

Clinical Report 1 (Acupuncture)

Safety and Effects of Acupuncture Treatment Using Filiform Needles for Hemodialysis Patients

Hinata Sakuraba¹⁾, Hiroshi Kondo¹⁾, Shuichi Katai²⁾,
Tomomasa Moriyama²⁾, Hiroaki Kinoshita^{1,2)},
Takashi Ishizu³⁾ and Aki Hirayama¹⁾

- 1) Center for Integrative Medicine, Tsukuba University of Technology, Tsukuba, Japan,
- 2) Faculty of Health Sciences, Tsukuba University of Technology, Tsukuba, Japan,
- 3) Department of Nephrology, Tsukuba Central Hospital, Ushiku, Japan

1. Introduction

The number of dialysis patients in Japan in 2010 was 300,000 and continues to grow¹⁾. Many patients on hemodialysis often suffer from various conditions like amyloidosis induced arthralgia or pruritus of unidentified etiology, hemodialysis induced fatigue etc.²⁾. It has been pointed out, that since the patients are complaining of the above mentioned physical symptoms, their Quality of Life (below abbreviated QOL) is worse than that of healthy persons^{3,4)}. Many of the listed symptoms can be treated with medications physicians prescribe, but often the achieved improvements are not satisfactory, so that many of the staff members in charge of the hemodialysis treatment agonizes over how to treat these conditions⁵⁾. Complementary and Alternative Medicine (below CAM) has received much attention for possible solutions it may provide and thus a "Study meeting for Research into Maintenance of Hemodialysis Patients with Complementary and Alternative Medicine" approved by the Japanese Society for Dialysis Therapy (JSDT) has been held⁶⁾. During this study meeting various results of CAM treatments have been reported, where many reports dealt with acupuncture treatment as a representative form of CAM. Acupuncture treatment has in Japan a long history as a therapy form and is both extremely popular and well known⁷⁾. It is also one of the few therapies of which a national qualification is approved. Our investigation reported many hemodialysis staff and hemodialysis patients

interested acupuncture therapy^{2,5,8)}.

Several reports both abroad and in Japan deal with the effect of acupuncture treatment for hemodialysis patients. Abroad effects related to the improvement of pruritus, erectile dysfunction, gastroparesis have been reported^{9,10,11)}. On the other hand, in Japan Okuno et al. used 0.6 mm press needles (Pyonex, SEIRIN Co., Ltd., Shimizu, Japan¹²⁾) for the treatment and reportedly achieved alleviation of pain and improvements of the QOL¹³⁾.

Okuno et al. also used similar press needles for a crossover comparative study and reported effectiveness for intractable pruritus in hemodialysis patients¹⁴⁾. Moreover, regarding case reports dealing with the use of filiform needles for the treatment of complications in hemodialysis patients Kasuya et al. reported effectiveness for lumbar spinal canal stenosis and Sakaguchi et al. for the treatment of intermittent claudication respectively^{15,16)}. However, in a systematic review of acupuncture treatment of hemodialysis patients published in 2010 only 6 relevant reports were analyzed and moreover no positive results could be deduced from studies with larger number of case reports¹⁷⁾. In other words, while reports pertaining to acupuncture treatment of hemodialysis patients can be found worldwide, there are only few studies guaranteeing a certain quality level. Also, the number of publications itself still remains rather low.

We observed during the performance of our study using filiform needles for the treatment many cases, where those had been effective. In this study we examined for the first time in Japan the safety and effectiveness of the use of filiform needles in acupuncture treatment of hemodialysis patients at the bedside.

2. Methods

1) Subjects

Subjects of the present study were hemodialysis outpatients at the T.C. Hospital Dialysis Center in Ushiku city of Ibaraki prefecture. A questionnaire was performed prior to the study and 3 of the patients requesting acupuncture treatment included as subjects (Table 1). On that occasion the hemodialysis

specialist at the same center confirmed, that there were no physical problems that would affect the performance of the acupuncture treatment. From all subjects a written and signed informed consent form was obtained for this study.

Table 1 Subjects

	Dialysis history	Age	Sex	Symptoms
Subject 1	5 years	74	male	low back pain, numbness of left leg
Subject 2	4 years	50	male	numbness of right hand, low back pain, pain
Subject 3	32 years	59	female	low back pain, pain of both shoulder joints, shoulder stiffness

(Symptoms classified according to hemodialysis history, age and sex)

Current symptoms of the subjects are as follows. Subject No. 1 was a 74-year old man with a dialysis history of 5 years. Symptoms treated with acupuncture are low back pain and numbness of left leg. The symptoms developed 5 years ago and worsened recently. At an orthopedic clinic he was diagnosed with lumbar spinal canal stenosis and treated in osteopathy clinics with electricity, but the condition did not improve. The second subject was a 50-year old man with a hemodialysis history of 4 years and treated for numbness of right hand, low back pain and pain of the right leg. The symptoms developed after a traffic accident in September 2008. They were treated with oral medication and compresses, which was not very effective. The third subject was a 59-year old woman with a hemodialysis history of 32 years and treated for low back pain, pain of both shoulder joints and shoulder stiffness. The symptoms developed several years ago and x-ray examination performed at an orthopedic clinic

showed degeneration of lumbar vertebrae and osteophytes at the shoulder joint. She is currently treated with oral medication and compresses.

2) Treatment

The treatment was performed at the bedside, while the patients underwent their hemodialysis. Needles were Seirin (Shimizu, Japan) disposable filiform needles with a diameter of 0.16 mm (No. 1) and 0.18 mm (No. 2) of a length of 40 mm and 50 mm respectively (Figure 1). The treatments were performed by an acupuncturist with more than 10 years of clinical experience. Points were selected depending on symptoms and conditions, patients were in supine position (Figure 2-1), or if needling of the back was necessary turned on their side while watching out for the shunt (Figure 2-2). The needles were inserted using a guide tube to a depth varying from several millimeter to several centimeter and retained for a period between 10 and 15 minutes.

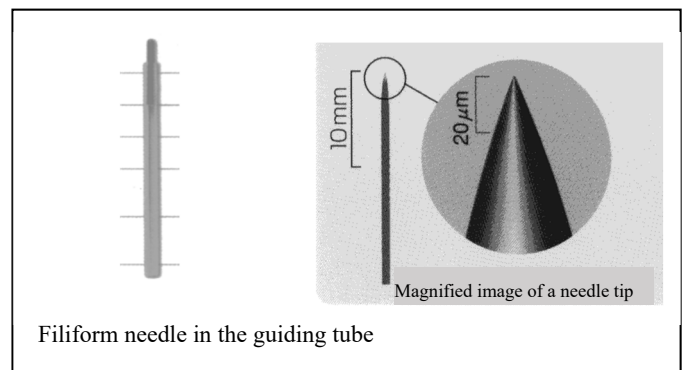


Figure 1 Disposable filiform needle



Figure 2-1 Treatment situation (supine position)



Figure 2-2 Treatment situation (lateral position)

3) Protocol and evaluation

One evaluation was performed prior to the start of the study and after that the duration defined as a 5-week treatment period and a following 5-week post treatment observation period. Treatments were administered once a week for a total of 5 weeks. During the post treatment observation period a total of 5 assessments were made at a rate of once a week (Table 2).

Table 2 Protocol

	Before	Intervention	Observation
Situation		treatment	resting
Period		5weeks	5weeks
Outcome	One time	Every week	

For the evaluation we used two different methods depending on the subject of the assessment. First we asked about the general condition and assessed the answers with the 6-step Face Scale (Figure 1). The other evaluation method was a Visual analog scale (below called VAS) where the patients assessed the severity of the treated symptoms between a level of 0 meaning "no problem at all" and 100 meaning "worst so far".

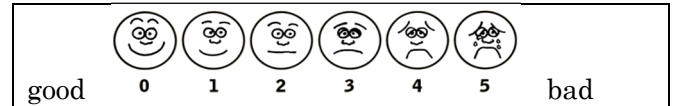


Figure 3 Face Scale

4) Incident, accident measures

There are no reports about using filiform needles for acupuncture treatment of patients undergoing hemodialysis in Japan. For us this was a new challenge too, so that we used past experiences as a reference in an effort to avoid or suppress the occurrence of incidents or accidents as shown in Table 3. Further, we asked the subjects to report any possible disadvantages caused by the acupuncture treatment directly to the physicians, nurses or dialysis staff in efforts to obtain still more detailed information.

Moreover, for the conduction of this study it was examined and approved by the ethics committee of the Center for East-West Integrative Medicine of affiliated with the Department of Health Sciences of the Tsukuba University of Technology.

Table 3 Incident, accident measures

* A sufficiently informed consent was obtained in advance.
* Use of disposable needles based on considerations pertaining to an easy susceptibility to infection.
* The physical condition was assessed and needling stimulation intensity gradually increased, to avoid acupuncture induced sudden drops in blood pressure.

* Physical and dialysis conditions were confirmed on the day in question prior to the treatment and in case of bad conditions the feasibility of the treatment itself was assessed and stimulus dose adjusted.

* No needling near visible blood vessels or shunts.

* Confirmation that the previous treatment site did not show signs of internal hemorrhage or other anomalies.

* Preparation of an incident report format used for detailed documentation and data accumulation regarding incidents.

3. Results

First we would like to address the occurrence of incidents and accidents. There were 3 cases (20%) out of the total of 15 treatments all three subjects received. Regarding their nature these incidents included internal bleeding, triggering of the alarm of the dialysis equipment during change of position and inadvertent touching the needles (retained needles) during the acupuncture treatment by the staff while attending to the patient. A physician took care of the situation in any case and critical events did not occur. The internal bleeding occurred at a needling site at the shoulder joint, but the patient him/herself did not complain about any pain or discomfort. The alarm was triggered by a change in position, turned off by a nurse and after that did not occur again. The contact with a needle while attending to a patient during an acupuncture treatment by a staff member was due to incomplete explanation for the staff members. After that we put up written announcements making it obvious, that the particular patient is receiving acupuncture and thereby solved this problem.

Next, Figure 4 shows how the subjects were classified depending on their general condition. The figure shows the average values of results obtained during the 5-week treatment and post treatment observation periods. Examination of the Face Scale showed, that it improved for subject 1 from the pretreatment value of 3.0 to 2.3 during the treatment period and 2.2 in

the post treatment observation period. For subject 2 the value improved from the pretreatment value of 4.0 to 2.3 during the treatment period, but aggravated to 2.7 during the post treatment observation period. For subject 3 the value almost did not vary from the pretreatment value of 2.0 to 2.3 during the treatment period and similarly 2.3 during the post treatment observation period (Figure 4).

Figure 4 Results of the Face Scale

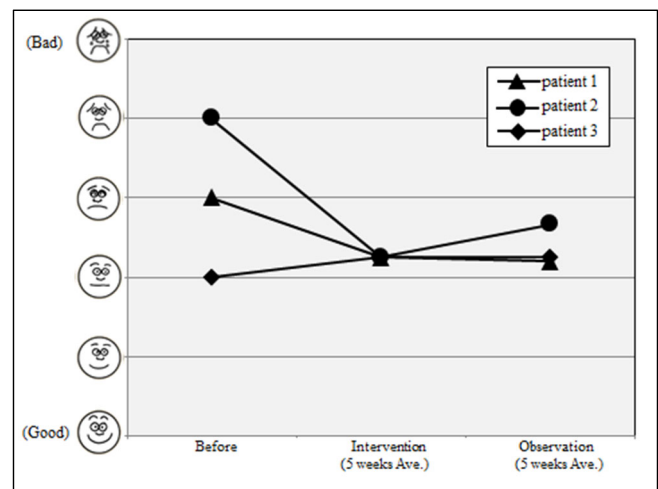


Figure 5 shows the evaluation results for each symptom obtained with a VAS. As with the Face Scale these too are the average values obtained during the 5-week treatment and post treatment observation periods. For subject No. 1 the two symptoms low back pain and numbness of the left leg, for subject No. 2 the three symptoms numbness of the right hand, low back pain and numbness of the right leg and for subject No. 3 the four symptoms low back pain, pain of both shoulder joints and shoulder stiffness were evaluated and the average values for each of the subject shown (Figure 5, left side). Looking at subject No. 1 shows a pretreatment value of 67.5, that decreased only little during the treatment period to 63.3. During the post treatment period, however, it rose to 69.5, which is higher than the pretreatment value. For subject No. 2 the pretreatment value was as high as 73.3, but markedly improved during the treatment period to 54.6 and almost maintained that level, namely 55.6,

during the post treatment period. Subject No. 3 showed during the pretreatment period a value of 60.0 that improved as in subject No. 2 during the treatment period to 50.3. During the post treatment period it showed a slight tendency towards returning to the pretreatment level to 54.7.

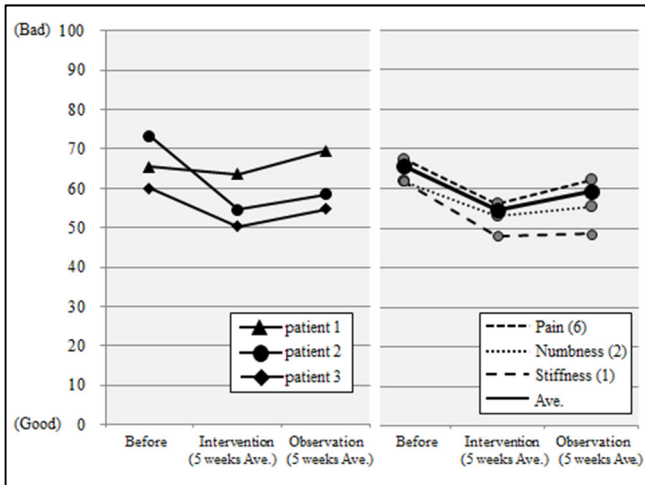


Figure 5 Results of the VAS

The following shows a classification of symptoms used for the examination of the results. The classification of therapeutic targets in all three subjects showed pain (6 cases), numbness (2 cases), stiffness (1 case). Examining first the complaints of pain showed a pretreatment VAS value of 67.5 that improved during the treatment period to 56.3. However, during the post treatment observation period it tended to return to a level of 62.2. Regarding the numbness the pretreatment value was 62.0 and improved similar to that of pain to 53.1. This value too returned slightly during the post treatment observation period to 55.6, but not as much as in the case of pain. Finally, the pretreatment value of 62.0 for a feeling of stiffness improved during the treatment period to 48.0 and was basically maintained at 48.5 during the post treatment observation period.

4. Discussion

We performed a multifaceted study about acupuncture treatment for hemodialysis patients

dealing with the concepts of the dialysis staff pertaining to the safety and effectiveness of acupuncture treatment, the needs of the patients and further the effectiveness of acupuncture treatment.

In this study we attempted to use filiform needles for the treatment of patients undergoing hemodialysis, for which previously no reports have been published in Japan. We kept the number of subjects low and conducted it as a pilot study. We made the best use of our previous therapeutic experiences and concentrated foremost on the safety. The results showed for this study an incidence of incidents/accidents of 20% requiring the intervention of a physician, but serious sequelae for the patients did not occur. Investigation of each incident showed that internal bleeding even occurred with 0.6 mm press needles, suggesting that this is unavoidable in hemodialysis patients presenting with a heightened bleeding tendency¹⁵). It is therefore essential to make sure patients understand this risk when obtaining an informed consent. Problems arising from staff coming contact with the patients were solved by putting up announcement boards. It is important to thoroughly announce the acupuncture treatment to the staff, implement all conceivable safety precautions and in case of incidents relevant measures should be examined one by one and implemented. Finally, fluctuations in blood pressure induced by changes in position are not limited to this particular study, but may occur whenever the patient changes his/her position. However, since there is a possibility of major accidents, the practitioner too should be careful to observe the shunt and any changes in position, possibly assisting the patient when necessary.

Regarding the treatment effects 2 of the subjects reported, their physical condition improved as compared to the pretreatment condition. Interestingly all subjects maintained a stable condition during the treatment and the post treatment observation period. This may be interpreted as lasting effects of the acupuncture treatment, but the physical condition is strongly

influenced by the dialysis method and the living environment, so that further studies are necessary. The symptoms of all patients improved during the treatment period, but tended to approach the pretreatment level again during the post treatment observation period. Classified by symptoms all complaints of pain, numbness and stiffness improved during the treatment period and tended to return slightly, but did not return to the pretreatment level. Based on the above described results treatment with filiform needles can to a certain degree be evaluated as being effective.

In this study we found that acupuncture treatment with filiform needles at the bedside during hemodialysis does not cause any serious adverse events and is to a certain degree effective for alleviating pain, numbness and stiffness. Yet, regarding pain and stiffness 0.6 mm press needles reportedly have also caused improvements¹³⁾. Compared to press needles filiform needles are considered to pose a higher risk, so that the balance between the risk of serious adverse events and beneficial effects is important. We therefore think, that it is necessary to collect more cases, compare and investigate them, accumulate incident/accident information and publish the relevant information pertaining to effects and safety.

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