

Clinical test report and result

(one) benefits the Laser Circulation Therapeutic Apparatus to treat Gao Zhanxue sickness or the hyperlipemia, the anemic heart cerebrovascular disease, rhinitis's clinical report
Huazhong University of Science and Technology Tongji University medical school attached
Tongji University hospital

Lu FuEr Chinese Medical Department Physician-in-charge
Zhang MingMin Chinese Medical Department Deputy chief physician

- Clinical common material:

1st, sickness plants

March, 2005 to June, 2005 in my branch outpatient service and in hospital patient altogether 128 people,①Including has a mind the cerebrovascular disease as well as pure Gao Zhanxue sickness or/and the hyperlipemia patient 64 people;②Rhinitis patient 64 people. Patient age between 18-75 years old, average 43.5 years old.

2nd, integrates the standard

①Gao Zhanxue sickness or/and hyperlipemia: In the blood rheology project has above two items to be higher than the normal person either/and in the blood plasma blood fats examination has two item or two item of above unusuality. ②Rhinitis patient: The diagnosis is the acute rhinitis, chronic rhinitis ute attack, allergic rhinitis patient.

3rd, elimination case:

①Pregnant woman; ②Malignant tumor patient; ③Psychopath; ④Serious hemoglutation function barrier

*Clinical trial method:

1st.clinical trial grouping:

Divide equally two kind of disease's patients for the treatment group and the control group. Treatment group: Uses profit Laser Circulation Therapeutic Apparatus treatment which the Hiner Sichuan Science and technology Company produces, 1 /3 day, 7/treatment courses, regard the patient symptom weight to be possible to choose 1-2 treatment course treatments. 64 examples including have a mind the cerebrovascular disease as well as pure Gao Zhanxue sickness or/and in the hyperlipemia patient, 32 example treatment group patient, in carries on outside the above method of treatment, also accepts the normal foundation pharmacological treatment, but the control group patients only accept the normal foundation pharmacological treatment. in 64 example rhinitis patient, 32 example treatment group patients treat the period stops using other medicines, the control group patients accepts the conventional treatment, with rhinitis piece or compound prescription achene of xanthium sibiricum capsule.

2nd, observation target:

2.1 contain has a mind the cerebrovascular disease as well as pure Gao Zhanxue sickness or/and the hyperlipemia patient before the treatment above the empty stomach 12 hours, in the morning takes venous blood 5ml, with the entire automated analyzer examination blood fats target (TC, TG, HDL-C, LDL-C,), (whole blood cuts return to original state viscosity, whole blood with the completely automatic blood rheology observer's apparatus examination blood rheology target to cut return to original state viscosity, blood plasma viscosity, red blood cell accumulation index, red blood cell distortion index, red blood cell high to press product, erythrocyte sedimentation rate lowly). After treating 1 treatment course, above the patient empty stomach 12 hours, take venous blood 5ml in the morning, the observation target before the treatment.

2.2 rhinitis clinical symptoms observation: Including the class tears, the stuffy nose, lose smell, the nose to itch with the headache. Uses method which the patient grades.
 nasoscope inspection: Observes the double concha nasalis inferior swelling, under nasal passage secretion situation.

Clinical trial report (continues)

Clinical trial result

Table 1: Around the hyperlipemia treats the group patients to treat the blood plasma blood fats change (mmo1/L)

| | Treatment group(n=32) | | Control group(n=32) | |
|-------|-----------------------|-----------------|---------------------|------------|
| | before treatment | after treatment | before treatment | after |
| TC | 6.43±0.51 | 5.0±0.43* | 6.28±0.62△ | 5.19±0.37* |
| TG | 4.10±2.58 | 2.14±0.14* | 4.64±1.89△ | 2.86±0.74* |
| HDL-C | 0.95±0.18 | 1.35±0.20* | 0.97±0.23△ | 1.15±0.36 |
| LDL-C | 4.85±0.98 | 2.78±0.43* | 4.69±0.78△ | 3.75±1.43 |

Treats the comparison and the treatment group before the treatment group treats compares P>0.05 ,Before the expression and the group treatment, compares p<0.05 The above result showed: The treatment group and the control group each target do not have the significance difference before the treatment, indicated that two groups of results have the commensurability. After treatment group process treatment, before each target and the treatment, has the difference, before TC, TG, LDL-C treat reduce, HDL-C has compared to before the treatment elevates. After the control group treats, TC, TG have the drop, but LDC-C does not have the obvious drop, before particularly HDL-C and the treatment, has not improved.

Table 2: Around the hyperlipemia treats the group patients to treat the blood changes study the target change

| | Treatment group(n=32) | | Control group(n=32) | |
|---|-----------------------|------------|---------------------|-------------|
| | before | after | before | after |
| The whole blood cuts the return to original state to mount high (1/S) | 15.81±3.72 | 9.93±0.74* | 16.23±2.85△ | 14.68±1.79* |

| | | | | |
|--|-------------|--------------|--------------|-------------|
| The whole blood cuts the return to original state to mount lowly (1/S) | 60.45±21.01 | 47.25±18.42* | 58.45±22.51△ | 56.38±19.34 |
|--|-------------|--------------|--------------|-------------|

| | | | | |
|------------------------|-----------|------------|------------|------------|
| Blood plasma viscosity | 1.83±0.86 | 1.42±0.28* | 1.91±0.74△ | 1.53±0.37* |
|------------------------|-----------|------------|------------|------------|

| | | | | |
|-----------------------------------|-----------|------------|------------|-----------|
| Red blood cell accumulation index | 6.74±1.22 | 4.23±0.56* | 6.85±1.46△ | 4.78±0.97 |
|-----------------------------------|-----------|------------|------------|-----------|

| | | | | |
|---------------------------------|-----------|------------|------------|-----------|
| Red blood cell distortion index | 0.53±0.21 | 0.91±0.11* | 0.56±0.18△ | 0.64±0.25 |
|---------------------------------|-----------|------------|------------|-----------|

| | | | | |
|--|-------------|--------------|--------------|--------------|
| The red blood cell presses the product | 68.42±21.63 | 48.36±11.56* | 71.45±28.65△ | 52.43±24.28* |
|--|-------------|--------------|--------------|--------------|

| | | | | |
|----------------------------------|------------|----------|-------------|-------------|
| Erythrocyte sedimentation (mm/H) | 26.45±3.61 | 3.4±5.6* | 27.67±3.82△ | 16.72±4.85* |
|----------------------------------|------------|----------|-------------|-------------|

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

The above result showed: The treatment group and the control group each target do not have the significance difference before the treatment, indicated that two groups of results have the commensurability. After treatment group process treatment, before each target and the treatment, is quite even has the difference, before the whole blood cuts the return to original state viscosity, the whole blood to cut the return to original state viscosity, the blood plasma viscosity, the red blood cell accumulation index, the red blood cell high to press the product, the erythrocyte sedimentation rate lowly to treat reduces, the red blood cell distortion index has the significance markup compared to before the treatment. After the control group treats, the blood cuts the return to original state viscosity, the blood plasma viscosity, the red blood cell to press the product, the erythrocyte sedimentation rate high to have the drop, but the whole blood cuts the return to original state viscosity, the red blood cell accumulation index not to have the obvious drop lowly, before particularly the red blood cell distortion index and the treatment, has not improved

* In the clinical trial discovered bad event and side effect and processing situation:

In the clinical process has not discovered an example bad event

* Clinical trial effect analysis:

Benefits the Laser Circulation Therapeutic Apparatus to use the laser medicine technology, by specific wave length and power illumination nose mucous membrane, substitution tradition helium neon laser treatment method, after laser energy by mucous membrane organization and blood absorption, the partial blood changes the index and the blood circulation has the distinct improvement, for example: Treats the hyperlipemia patient, around the treatment blood plasma blood fats various targets have the change, after the

treatment, TC, TG, LDL, reduces, the difference has the significance significance, but HDL-C has the enhancement, its change also has the significance significance.

Gao Zhanxue in the sickness patient his/her blood changing target the whole blood cuts the return to original state viscosity, the whole blood to cut the return to original state viscosity, the blood plasma viscosity, the red blood cell accumulation index, the red blood cell ratio high to accumulate and so on lowly to have reduces, the red blood cell distortion index has the significance compared to before the treatment to advance, the difference has the significance significance.

Gao Zhanxue sickness and/or hyperlipemia Aini (laser) circulates the treatment meter treatment group and the convention pharmacological treatment group compares, although the total effectiveness does not have the remarkable difference ($P > 0.05$), but the treatment group obviously efficiency is higher than the pharmacological treatment group, the difference has the extremely significance significance ($P < 0.01$); Moreover, whether there is benefits the Laser Circulation Therapeutic Apparatus to create, not hepatorenal function harm characteristic.

Uses benefits Laser Circulation Therapeutic Apparatus to treat rhinitis patient, obviously the efficiency is higher than the pharmacological treatment group, the difference has the significance significance ($P < 0.01$), moreover the clinical symptoms improvement is obvious, the improvement time is its merit quickly.

*clinical trial conclusion:

Benefits the Laser Circulation Therapeutic Apparatus to be able to use in treating Gao Zhanxue sickness and/or the hyperlipemia, the anemic heart cerebrovascular disease.

Benefits the Laser Circulation Therapeutic Apparatus to be able to use in treating the allergy, the anxious chronic rhinitis.

(two) benefits the Laser Circulation Therapeutic Apparatus clinical test report

Huazhong University of Science and Technology Tongji University medical school attached Xiehe Hospital Chinese Medical Department

Xie Jiwen Deputy chief physician

Liu Jianguo Physician-in-charge

*Clinical common material(sickness plants, case total and case's choice:

1. sickness plants: a> Gao Nianxue sickness and hyperlipemia patient (including heart cerebrovascular disease as well as pure Gao Nianxue sickness and/or hyperlipemia blood stasis sickness and so on), b> rhinitis patient;

2. the case total is 64 people, sickness plants the patient is 32 people, the patient who sickness plants b is 32 people;

3. case's choice: Plants to two kind of sickness chooses the age separately between 15-79 years old, the male 21 examples, the female 11 example patient, removes: (1) pregnant woman; (2) malignant tumor patient; (3) psychopath; (4) has the serious hemoglutation function barrier.

Clinical trial result

Table 1 Comparison on hemorheology parameters and blood lipid between two treated groups before and after treatment($x \pm s$)

Note: Compares with the normal control group* $1P < 0.05$, * $2P < 0.01$; Compares before the treatment: # $1P < 0.05$, # $2P < 0.01$

Table 2: clinical effect OF Laser Circulation therapeutic Instrument in treating infarction with

blood stasis syndrome

The curative effect divides into the appearance, effectively, the invalid 3 ranks. Around the distinction examination patient treats the blood stream changes with the blood fats target: Whole blood Gao Qie, whole blood low cutting, the red blood cell press the product, the blood plasma specific viscosity, the glycerin, the total cholesterol, the whole blood viscosity, the red blood cell distortion index. The measure results divide into: Appearance: The difference has the unusual significance significance ($P < 0.01$); Effective: The difference has the significance significance ($P < 0.05$); Invalid: Difference non-significance significance ($P > 0.05$). Carries on counts and obtains is always effective.

Flows the tears, Stuffy nose, Loses smells, The nose itches, Headache, The nasoscope observes, Total curative effect, Effectiveness, The total effectiveness is 81.25%. The use benefits the Laser Circulation Therapeutic Apparatus to treat Gao Nianxue around the sickness treatment the whole blood viscosity, the blood plasma viscosity, the relative viscosity and the accumulation index (attaches data sheet); Treats rhinitis to be obvious to five big clinical symptoms change influence, has the good curative effect.

* clinical trial effect analysis

The use benefits the Laser Circulation Therapeutic Apparatus effective use low power laser show nose mucous membrane, after the laser energy by the blood absorption, and/or the hyperlipemia has to Gao Nianxue sickness reduces the blood viscosity, the blood accumulation and the blood fats function, treats rhinitis also to have the obvious distant effect.

* clinical trial conclusion

The use benefits the Laser Circulation Therapeutic Apparatus, in treats Gao Nianxue sickness and/or the hyperlipemia as well as in prevents and treats in rhinitis's occurrence, the development to have the good curative effect, this therapy has the originality.

FOURTEEN: stochastic appendix

1. treatment meter main engine 1
2. laser curer 1 set
3. restricting 1 package
4. special-purpose battery charger 1
5. instruction for use 1 book
6. maintenance card 1

FIFTEEN: product guarantee explanation

Respect customer:

Thanks you to select and purchase this company's product, "customer satisfaction is the sole criterion" is Our company's service idea, to protect your legitimate rights and interests, avoids you to purchase the use the extra worries, Our company makes the following pledge to you, and provides the standard perfect after service according to this to you.

(1) Guarantee exchanges or the maintenance scope:

1. has the quality problem date of one year from purchase in the normal service condition, maintains Shan Ji depending on the product to maintain the card, free replacement. above 2.1 years, this company provides the free service, but uses judgment to charge the material cost price.

(2) The following situation in does not guarantee exchange, in the maintenance scope, this company will charge certain repair expense:

1. has not shown the product to maintain Shan Ji to maintain the card. 2. because of uses the damage which carelessly or wrong causes.because 3. disassembles the breakdown which voluntarily produces. 4. the damage which causes because of the natural disaster. 5. surpasses the warranty period the user, uses judgment to charge the materials expenses.because 6. the accidental factor either the artificial reason (scratch, immersion, to replace the breakdown which or the damage secretly disposition and so on) causes. 7. appendices and so on tool housing, instruction booklet, packing.
Product post-sale service name plate

User name:

User address:

User call:

Product code:

Purchase date:

Manager:

Maintenance records:

(one)、

(two)、

(three)、

(four)、

Customer suggestion:

Certificate

According to product enterprise standard: The YZB/Hubei 0319-2007, Our company produces benefits the Laser Circulation Therapeutic Apparatus.

The product code is:

Through the leaving the plant quality restriction, the examination content has been smoothly as follows:

Terminal laser output power $\sqrt{\quad}$

| | | | |
|------------------------------------|---|---|---|
| Laser output instability | √ | | |
| Fixed time scope and precision | | √ | |
| Treatment work management function | | | √ |
| Outward appearance | | √ | |
| Safety requirements | √ | | |
| Special-purpose battery charger | | | √ |

Inspector :

Examination date :