J Acupunct Res 2019;36(4):272-276

Journal of Acupuncture Research

Journal homepage: http://www.e-jar.org

Original Article

A Pilot Clinical Study on the Accuracy and Safety of Ultrasound-guided *Gyeontonghyeol* (BP-LE6) Acupuncture: A Prospective Randomized, Single Blinded Crossover Study

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Article history:
Submitted: October 25, 2019
Revised: November 9, 2019
Accepted: November 12, 2019

Keywords:
acupuncture, medicine Korean traditional, shoulder pain, ultrasound

ABSTRACT

Background: The purpose of this study was to assess the accuracy and safety of procedures using ultrasound equipment for acupuncture treatment.
Methods: A pilot, prospective randomized, single blinded, crossover clinical study on the accuracy and safety of ultrasound-guided *Gyeontonghyeol* (BP-LE6) acupuncture treatment was conducted. Patients (n = 13) with shoulder pain were randomly divided into 2 groups. During Visit 1, ultrasound-guided BP-LE6 acupuncture was administered to the experimental group. In the control group, patients received BP-LE6 acupuncture (without checking ultrasound images) by manipulating the ultrasound probe as if administering ultrasound-guided acupuncture. Visit 2 was arranged within 7-14 days and the remaining procedures, other than those administered in Visit 1, were performed. In both the experimental group and control group, the number of needle insertions, and time required for the treatment to result in the patients feeling *de-qi* was recorded. The numeric rating scale (NRS) score for shoulder pain was recorded before and after the acupuncture treatment.
Results: The number of needle insertions was 5.31 ± 3.50 times in the experimental group, and 6.62 ± 3.38 times in the control group, however, there was no statistically significant difference between the groups ($p > 0.05$). The mean time required to perform the procedure was 151.54 ± 48.59 seconds in the experimental group and 86.69 ± 37.17 seconds in the control group, which was statistically significantly different ($p < 0.05$). The changes observed in numerical rating scale scores between groups were not statistically significantly different.
Conclusion: Although there was no statistically significant difference, administering acupuncture using ultrasound guidance may lead to accurate needling with a reduced number of needle insertion attempts. A large-scale clinical study of better design should be conducted in the future.

https://doi.org/10.13045/jar.2019.00325
pISSN 2586-288X eISSN 2586-2898

Introduction

Acupuncture procedures are relatively safe, effective Korean medicinal therapies that are used in a variety of ways for the treatment of various diseases. However, acupuncture procedures performed on high-risk regions may be so dangerous that death may occur. In the case of some acupuncture methods that require insertion into specific anatomical structures, acupuncture procedures by palpation may have limitations due to accuracy of locating the acupoint to induce the necessary *de-qi*.

Ultrasound equipment is a very efficient and convenient diagnostic tool that enables the non-invasive identification of anatomical structures inside the human body by using ultrasound waves which are harmless to the human body. It is a tool that can accurately and safely guide the process of treatment using needles and other implements, in addition to aiding the diagnosis of diseases [1].

Kim et al [2] reported that ultrasound-guided acupuncture, pharmacopuncture and acupotomy has been used to accurately identify the anatomical structures of the treatment regions, and

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enhance the accuracy of the procedure. It was also reported that ultrasound equipment was used to avoid the adverse effects of acupuncture procedures, such as pneumothorax. However, ultrasound equipment used to identify anatomical structures, provide more benefits than harm in terms of accuracy and safety. Korean medicine doctors cannot freely use ultrasound equipment due to the medical regulations of use of ultrasound in Korea.

The aim of this study was to provide the grounds and justification for the use of ultrasound equipment in the process of Korean medicinal treatment. This study was a pilot, prospective randomized, single-blinded, crossover clinical study on the accuracy and safety of ultrasound-guided *Gyeontonghyeol* (BP-LE6) acupuncture administered to patients with omalgia.

Materials and Methods

Patients

The patients were aged 19–70 years old who had omalgia. They were willing to consent to participate in the clinical trial after hearing an explanation about the purpose, and characteristics of the clinical trial, and all patients gave signed informed consent.

Criteria for exclusion from the clinical trial included individuals who had taken analgesics in the week prior to the trial, those who were afraid of acupuncture or a syringe needle, or had previously experienced shock during a procedure, those who had accident trauma or congenital malformation of a region required to be needled, and those whose participation was judged to be improper by the person in charge of the clinical trial.

The total number of patients was 13, considering the minimum number of patients required to show a difference between groups (if a difference was present), and considering an expected dropout rate of 20%.

This study was approved by the Institutional Review Board (IRB) of Korean Medicine Hospital of Woosuk University (IRB no.: WSOH IRB M1806-02-03).

Research design

Methods of procedures to be administered during Visit 1 to the experimental group, and the control group were determined by selecting random patient numbers. The random numbers were generated by using block randomization (Excel 2016, Microsoft, USA) and were individually sealed in opaque envelopes. The envelopes were opened sequentially according to patient numbers, and patient procedures were confirmed.

The treatment proceeded 7-14 days after Visit 1 and a crossover design was performed with the remaining procedures (other than the procedures administered in Visit 1). The trial was unblinded at the end of the clinical trial.

The Visit 3 was conducted within 7–14 days of Visit 2, and the patients were asked to confirm the numerical rating scale (NRS) score and report any adverse events (Fig. 1).

Diagnostic equipment and procedure tools

The ultrasound equipment used to administer the *Gyeontonghyeol* (BP-LE6) acupuncture procedure was the Aplio 300 (manufactured by Toshiba, Japan). During the acupuncture procedure, disposable sterile stainless-steel acupuncture needles 0.30 mm × 40 mm were used.

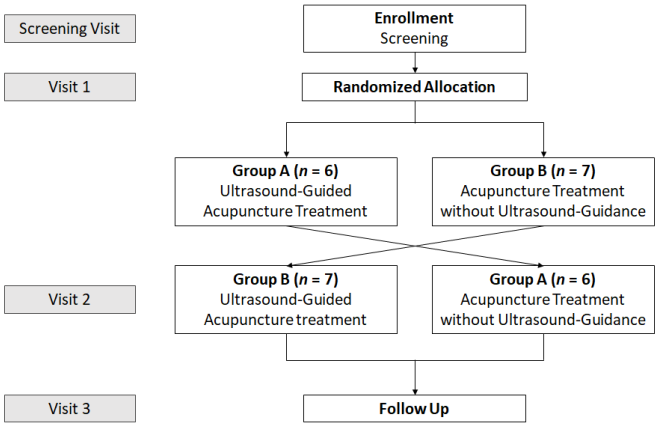

Fig. 1. Flow of the study.

Methods of procedure

Ultrasound-guided *Gyeontonghyeol* (BP-LE6) acupuncture was administered in the experimental group and *Gyeontonghyeol* (BP-LE6) acupuncture was administered in the control group without checking ultrasound images, but the ultrasound probe was used to resemble the action of ultrasound-guided acupuncture.

Acupuncture rationale

① Name of acupuncture point- *Gyeontonghyeol* (Shoulder pain point, BP-LE6) of balanced acupuncture [3].
② Position of acupuncture point- located at a position that is 1/3 of a line connecting the front of the tip of the malleolus lateralis and the depression at the anterior fibular head. That is, it is located two *cun* below Joksamni (ST36) and 1 *cun* behind it.
③ Needled nerve- Superficial fibular *n*.

Details of needling

① A total of 1 needle insertion per session.
② Name of acupuncture point used- *Gyeontonghyeol* (BP-LE6) of balanced acupuncture.
③ Depth of insertion- about 2 cm.
④ Response sought- Local needling sensation or the needling sensation of electrical tingling.
⑤ Needle stimulation- Lifting and thrusting.
⑥ Needle retention time- The needle is pulled out when *de-qi* is confirmed after needling.
⑦ Needle type- Stainless-steel needle 40 mm in length and 0.3 mm in diameter.

Treatment regimen

① Number of treatment sessions - Two in total.
② The frequency and duration of treatment sessions- The second treatment was administered 7–14 days after the first treatment. The (expected) duration of a treatment session was about 10 minutes.

Other components of treatment

① Details of other interventions administered to the acupuncture group- There was no restriction on other interventions except during the present clinical trial.

② Setting and context of treatment- The clinical trial was carried out in a clinical room equipped with ultrasound equipment, a bed for acupuncture and moxibustion, and acupuncture materials.

Practitioner background

① Description of participating acupuncturists- The acupuncturists were Korean medicine doctors with less than 5 years of clinical experience.

Active comparator control and experimental treatment

① To check the accuracy and safety of the ultrasound-guided *Gyeontonghyeol* (BP-LE6) acupuncture, the Korean medicine doctor used the ultrasound equipment during the acupuncture to check the location of the anatomical structures in the treatment region. In the case of the control group, the Korean medicine doctor manipulated the ultrasound probe to mimic the experimental group such that the patients would not be able to distinguish the difference. In the control group, needling was performed by palpation until the patients felt *de-qi*, and then the ultrasound equipment was used to check the needling positions. The patients of both groups were prevented from viewing the screen of the ultrasound equipment.

② Precise description of the control or comparator- The experimental group and the control group were assigned randomly (block randomization) into groups at a ratio of 1:1 at Visit 1 using a computer program.

Use of ultrasound equipment

① In the case of the experimental group, the Korean medicine doctor administered the acupuncture procedure to the target (BL-LE6), checking the superficial peroneal n. around the anterior fibular head where *Gyeontonghyeol* (BL-LE6) is located. In the case of the control group, the Korean medicine doctor manipulated the ultrasound probe to mimic the procedure of the experimental group, and performed needling by palpation until the patients felt *de-qi*. Only then the ultrasound equipment was used to check the needling positions. All patients were prevented from watching the screen of the ultrasound equipment.

Outcomes

① Primary outcome- In both the experimental group and control group, the number of needle insertions and the time required for procedure to result in the patients feeling *de-qi* like electric sensation according to balanced acupuncture theory were recorded. The time required for procedure is the time from beginning of the acupuncture needle insertion until pulling the needle out.

② Secondary outcome- The numeric rating scale (NRS) scores for shoulder pain were checked before and after acupuncture procedure.

Adverse events

① Patients' discomfort or adverse events (Table 1) caused by the acupuncture procedure were checked and recorded immediately after acupuncture procedure.

Statistical data analysis

Statistical analysis was carried out, using SPSS 25.0 for Windows (SSPS Inc., IL, USA). The differences between the experimental group and the control group number of needle insertions and the time required for the procedure were analyzed using the Independent *t* test after the Shapiro-Wilk test. Changes in the NRS score pre- and post-treatment were analyzed in both the experimental group and the control group using paired *t* test. When the $p < 0.05$ the difference was statistically significant.

Table 1. Checklist of Discomforts or Adverse Events Caused by Acupuncture Treatment.

Redness	Vertigo	Blister
Itchy sensation	Cold sweating	Arthralgia
Heat sensation	Chest discomfort	Spasticity
Edema	Hyperventilation	Erythredema
Subcutaneous bleeding	Palpitation	Lack of energy in limbs
Pustulation caused by infection	Sensory disturbance such as numbness	Myalgia
Discoloration	Headache	
Induration	Sleep disorder (insomnia, lethargy)	
Pain	Local paralysis	
Sense of nausea	Local edema	

Table 2. Comparison of the Number of Needle Insertions and the Time Required for the Procedure.

Group	No. of needle insertions	Procedure time (sec)
EG	5.31 ± 3.50	151.54 ± 48.59
CG	6.62 ± 3.38	86.69 ± 37.17
p	> 0.05	< 0.05*

Data are presented as mean ± SD.
*$p < 0.05$ using the t test.
CG, control group; EG, experimental group (ultrasound-guided acupuncture).

Results

Demographic information

The mean age of the participants was 38.23 ± 14.92 years, their mean height was 166.32 ± 9.23 cm, and their mean weight was 65.79 ± 13.57 kg.

Comparison of the numbers of needling

The mean number of needle insertions in the experimental group was 5.31 ± 3.50 times, and 6.62 ± 3.38 times among the control group. However, there was no statistically significant difference in the number of needle insertions between the 2 groups ($p > 0.05$; Table 2).

Comparison of the time required for procedure

The mean time required for the procedure in the experimental group was 151.54 ± 48.59 seconds, and in the control group was 86.69 ± 37.17 seconds, and thus more treatment time was spent in

Table 3. Comparison of Changes in NRS Score.

Group	Before Treatment	After treatment	*p*
EG	4.08 ± 1.61	4.00 ± 1.41	> 0.05
CG	3.92 ± 1.26	3.92 ± 1.26	< 0.001

Data are presented as mean ± SD.
p values obtained using the paired t test.
CG, control group; EG, experimental group (ultrasound-guided acupuncture); NRS, numeric rating scale.

the experimental group ($p < 0.05$; Table 2).

Comparison of changes in NRS

In the experimental group, the NRS score decreased from 4.08 ± 1.61 before treatment to 4.00 ± 1.41 after treatment, but this was not statistically significant ($p > 0.05$). In the control group, the score NRS before and after treatment was the same 3.92 ± 1.26 (Table 3).

Adverse events

There were 3 cases of pain during needle insertion identified in the experimental group. There were 2 cases of pain during needle insertion and 2 cases of pain immediately after needle insertion identified in the control group.

Qualifying single blind

After the acupuncture had been completed, the patients were asked to select the procedure they thought was administered, either ultrasound-guided or not. There were 8 patients whom inaccurately chose their treatment, therefore, the single blind aspect of the study was considered to have been well performed.

Discussion

Ultrasound is a term derived from the Latin. " "Ultra" meaning "beyond the range or limits of," and "sonus" meaning "sound." Therefore, ultrasound is sound waves of frequencies higher than the upper audible limits of human hearing [4]. Ultrasound equipment utilizes ultrasound waves to enable the visualization of structures inside the body. Electrical signals sent to the probe (transducer) of the ultrasound equipment are converted into ultrasound waves which enter the tissues directly through the skin, and some of the ultrasound waves are reflected back into the probe from the interface between tissues. The probe converts the reflected ultrasound waves into an electrical signal which is converted into an image on the screen [5].

Ultrasonography is useful because it provides real-time video and cross-sectional images, as well as being completely harmless to the human body. Ultrasound technology enables follow-up comparative examinations that can be obtained conveniently, and results of the inspection can be obtained immediately [4]. In addition, real-time video and cross-sectional images that ultrasound provides, allow accurate and safe administration of an injection or acupuncture because the anatomical structure of the human body can be observed.

In traditional Korean medicine ultrasound equipment has been used during acupuncture, pharmacopuncture, and acupotomy. Kim et al [6] used ultrasound in a RCT using bee venom pharmacopuncture treatment of knee osteoarthritis. Park et al [7] reported a case where ultrasound-guided acupotomy was administered to treat a posterior headache. Kim et al [8,9] used ultrasound to treat peroneal nerve palsy whilst administering acupotomy, and Jeong et al [10] reported a case where ultrasound-guided bee venom pharmacopuncture was administered for the treatment of rotator cuff pain. Zeng et al [11] reported 861 cases of the ultrasound-guided electro-acupuncture treatment of superficial angioma. Chen et al [12] reported a RCT on ultrasound-guided acupuncture administered to patients with shoulder pain. Guo et al [13] and Liang et al [14] reported a RCT on ultrasound-guided needle knife therapy administered to patients with scapulohumeral periarthritis. Roy et al [15] reported ultrasound-guided dry needling administered to patients with supraspinatus tendinopathy. Su et al [16] reported a RCT on high frequency color doppler ultrasound-guided little needle knife treatment administered to patients with neck and back fasciitis. Ding et al [17] and Li et al [18] reported RCTs on ultrasound-guided acupotomy treatment administered to patients with knee osteoarthritis.

Research on acupuncture procedures using ultrasound has been actively pursued both in Korea and more actively overseas. Ideally, ultrasound could be used more frequently in Korean traditional medicine clinical settings.

In this study, it was judged necessary to establish the grounds for the use of ultrasound equipment in the process of invasive Korean medicine treatment such as acupuncture. Accordingly, this study was a pilot clinical study on the accuracy and safety of ultrasound-guided *Gyeontonghyeol* (BP-LE6) acupuncture which was administered to 13 patients with omalgia.

The electrical sensation that occurs when an acupuncture needle touches the superficial peroneal nerve during BL-LE6 acupuncture of the lower extremity, is known as the *de-qi* sensation. The superficial peroneal nerve can be identified by ultrasound diagnostic equipment, so it was determined that ultrasound-guided BL-LE6 acupuncture would be used in this study.

In order to exclude error caused by individual differences in the anatomical structure of the procedure region due to the small sample size of this pilot study, a crossover design was conducted. Both procedures were randomly assigned at a fixed interval to enable a suitable washout period between the 2 treatment groups. Among the experimental group, the Korean medicine doctor administered the ultrasound-guided acupuncture procedure, observing the superficial peroneal nerve. This was equivalent to the procedure target of *Gyeontonghyeol* (BP-LE6) with the use of ultrasound equipment. The number of needlings until the patients at felt the sensation of *de-qi* was confirmed. Among the control group, the Korean medicine doctor administered acupuncture without ultrasound guidance. The Korean medicine doctor reported the duration and amount of needling until the patients felt the sensation of *de-qi*. NRS scores before and after the procedure, and any adverse events after the procedure were compared between groups.

As a result of the clinical trial, it was observed that the number of needle insertions attempted until the patients felt *de-qi* was slightly less among the experimental group but this was not significant ($p > 0.05$). Administering acupuncture using ultrasound guidance may lead to accurate needling with a reduced number of needle insertion attempts.

The time required for the procedure was an average of 151.54 ± 48.59 seconds in the experimental group, compared with 86.69 ± 37.17 seconds in the control group ($p < 0.05$). This result was to be expected because the Korean medicine doctor was not familiar with the operation of the ultrasound equipment, and it requires

more time administering acupuncture while checking ultrasound images. A longer duration of acupuncture procedure may increase a patient's inconvenience, and attempt to decrease the time required for an ultrasound-guided acupuncture procedure will be made in future studies.

As for the change in pain (NRS) pre- and post-procedure, both the experimental group and the control group showed no statistically significant difference. To observe real differences in the validity of ultrasound-guided acupuncture between the two groups, the clinical study design would need to change to specialize in the confirmation of validity, and the narrowing of the range of patients will be necessary.

As for the adverse events observed, only pain during needle insertion or directly after needle insertion were confirmed and only in a small number of patients of both groups.

This study was a pilot clinical trial, and it will be necessary to perform a larger-scale clinical trial which is well designed to validate the accuracy and safety of acupuncture treatment using ultrasound guidance.

Conflicts of Interest

The authors have no conflicts of interest to declare.

Acknowledgments

This study was supported by the Korea Institute of Oriental Medicine (K18503).

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