower than that of the single group at 2, 4, and 6 d after operation ( $p < 0.05$ ) (Table 3).

Bleeding score was studied in which the compound group showed significantly lower score than that of the single group ( $p < 0.05$ ) (Table 4).

Further, the wound healing time and granulation growth time of the composite group were also significantly lower than those of the single group ( $p < 0.05$ ) (Table 5).

Similarly, the edema score of the compound group was significantly lower than that of the single

group ( $p < 0.05$ ) (Table 6).

Anal function was also studied. After medication, the index values of anal function in the composite group were better than those in the single group ( $p < 0.05$ ) (Table 7).

Before medication, there was no significant difference in the Wexner score of anal function between the two groups ( $p > 0.05$ ). After medication,

the Wexner score of anal function in the compound group was significantly lower than that in the single group ( $p < 0.05$ ) (Table 8).

The incidence of adverse drug reactions was studied. The compound group denoted 10.2 %, and while the single group was 8.16 %, and there was no significant difference between the two groups ( $p > 0.05$ ) (Table 9).

**TABLE 2: COMPARISON OF EFFECTIVE RATES OF DRUGS ( $\bar{x} \pm s$ , NUMBER OF CASES)**

Group	n	Cure	Markedly effective	Efficient	Invalid	Drug effectiveness
Compound	49	22	19	5	3	93.88 %
Single	49	12	21	6	10	79.59 %
$\chi^2$						1.295
p						<0.05

**TABLE 3: COMPARISON OF WOUND PAIN SCORES ( $\bar{x} \pm s$ , POINTS)**

Group	n	VAS		
		2 d after surgery	4 d after surgery	6 d after surgery
Compound	49	4.89 $\pm$ 1.21	2.43 $\pm$ 0.98	1.18 $\pm$ 0.56
Single	49	6.02 $\pm$ 1.31	3.97 $\pm$ 1.18	2.52 $\pm$ 0.89
t		1.875	2.628	4.239
p		<0.05	<0.05	<0.05

**TABLE 4: COMPARISON OF BLEEDING SCORES ( $\bar{x} \pm s$ , POINTS)**

Group	n	Bleeding score		
		2 d after surgery	4 d after surgery	6 d after surgery
Compound	49	1.47 $\pm$ 0.28	0.86 $\pm$ 0.12	0.42 $\pm$ 0.08
Single	49	1.76 $\pm$ 0.29	1.34 $\pm$ 0.19	1.02 $\pm$ 0.13
t		1.842	2.476	4.729
p		<0.05	<0.05	<0.05

**TABLE 5: COMPARISON OF WOUND HEALING ( $\bar{x} \pm s$ , d)**

Group	n	Wound healing time	Granulation growth time
Compound	49	11.27 $\pm$ 1.76	5.38 $\pm$ 1.25
Single	49	16.36 $\pm$ 2.13	9.15 $\pm$ 1.88
t		2.392	3.127
p		<0.05	<0.05

**TABLE 6: COMPARISON OF EDEMA SCORES ( $\bar{x} \pm s$ , POINTS)**

Group	n	Edema score		
		2 d after surgery	4 d after surgery	6 d after surgery
Compound	49	1.62 $\pm$ 0.26	1.14 $\pm$ 0.18	0.75 $\pm$ 0.09
Single	49	1.98 $\pm$ 0.32	1.57 $\pm$ 0.25	1.09 $\pm$ 0.11
t		1.887	1.963	2.412
p		<0.05	<0.05	<0.05

**TABLE 7: COMPARISON OF INDICATORS OF ANAL FUNCTION ( $\bar{x}\pm s$ )**

Group	n	Time	MSPAC (mmHg)	DPAC (mmHg)	RPAC (mmHg)	LHPZAC (cm)
Compound	49	Before medication	102.63±9.89	71.52±7.48	48.23±3.38	3.09±0.21
		After medication	121.46±11.25 <sup>b1</sup>	168.54±15.86 <sup>b1</sup>	56.28±4.78 <sup>b1</sup>	2.54±0.19 <sup>b1</sup>
Single	49	Before medication	102.58±9.91	71.49±7.47	48.24±3.39	3.08±0.21
		After medication	11253±10.65 <sup>b</sup>	142.62±13.85 <sup>b</sup>	52.31±4.36 <sup>b</sup>	2.82±0.2 <sup>b</sup>

Note: <sup>b</sup>p<0.05 and <sup>b1</sup>p<0.05, relative comparison before and compared with the single group

**TABLE 8: WEXNER SCORE OF ANAL FUNCTION OF TWO GROUPS OF PATIENTS ( $\bar{x}\pm s$ , POINTS)**

Group	n	Wexner score	
		Before medication	After medication
Compound	49	14.43±2.37	6.18±0.54
Single	49	14.41±2.36	10.08±0.86
t		0.0926	2.936
p		>0.05	<0.05

**TABLE 9: COMPARISON OF THE INCIDENCE OF ADVERSE DRUG REACTIONS BETWEEN THE TWO GROUPS ( $\bar{x}\pm s$ , NUMBER OF CASES)**

Group (n=49)	Anal swelling	Difficulty defecating	Urinary retention	Gastrointestinal reaction	Rash	Loss of appetite	Total incidence
Compound	1	1	0	1	2	0	10.2 %
Single	1	1	0	1	0	1	8.16 %
$\chi^2$							0.0959
p							>0.05

The drug effect of diosmin tablets after mixed hemorrhoid surgery was studied. Diosmin is a drug that enhances venous tension and vascular protection. It can reduce venous dilatation and venous blood stasis, improve local microcirculation in the anus, normalize the permeability of capillary walls and enhance their resistance, thereby relieving congestion and edema of the tissue around the anus in order to achieve the purpose of relieving pain. Diosmin can also promote the repair and healing of tissues around the anus, shorten the formation time of hemorrhoids, and effectively prevent and treat postoperative complications of mixed hemorrhoids. The pharmacological effect of diosmin is mainly to increase the tension of the vein by prolonging the contraction time caused by the action of norepinephrine on the vein wall, and has a specific affinity for the vein. Diosmin also has the function of reducing blood viscosity and enhancing the flow rate of red blood cells. Diosmin tablets increase the lymphatic drainage speed and the contraction of lymphatic vessels,

thereby accelerating the return of interstitial fluid, improving lymphatic return, and achieving the effect of relieving tissue edema and congestion. Diosmin can be administered in a variety of ways, such as anal patch, anal spray, etc. Another drug used in this study is Mayinglong Shexiang hemorrhoid ointment, which is also meant for external application. So when choosing diosmin, tablets were used in the form of oral medication. Studies have shown that diosmin can effectively relieve the pain and edema after mixed hemorrhoid surgery, reduce the incidence of difficulty in defecation and constipation, and improve the quality of life of patients<sup>[5]</sup>. Some researchers also pointed out that diosmin can accelerate tissue repair and healing, greatly shorten the formation time of hemorrhoids, prevent and treat postoperative complications of mixed hemorrhoids, and improve the therapeutic effect of surgery<sup>[6]</sup>.

The drug effect of Mayinglong Shexiang hemorrhoid ointment for mixed hemorrhoid surgery has been studied. The main ingredients of



Mayinglong Musk hemorrhoid ointment include musk, sulfur, burnet, borneol, gallnut, gentian, *flavescens*, peppermint oil and other Chinese herbal medicines. Its pharmacological mechanism can be summarized as anti-inflammatory effect, astringent effect, antibacterial effect, promoting blood circulation and antioxidant effect<sup>[7]</sup>. Mayinglong Musk hemorrhoids ointment contains a variety of anti-inflammatory Chinese medicinal ingredients, such as *Coptidis Rhizoma*, *Cortex Phellodendron*, Burnet, *Sophora flavescens*, etc., and these ingredients can inhibit the occurrence of inflammation, reduce inflammation and edema of the tissues around the anus to achieve purpose of pain relief. In addition, musk can also play an analgesic and antipruritic effect. Its astringent effect is mainly due to the traditional Chinese medicines such as *Phellodendron* and gallnut, which can shrink blood vessels, reduce exudation, edema, and speed up the repair and healing around the anus. These ingredients can form a protective film, so that the tissues around the anus will not be stimulated by the outside environment to speed up the healing of the wound. The antibacterial effect of the drug is mainly due to the ingredients contained in it, such as *Cortex Phellodendron*, *Coptidis Rhizoma*, and *Sophora flavescens*, which can inhibit the growth and proliferation of bacteria, so as to prevent and treat infection and inflammation after mixed hemorrhoid surgery. Similarly, these ingredients can also accelerate the healing of wounds, so that the tissues around the anus can be quickly repaired and restored. In addition, the peppermint oil contained in the drug has the effect of stimulating blood vessels to dilate, which can promote blood circulation and accelerate the metabolism and repair of tissues around the anus<sup>[8]</sup>. *Coptidis Rhizoma* and *Phellodendron* also have anti-oxidation effects, which can scavenge free radicals, reduce lipid peroxidation and cell damage, so as to prevent and treat postoperative complications of mixed hemorrhoids. Studies have shown that Mayinglong Musk hemorrhoid ointment can quickly relieve hemorrhoid symptoms, such as swelling, pain, itching, etc., and has good safety and tolerance<sup>[9]</sup>. Some studies pointed out that Mayinglong Musk hemorrhoid ointment has a good effect in relieving pain and promoting wound healing in the treatment of mixed hemorrhoids after surgery, which can effectively reduce postoperative symptoms and accelerate wound

healing, with high drug safety<sup>[10]</sup>. Further, some studies also pointed out that Mayinglong Shexiang hemorrhoid ointment has significant pain relief, anti-inflammatory, astringent, and wound healing effects, and can quickly relieve symptoms and promote wound healing without obvious adverse reactions<sup>[11]</sup>.

Common adverse drug reactions of the two drugs have also been discussed. Some adverse reactions may occur during the use of diosmin tablets, including digestive system reactions, nervous system reactions, reproductive system reactions, liver function damage, allergic reactions, etc.,<sup>[12]</sup>. A very small number of patients will experience common digestive system reactions such as nausea, vomiting, diarrhea, and constipation after taking diosmin tablets. These mild adverse reactions can be relieved by taking a smaller dose or taking the medicine after meals. There are also very few patients who might be affected with nervous system reactions such as headache and dizziness. Some studies pointed out that diosmin tablets may cause sexual dysfunction, such as decreased libido, erectile dysfunction, etc. Generally, these side effects are reversible. Very rarely, liver function damage, such as elevated transaminases, jaundice, etc., may occur. In these cases, the drug should generally be stopped for observation. Some patients also experience allergic reactions such as rashes and urticaria. There are also a very small number of patients with adverse reactions such as water retention, high blood pressure, arrhythmia, and anal swelling. Some researchers compared diosmin tablets and nitroglycerin in the treatment of hemorrhoids, and found that diosmin tablets had fewer and mild adverse reactions<sup>[13]</sup>. Some studies have also found that when diosmin tablets are used to treat hemorrhoids, a small number of patients have adverse reactions such as intestinal discomfort<sup>[14]</sup>. Other studies have found that the combined use of diosmin tablets and other drugs can improve the therapeutic effect, but it may also increase the risk of side effects<sup>[15]</sup>.

The adverse reactions of Mayinglong Musk hemorrhoid ointment mainly include allergic skin reaction, irritation, skin pigmentation, abnormal liver function, digestive system reaction, toxic reaction, etc. Because Mayinglong Musk hemorrhoid ointment contains some pharmaceutical ingredients that may cause allergic reactions, such as musk, cork, *flavescens*, borneol, etc., a

small number of patients may have skin allergic reactions during use. Its main manifestations are skin itching, rash, redness, and heat sensation. Some patients also experience skin irritation, such as burning, tingling, dry skin, etc. Long-term use of Mayinglong Musk hemorrhoid ointment may cause skin pigmentation. For this study, there was no long-term use scenario. Mayinglong Musk hemorrhoid ointment also contains plant ingredients such as *Phellodendron* and *Sophora flavescens*, long-term use in large quantities may lead to abnormal liver function. There is no such long-term heavy use in this study. There are also a small number of patients with digestive system reactions, such as nausea, vomiting, and stomach discomfort. Overall, Mayinglong Musk hemorrhoid ointment is relatively safe, and its main adverse reactions are skin allergies and skin irritations. This medicine contains many kinds of Chinese herbal ingredients, and the direct action on the skin shows that some of these ingredients themselves are irritating to the skin. A study found that the adverse reactions of Mayinglong Musk hemorrhoid ointment showed that skin allergic reaction as one of the main adverse reactions of this drug, and its incidence rate accounts for 2 %-5 %<sup>[16]</sup>. Another study pointed out that about 10 % of patients who used Mayinglong Musk hemorrhoid ointment experienced mild adverse reactions in the digestive system, mainly nausea, vomiting, and stomach discomfort<sup>[17]</sup>.

In this study, the drug effect of the compound group was significantly better than that of the single group. The reason may be that the Mayinglong Shexiang hemorrhoid ointment in the compound group directly acts on the lesion area of the patient, causing the drug effect to occur rapidly, and the combination of diosmin tablets with other drugs can significantly improve the therapeutic effect. So in this study, the improvement of the wound condition of patients in the compound group was better than that of the single group. The reason may be that the efficacy of the drug is limited by the way of oral administration. It is not direct to promote the absorption of congestion and edema; in the compound group, Mayinglong Musk hemorrhoid ointment acts directly on the wound area, and the drug effect occurs faster and more directly. Further, the improvement of anal function of patients in the compound group was also better in compound group than that of the single group.

The reason may be that some Chinese medicinal ingredients in Mayinglong Musk hemorrhoid ointment can relieve anal pain and itching, relax the anus, and improve anal function. There was no significant difference in adverse drug reactions between the two groups, but the adverse reactions in the compound group were slightly higher, and 2 patients developed rashes. The reason may be that Mayinglong Shexiang hemorrhoid ointment causes irritation to the skin more. In summary, in this study, the effect of compound medication is better than that of single medication, and the medication safety of the two groups is relatively high, but attention should be paid to the dosage of Ma Yinglong Shexiang hemorrhoid ointment during the medication process.

#### Conflict of interests:

The authors declared no conflict of interest.

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