

원저

Study of the Effect of Blood-letting Cupping Treatment for Acute Ankle Sprain: A Randomize Controlled Trial

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Abstract

급성기 족관절 염좌에 있어 자락발관법의 효과에 대한 연구: 무작위 대조 실험

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목적 : 급성기 족관절 염좌 환자에 있어서 자락발관법이 실제 효과가 있는지 근거 중심 의학(Evidence Based Medicine)적으로 연구된 사례가 드물어서 이를 객관적으로 검증하기 위하여 본 연구를 시행하였다.

방법 : 골절이 배제되고, 명백한 외상력이 있으며, 발병 후 1주일 이내에 내원하였으며 다른 치료를 받지 않은 환자 29명을 대상으로 무작위로 실험군과 대조군으로 나누어 자락발관법 유무의 차이를 두고 시술하였다. 치료시작점과 3회 시술 후 Ankle-Hindfoot Scale(AHS)와 Numerical Rating Scale(NRS)을 평가하여 비교 분석하였다.

결과 : 29명중 19명이 최종 평가되었다. 자락발관법을 시행한 실험군(n=11)이 자락발관법을 시행하지 않은 대조군(n=8)에 대해 AHS와 NRS 모두 통계적으로 유의한 차이를 보였다(p=0.041, 0.026).

결론 : 급성기 족관절 염좌에 있어 자락발관법의 시행은 통증을 비롯한 증상 감소에 객관적인 효과가 있다.

Key words : blood-letting cupping treatment, ankle sprain, Ankle-Hindfoot Scale(AHS), Numerical Rating Scale(NRS)

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I. 緒 論

Ankle injuries are among the most frequent musculoskeletal injuries presenting at accident and emergency departments¹⁾. Most (85%) ankle injuries are sprains²⁾, and over 50% of all ankle injuries involve a degree of disruption to the soft tissues of the lateral ligament complex³⁾, often resulting in acute pain, reduced range of movement and impaired physical function. Approximately 40% of people with ankle sprain experience chronic problems, including recurrent sprain and persistent functional limitation⁴⁾. The typical treatment of ankle ligament injury is optional⁵⁾. In most cases, the conservative treatment such as casting is widely done, where surgical operation is rare, so using acupuncture or blood-letting cupping treatment can be effective and economical.

The blood-letting therapy is also named bleeding therapy or collateral pricking therapy. It is a therapeutic technique to prick the superficial blood vessels and draw out a proper amount of blood with a three-edged needle, a small eyebrowlike knife or a cutaneous needle⁶⁾. And blood-letting cupping is one of the cupping methods, referring to blood-letting with a three-edged or cutaneous needle, followed by cupping, so as to draw out a small amount of blood. It is mainly used to treat soft tissue injury, sprain, pain or the shoulder and back, or lumbago etc⁶⁾.

There are a few literatures regarding applications of blood-letting therapy to low back pain, which was stated by Lee⁷⁾ and Song⁸⁾, and studies about its healing effect in accordance with insertion depth of acupuncture needle by Park⁹⁾. However, objective evidences of effectiveness of blood-letting treatment for ankle sprain is not fully sufficed yet.

Hereupon, randomized controlled trial is adopted for assessing the effectiveness of blood-letting therapy and the result will be given in this report.

II. Methods

1. Objects of this study

Patients, who visited Bundang Oriental Hospital of Dongguk University for ankle sprain from 24th May 2004 to 15th December 2004, were selected for this research. At the time of selection, those patients were suffering from the ankle sprain that was not accompanied with fracture, which was previously checked by X-ray. Patients with a certain conditions were excluded and those conditions were; 1) fracture shown on the X-ray, 2) having been treated before visiting hospital, 3) not having injured by external force, 4) having more than 1 week passed since onset. Patients were randomly divided into two groups, control group and treatment group, by flipping a coin. The control group was treated with acupuncture only and the treatment group was treated with acupuncture and blood-letting cupping.

2. Treatment

Acupuncture treatment was applied to two patients groups for 3 times per a week. The acupoint was selected by lesions. If patient had lateral ankle pains, G40(Quixu), B62(Shenmai), B60(Kunlun), B61(Pucan) and G39(Xuanzhong) points were used. In case of medial pains, Liv4(Zhongfeng), Sp5(Shanqiu), K6(Zhaohai), K3(Taixi) and G39(Xuanzhong) points were used. For the patients who were suffering from both sides of the pains, all the

acupoints shown above were treated. The number of acupuncture needles are 5 for one side injury and 9 for both sides and electroacupuncture and infra-red were used as the treatment devices. For treatment group, blood-letting cupping was applied on the legion for 5 minutes before acupuncture. There was not any differences between the treatment group and the control group except blood-letting cupping treatment and no additional treatment (e.g. medications or physical treatments) was done for closer investigation on blood-letting cupping treatment. Only short leg splint or ankle support for fixation of the ankle were of the interest in this research.

The acupuncture needle was stainless steel needle(Dongbang acupuncture manufacture company, Seoul, Korea, 0.30mm diameter 30mm length), and was twirled after insertion in order to provide patients with response of acupuncture(De-qi). Electroacupuncture (SONOTRON PGA300N, Neomyth Corporation, Seoul, Korea) was followed at 5mA mixed pulse (low frequency 2Hz , high frequency 8Hz). The time for needle retaining was 15 minutes. During retaining the needle, infra-red was radiated to the pain lesion from the 40 to 50 cm above. The diameter of cupping (Dagun company, Seoul, Korea) was 5mm and blood-letting and lasting cupping 5 minutes after disinfection of lesion by alcohol and betadine.

3. Assessment

Assessor measured Ankle-Hindfoot Scale (AHS)(10) and Numerical Rating Scale (NRS)(11) in the inspection room before the treatment was initiated. This assessments were followed by three treatments. Assessor was not allowed to know what category the

patient was included. AHS, announced by American Orthopedic Foot and Ankle Society in year 1994, is the method to assess ankle joints in objective and subjective analytical items, which is consisted of functional assessment (50 point), pain (40 point), and joint alignment (10 point). NRS is the method to evaluate the amount of pain that patients perceive by assigning numbers from 0, which represents "no pain", to 10, which appoints "extremely severe pain".

4. Statistical Analysis

Analysis regarding variations in AHS and NRS is carried out by applying Mann-Whitney test and Wilcoxon signed rank test sign test with level of significance at 5%.

III. Results

1. Characteristics of participating patients

There were 29 patients who visited Bundang Oriental Hospital of Dongguk University and participate conditions underlying this research. Data taken from 19 participants out of 29 were used and, within those 19 participants, 11 patients were categorized in treatment group, where 5 people were, after all, excluded, and the rest was

Table 1. Reasons for Withdrawal During the Treatment

Reason	Number
Recovered from the ankle injury	7
Locational limitations	2
Others	1
Total	10

assigned to control group, where 5 people were also dropped out to continue participating in this research. Reasons for withdrawal is followed(Table 1)

There were few differences shown in accordance with age, injured area, the time taken for participants to visit the hospital since the time when the initial injury happened. Only sex was assumed to be related to some differences in results, which is explained in Table 2.

Table 2. Demographic Characteristics of Patients

Characteristics	Treatment Group (n=11)	Control Group (n=8)
Age(yr)	27.7±12.36	33.4±17.15
Female(%)	63.6	12.5
Lesion:		
Lat./Med./Both(%)	75.0 / 0 / 25.0	72.7 / 9.1 / 18.2
Duration(day)	0.38±0.52	1.45±1.04

Values=mean±SD

2. Assesment of clinical manifestations

Treatment group and control group did not show any differences in AHS and NRS when the study initiated. However, treatment group became to differ from control group in AHS

Table 3. Clinical Manifestation of Groups, Where Acupuncture Was Applied With or Without Blood-letting Cupping Treatment

	Control Group	Treatment Group	p
Baseline			
AHS	61.5, 28	68, 45	ns
NRS	6.5, 6	6, 4	ns
After 3rd treatment			
AHS	74.5, 23	81, 42	0.041*
NRS	4, 4	2, 5	0.026*

Values=median, range, ns=non significant, *:p<0.05 by Mann-Whitney test

and NRS by 5% level of significance after 3 treatment were applied to each of participant(Table 3).

Both of treatment and control group held differences in AHS and NRS with level of significance at 5% from baseline to 3rd treatment(Table 4).

Table 4. Clinical Manifestation of Acupuncture With and Without Blood-letting Cupping Treatment (Within Group Comparison)

	Baseline	After treatment	3rd p
Control Group			
AHS	61.5, 28	74.5, 23	0.018*
NRS	6.5, 6	4, 4	0.034*
Treatment Group			
AHS	68, 45	81, 42	0.003*
NRS	6, 4	2, 5	0.003*

Values=median, range, *:p<0.05 by Wilcoxon signed rank test sign test

IV. Discussion

Ankle joint is supported by many ligaments. Stabilizing the medial side of the ankle both anteriorly and posteriorly is the strong, flat, triangular deltoid ligament. Laterally the three ligaments that stabilize the ankle vary somewhat in structure. Anderson, LeCocq, and Clayton¹²⁾ describes them as follows: (1) the anterior talofibular ligament is attached posteriorly to the anterior border of the lateral malleolus and anteriorly to the neck of the talus; (2) the calcaneofibular ligament is stronger than the first named and is attached superiorly to the tip of the lateral malleolus and inferiorly to the lateral surface of the calcaneus; (3) the posterior talofibular ligament is even stronger and is attached anteriorly to

Table 5. Ankle Injury Grade

	Type of sprain	Sign & Symptom	Treatment
Grade I	no tearing of ligament, and joint function is lost	no may be tenderness & swelling	slight elastic band or taping, soft exercise
Grade II	a partial tear in the ligament	obvious swelling, bruising, pain, difficulty bearing weight, & reduced function of the joint	extensive fixation of cast in 3 weeks
Grade III	complete tearing of the ligaments	severe pain, loss of joint function, widespread swelling and brushing inability to bear weight. Symptoms are similar th those of bone fracture	fixation of cast or surgery

the distal fossa of the fibula and posteriorly to the lateral tubercle on the posterior aspect of the talus. The lateral talocalcaneal ligament lies between the anterior ligament and calcaneofibular and blends with both¹³⁾. Anatomical structure of ankle is so complex that sprain becomes very likely when even small external force is imposed, which may cause discomfort to patients who did not have their affected parts completely cured.

Injuries can be divided into three classes in accordance with the amount of damage, which are minor ligamentous injuries(Grade I), incomplete ligamentous injuries (Grade II), or complete disruption of the ligament or ligaments(Grade III)¹⁴⁾(Table 5).

Blood-letting therapy is described in Ling shu(靈樞) and Su Wen(素問). For example "Blood stasis should be removed prior to applying treatment."(凡治病 必先去其血)¹⁵⁾ "Qi and blood flow, when congested for a long time, should be eliminated."(宛陳則除之)¹⁶⁾, "Collateral pricking should be operated in the event that blood is filled with pathogen."(血實宜決之)¹⁵⁾ Thus, 40 chapters out of 162 chapters discuss about naming, methodology, scopes of treatability, inhibition, principle, etc.

The blood-letting therapy is also named

bleeding therapy or collateral pricking therapy. It is a therapeutic technique to prick the superficial blood vessels and draw out a proper amount of blood with a three-edged needle, a small eyebrow-like knife or a cutaneous needle⁶⁾. And blood-letting cupping is also named bleeding cupping. It is one of the cupping methods, referring to blood-letting with a three-edged or cutaneous needle, followed by cupping, so as to draw out a small amount of blood. It is used to treat tonsillitis, neurodermatitis, allergic dermatitis, acute sprain, heatstroke, fever, headache, rhinitis, lymphangitis, etc. It is so widely used and has little of side effect but careful consideration should be given to patients with a weak constitution, anemia, or hypotension, and patients who are pregnant or have just given birth⁶⁾.

Ankle-Hindfoot Scale(AHS)¹⁰⁾ was published by American Orthopedic Foot and Ankle Society (AOFAS) at 1994 in order to suggest standardized assesment method regarding ankle and foot. Various elements associated with foot and ankle were considered in AHS, where non-numerical grading (e.g., excellent, good, fair and poor results) was excluded from evaluating process. Neither sophisticated

equipment, such as a force plate of foot pressure measurement system, nor radiological factors were included in AHS since scoring requires being strict clinical. A score of 100 point is possible in a patient with no pain, full range of sagittal and hindfoot motion, no ankle instability, good alignment, ability to walk more than six blocks(300m), ability to ambulate on any walking surface, no discernible limp, no limitation of daily or recreational activities, and no assistive devices needed for ambulation. Fifty points were assigned to function, 40 to pain, and 10 to alignment. The Ankle-Hindfoot scale is detailed in Appendix 1.

In Numerical Rating Scale (NRS)¹¹⁾, the amount of pain the participants perceive is scored by numbering from 0 (no pain) to 10 (extremely severe pain), which is presented in either verbal (Verbal Numerical Scale) or written form. The concept of Visual Analogue Scale (VAS), for instance, can be modified by marking numbers on the straight line, which may be used for participants' responses about the amount of received pain. In addition, Verbal Rating Score (VRS) can be used as one of the NRS methods by assigning numbers (0~4) to words that represents feeling such as bad, not bad, intermediate, good, and very good.

The methodology for this research is as follows; The participants, who visited Bundang Oriental Hospital for ankle sprain, were randomly divided into treatment and control group by having them flip the coin and were treated 3 times per a week. Blood-letting cupping treatment followed by acupuncture was applied to treatment group and control group was treated with acupuncture only. Medications or other treatments were prohibited in order to reduce possible biases. Ankle supporter or short leg splint was carried

to fixate injured areas in this research. Treatment group was treated with blood-letting cupping treatment before acupuncture, which was the only difference from control group.

10 people were dropped out during this research. 7 were presumed to recover from their injury before 3 treatments were applied. 2 patients was not able to participate in the research since their residential areas were too far and 1 patient did not join the research due to unidentifiable reason. Eventually, 11 participants out of 16 from treatment group and 8 patients out of 13 from control group took part in both of treatment process and assesment process. In order to acquire highly objective outcomes, it is thought to be necessary to have those 7 drop-outs, who were presumed to recover from their ankle injury before 3 treatments, investigated for the improvement and to analyze these data statistically. As shown in Table 2, treatment group was not significantly different from control group in age, injured area, and the time taken for participants to visit hospital since the time when the initial injury happened. Only sex seemed to be related to some differences in results.

In order to induce objective evaluation, AHS and NRS were utilized to measure the amount of pain. Participants were evaluated their perceptions about pain by the assessor, who was not involved in the treatment. Those patients were re-evaluated after 3 treatments. Assessor was not allowed to know which group the patients included. At the baseline, both groups did not show any significant differences. After 3 treatments, AHS and NRS of treatment group revealed significant difference from control group, which is detailed in Table 3. 3 treatments were effective enough to bring significant improvement to both

treatment and control groups, which is shown in Table 4.

Double blinding was the most difficult scheme in randomized controlled trial study of oriental medicine. Since it is impossible to blind operators from the details about the operation, single blinding is prevailing in most of the similar studies.

At this research, assessors were blinded to induce unbiased evaluations and participants were also blockaded from informations that they were treated with two separate treatments. It is thought that appropriate sham treatment regarding blood-letting cupping treatment is necessary. Even though only single blinding was adopted, this research succeeded in showing better treatment effect of blood-letting cupping treatment with respect to acute ankle sprain. Since that relatively small number of patients participated in this study, more case-based researches, hereupon, are thought to be required to build base for future similar researches.

It is judged that researches regarding Oriental medicine is supposed to be performed based on Evidence based medicine by propagating randomized controlled trial(RCT) and meta analysis.

V. Conclusion

The results acquired from randomized controlled trial regarding effectiveness of blood-letting cupping treatment on ankle sprain are as follows;

1. After 3rd treatment from baseline, the group, which was treated with both of acupuncture and blood-letting cupping

treatment, showed significant improvement in AHS and NRS ($p=0.041, 0.026$) in comparison with the group, which was treated with acupuncture only.

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<Appendix 1> The Ankle Hindfoot Scale Chart

Ankle-Hindfoot Scale (100 Points Total)

Pain (40 points)

None	40
Mild, occasional	30
Moderate, daily	20
Severe, almost always present	0

Function (50 points)

Activity limitations, support requirement

No limitations, no support	10
No limitation of daily activities, limitation of recreational activities, no support	7
Limited daily and recreational activities, cane	4
Severe limitation of daily and recreational activities, walker, crutches, wheelchair, brace	0

Maximum walking distance, blocks

Greater than 6	5
4-6	4
1-3	2
Less than 1	0

Walking surfaces

No difficulty on any surface	5
Some difficulty on uneven terrain, stairs, inclines, ladders	3
Severe difficulty on uneven terrain, stairs, inclines, ladders	0

Gait abnormality

None, slight	8
Obvious	4
Marked	0

Sagittal motion (flexion plus extension)

Normal or mild restriction (30° or more)	8
Moderate restriction (15°-29°)	4
Severe restriction (less than 150)	0

Hindfoot motion (inversion plus eversion)

Normal or mild restriction (75%-100% normal)	6
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Moderate restriction (25%-74% normal)	3
Marked restriction (less than 25% normal)	0
Ankle-hindfoot stability (anteroposterior, varus-valgus)	
Stable	8
Definitely unstable	0
Alignment (10 points)	
Good, plantigrade foot, ankle-hindfoot well aligned	10
Fair, plantigrade foot, some degree of ankle-hindfoot malalignment observed, no symptoms	5
Poor, nonplantigrade foot, severe malalignment, symptoms	0