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Original Article

Effects of High Voltage Galvanic Stimulation on Sleep and Health-related Quality of Life among Hemodialysis Patients

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Background/Purpose: Disturbances in sleep and health-related quality of life (HRQL) are common in hemodialysis patients. The aim of this study was to investigate the effects of high voltage galvanic stimulation (HVGS) on blood chemistry, sleeping quality and HRQL among hemodialysis patients.

Methods: This is an experimental one way repeated measure design. We enrolled 19 patients from a major hemodialysis center. All patients underwent whole body FT-9000 HVGS therapy, 20 minutes per session, three times per week, for 12 weeks. The assessments of therapeutic effectiveness including basic blood cell counts and biochemistry, Short Form-36 (SF-36) health survey, and the Pittsburgh sleep quality index (PSQI) were performed 1) at pre-treatment, 2) at the end of the 12-week of treatment (post-treatment) and 3) at the 12th week after the completion of treatment as the follow up test.

Results: A total of 12 patients (8 men and 4 women) completed the entire 24-week study. The mean age was 55 ± 12 years. There were no statistically significant differences in the blood cell counts and biochemistry studies performed at pre-treatment, post-treatment and at follow-up. The PSQI scores were significantly different between the pre-treatment and post-treatment data (17.17 ± 0.84 *vs.* 14.50 ± 1.62) ($F=35.2$, $p < 0.01$). The PSQI score improved significantly after 12 weeks of HVGS therapy; however, the PSQI score of the follow-up data (17.25 ± 1.14) had returned to the pre-treatment level. The result of SF-36 health survey revealed significant improvements in physical functioning, bodily pain, general health, vitality, and role limitation in emotional status ($p<0.05$) after HVGS treatment. But those scores returned to the level of pre-treatment at follow-up assessment.

Conclusion: HVGS may be a valuable modality for improving the quality of sleep and the quality of life for patients undergoing hemodialysis.(Tw J Phys Med Rehabil 2009; 37(2): 83 - 89)

Key Words: high voltage galvanic stimulation, quality of life, sleep, hemodialysis.

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INTRODUCTION

Sleeping problems are common in dialysis patients with end-stage renal disease. Common complaints include delayed sleep onset, frequent awakening at night, daytime sleepiness and restlessness.[1, 2] Iliescu et al and associates described that poor sleep in dialysis patients was associated with low health-related life quality (HRQL). They hypothesized that the end-stage renal disease itself directly influenced the quality of sleep, which in turn impacted on HRQL. [3] These problems are usually treated with medicine, but the results are usually unsatisfactory.

High voltage galvanic stimulation (HVGS) is a physical modality, which has been used for pain control, for treatment of edema, dizziness, hypertension, and irritable colon, and for facilitation of wound healing. [4-22] This equipment contains a stimulator, which applies high voltage current to the insulated human body. It is safe and does not cause any discomfort. Clinically, we have applied this to patients for pain control in our rehabilitation clinic. On one occasion, we tried this therapy on a hemodialysis patient with sleeping disturbance; the result was very effective. For this reason, we designed this study to investigate the effects of HVGS on sleep quality and HRQL among hemodialysis patients.

METHODS

Design: This was an experimental one way repeated measure design. Basic blood biochemistry, self-assessment on heath status, sleeping quality and HRQL were assessed 1) at pre-treatment, 2) at the end of the 12 week treatment (post-treatment), and 3) at the 12th week after the completion of the HVGS treatment course (follow up). One course of HVGS therapy was applied for 20 minutes, three times per week, for 12 weeks.

Subjects: We recruited 19 patients from a major hemodialysis center in Yu-Lin County who were being treated with hemodialysis. All patients suffered sleeping problems for at least one month and had taken medication for this problem with poor results. They all signed consent forms that were approved by the Institution Review Board (IRB) of the China Medical University.

The exclusion criteria included: 1) deterioration of medical condition, such as fever, poorly controlled blood pressure, admission for medical or surgical conditions and 2) any change in the hemodialysis protocol (including drugs) due to medical condition. Medication could not be changed for 4 months from 4 weeks before HVGS treatment to 12 weeks after HVGS treatment.

Treatment: Each patient underwent a 12-week course of whole body HVGS therapy (Electrostatic Potential Therapy Apparatus, FT-9000, Shenpix Co., LTD, Japan). The stimulation was applied while the patient sat in a chair specially designed for whole body stimulation. The electric potential supplied from a commercial source of 110V/60 Hz alternating current charged to the electrode was 7,000V/1mA (Figure 1). The output was set at 7,000V for 20 minutes each session. The patients were carefully monitored for vital signs to ensure safety during therapy.

Assessments: Blood counts and biochemistry study: Basic blood tests measuring hematocrit, potassium, calcium, phosphate, blood urea nitrogen (BUN), creatinin, and albumin were carried out. Each patient was requested to fast except for water intake for at least 8 hours before the collection of blood samples.

Health status survey: The SF-36 Health Survey is a multiple-purpose, short-form health survey containing 36 questions. It yields an eight-scale profile of scores as well as a summary of physical and mental measures. The Physical measures included ten questions related to physical functioning, four questions related to role limitation in physical status, two questions related to bodily pain, five questions related to general health, and four questions related to vitality. The Mental measures included two questions related to social functioning, three questions related to role limitation in emotional status, and five questions related to mental health. For each question, a score from 1 to 100 was selected by the patient (0 = the worst status, 100 = the best status). The mental component correlates most highly with the mental health, role limitation in emotional status, and social functioning scales, which also contribute most to the scoring of the mental component summary measure. The scores were calculated based on the formula in the manual of the SF-36 Health Survey Manual and Interpretation Guide. [23,24]

Sleep status survey: PSQI assesses sleeping quality and disturbances over a one-month time interval. The patient was asked to differentiate 'poor' from 'good' sleep over the last month in seven categories: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction. [25,26]

Figure 1. Stimulation was applied to patients seated in a chair designed for whole body stimulation. The electric potential supplied from a commercial source of 110 V/ 60 Hz alternating current charged to the electrode was 7,000 V/ 1mA.

Data Analysis: Data were analyzed using SPSS for windows (version 10.0) software. One-way repeated measures analysis of variance (ANOVA) was performed for each SF-36 component scale and global PSQI score. Bonferoni tests were used for the post-hoc analysis. The level of significance was set at p <0.05.

RESULTS

Of the 19 patients recruited for this study, only 12 patients (63.15%) completed the 24-week study. Medical conditions and scheduling conflicts forced 7 patients to drop out of the study. The mean age of all 12 patients (8 men and 4 women) was 55±12 years (range 27-75 years).

Blood count and biochemistry: Comparisons of blood count and biochemistry results are shown in Table 1. There were no statistical differences in blood count and biochemistry among the pre-treatment, post-treatment and follow-up data.

Sleep status: The PSQI scores differed significantly between pre-treatment (17.17±0.84) and post-treatment groups (14.50±1.62) (F=35.2, p<0.01). PSQI scores improved significantly at post-treatment group. However, for the follow-up group, PSQI scores (17.25±1.14) returned to the level of pre-treatment (17.17±0.84) (F=0.314, p>0.01) (Table 2).

Health-related life quality: Results of SF-36 health survey of hemodialysis patients are listed in Table 3. The SF-36 health survey revealed differences at post-treatment group in physical functioning, bodily pain, general health, vitality, and role limitation in emotional status (p<0.05). But those scores returned to the level of pre-treatment at follow-up assessment.

DISCUSSION

Table 1. Comparisons of blood counts and biochemistry among hemodialysis patients

Items	Pre-treatment	Post-treatment	Follow-up
Hematocrit (%)	31.77±2.87	31.67±3.10	32.27±3.71
BUN (mg/dl)	86.14±25.99	85.30±28.94	82.75±24.59
Cretinine (mg/dl)	11.11±2.25	10.29±1.97	11.36±1.76
P (mg/dl)	5.45±2.67	5.36±1.86	4.57±1.16
Ca (mg/dl)	9.62±0.97	9.65±0.80	9.72±0.79
Albumin (g/dl)	3.33±0.31	3.33±0.23	3.29±0.21

Note: mean±SD
No statistical differences were found among pre-treatment group, post-treatment group and follow-up group.

Table 2. Comparisons of PSQI among hemodialysis patients

Component	Pre-treatment	Post-treatment	Follow-up
Component 1	2.17±0.72	1.83±0.72	2.17±0.72
Component 2	2.58±0.52	2.08±0.52	2.58±0.52
Component 3	2.67±0.49	2.17±0.58	2.67±0.49
Component 4	1.58±0.52	1.17±0.72	1.58±0.52
Component 5	2.67±0.49	2.42±0.51	2.67±0.49
Component 6	2.83±0.39	2.67±0.49	2.92±0.29
Component 7	2.67±0.65	2.17±0.39	2.67±0.49
Global PSQI score	17.17±0.84	14.50±1.62 *	17.25±1.14†

*: Post-treatment *vs* Pre-treatment group, F=35.2, $p < 0.01$. †: Follow-up *vs* Post-treatment group, F=22.2, $p=0.01$.
No statistical difference between pre-treatment group and follow-up group was found.

Table 3. Comparisons of SF-36 health survey among hemodialysis patients

Scales	Pre-treatment	Post-treatment	Follow-up
Physical Functioning	24.2±14.3	34.2±12.6*	25.0±15.1
Role Limitation in physical	37.5±29.2	43.8±18.8	37.5±29.2
Bodily Pain	61.6±13.4	67.5±8.2*	61.6±13.4†
General Health	23.7±7.4	32.0±5.0*	24.1±7.7†
Vitality	41.3±5.7	45.4±4.0*	40.4±5.0†
Social Functioning	46.9±18.6	52.1±13.9	46.9±18.6
Role Limitation in emotional	38.9±27.8	61.1±23.9*	38.9±27.8†
Mental Health	44.0±5.1	46.3±6.3	43.7±5.2
Summary measures			
Physical Component	27.7±3.4	32.9±3.1*	27.8±3.1†
Mental Component	38.1±4.5	41.2±3.7	37.8±4.6

*: Post-treatment *vs* Pre-treatment group, $p < 0.05$. †: Follow-up *vs* Post-treatment group, $p < 0.05$.
No statistical difference between pre-treatment and follow-up groups was found.

Therapeutic effectiveness of HVGS: This study has demonstrated that a 12-week therapy course of HVGS significantly improved sleep and health status of hemodialysis patients. The mechanism remains unknown, and was not related to blood counts or the biochemical changes investigated in this study. A possible mechanism is the improvement in circulation.[5,6] In animal studies, it has been demonstrated that HVGS improves limb edema, oxygen saturation, and muscle contraction status as a consequence of improvement in capillary circulation.[7,14] Increased oxidative damage of proteins and lipids plays a role in the pathogenesis of skeletal myopathy.[27] The therapeutic effectiveness of the first three items could be related to an improvement in general circulation and tissue blood flow, but how HVGS affects constipation is unknown. Furthermore, we are uncertain about the exact mechanism in uremic patients.

Blood count and biochemistry: Electrical stimulation may facilitate catabolic metabolism and may cause rapid tissue catabolism particularly in uremic patients who have pre-existing nutritional deficiency. In this study, we did not find changes in BUN and albumin levels. Therefore, it may be safe to apply this therapy to hemodialysis patients. However, this conclusion may not be generalisable because our sample size was small and the duration of therapy was short.

Sleep status: The PSQI is an effective instrument used to measure the quality and patterns of sleep in elderly adults. [3,25,28] In general, most patients on hemodialytic therapy have sleeping problems. The high PSQI scores before treatment in our study further support this phenomenon. Most uremic patients in this study reported that the most obvious and important effect of HVGS therapy was improvement in sleep status. It has been suggested that PSQI scores are reversibly related to HRQL scores. [3] The improvement in sleep found in our study was probably due to improvement in health status.

Health-related life quality: It has been suggested that most uremic patients have impaired physical and mental function because of the long period of hemodialysis, the disease process itself, or associated medical problems (diabetes, hypertension, and arthritis). [1,2] The tools used for assessing health related quality of life are not always comparable. Several methods provide more objective assessment. [26] One of the most frequently used tools is SF-36. This protocol is comprehensive and generalized. It contains questions covering 3 major fields (physical, mental, and social) in 8 categories. The quality of life of the hemodialysis patients in this study improved significantly after HVGS therapy, but returned to the original level at follow up. The therapeutic effectiveness of HVGS was only temporary on quality of sleep and quality of life. We did not observe any adverse effects during or after the HVGS therapy. It appears that HVGS is a safe therapeutic tool in physical medicine.

There are some limitations in this study. This study was an experimental one-way repeated measure design, and no control samples were collected in this study. The sample size was small. Only 12 patients completed the study. The mechanism by underlying improved sleep status after HVGS in this study is worth of further investigation. More studies are needed to understand the effects of HVGS. Since oxidative damage of proteins and lipids possibly plays a role in the pathogenesis of skeletal myopathy, further study of the effects HVGS on reducing oxidative damage of lipids and proteins in skeletal muscle is suggested.

Conclusion: HVGS may be a valuable modality for improving the quality of sleep and the quality of life for patients undergoing hemodialysis.

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高壓電位刺激儀對血液透析患者在睡眠及與健康相關的生活品質之療效

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背景或目的：血液透析患者常見睡眠和與健康相關的生活品質的困擾。本研究的目的將評估高壓電位刺激儀對血液透析患者在血球細胞計數、血液生化、睡眠和與健康相關的生活品質的療效。

方法：這是一個實驗性單程重覆的實驗設計。我們從一個血液透析中心收集了 19 名患者。所有血液透析患者接受了全身高壓電位刺激儀(FT-9000 HVGS)治療，療程爲每周三次、每次 20 分鐘、共 12 周。對療效的評估包括基本的血球細胞計數和血液生化，短版-36 健康量表(Short Form-36)和匹茲堡睡眠品質量表(PSQI)。三次評估分別在 1)在治療前，2)在 12 周治療後和 3)在治療的完成後 12 周的追蹤。

結果：共 12 名患者(8 名男性和 4 名女性)完成了整個 24 周研究。年齡平均爲 55±12 歲。在血球細胞計數和血液生化資料上，三次評估沒有統計的差異。匹茲堡睡眠品質量表比分在治療前和治療後數據比較有顯著的不同(17.17±0.84 *vs* 14.50±1.62) (F=35.2, $p<0.01$)。匹茲堡睡眠品質量表比分在 12 周高壓電位刺激儀療法後有極大改善了；然而，治療的完成後 12 周的追蹤數據，匹茲堡睡眠品質量表又回到了治療前的水準(17.25±1.14)。根據短版-36 健康量表結果，在高壓電位刺激儀治療後，發現在理學功能、疼痛、一般健康、生命力和情感狀態的角色局限有改善($p<0.05$)。

結論：高壓電位刺激儀是一種有治療效果的理療工具，可能可以減少病人在血液透析期間遇到睡眠困擾並改善其健康相關的生活品質。

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關鍵詞：高壓電位刺激儀(high voltage galvanic stimulation)，生活品質(quality of life)，睡眠(sleep)，血液透析(hemodialysis)

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