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Investigating the Effects of Nintendo Wii on Ankle Spasticity in Patients with Stroke: A Randomized Clinical Trial

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ABSTRACT

Introduction: Stroke is one of the most common causes of disability. Spasticity is a common clinical impairment that occurs after a stroke. This study investigates the effect of Nintendo Wii games on the outcomes of spasticity, functional mobility, and quality of life in patients with stroke.

Materials and Methods: In this single-blind clinical trial study, 30 patients with stroke were randomly assigned to one of the experimental and control groups. Subjects of both groups received conventional physiotherapy. In addition, the experimental group also received Nintendo Wii games for 30 min, three times a week for a total of 12 sessions. The primary outcomes spasticity and functional mobility that respectively evaluated using the modified modified Ashworth scale (MMAS) and the timed up-and-go test before and after the treatment. The assessor was blind about group assignment. Meanwhile, the secondary outcome included quality of life. All statistical analyses were performed using the SPSS software, version 20.

Results: The intragroup results showed that in the experimental group, spasticity was significantly reduced (P=0.001), functional mobility improved (P=0.001), and the quality of life increased significantly (P<0.001); however, in the control group, only a significant improvement in functional mobility (P=0.04) was observed. The comparison between the two groups showed that there is no statistically significant difference in the results between the experimental and control groups (P>0.05).

Conclusion: Considering these results, the use of Nintendo Wii can be suggested as a treatment modality alongside the usual treatments to achieve more and faster effectiveness in patients with stroke.

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Introduction

Stroke is one of the main causes of permanent disability in today's advanced societies, which imposes short-term and long-term costs on the family, society, and the medical system of countries [1]. Spasticity is one of the most common clinical symptoms explored after stroke. About 30% to 40% of people experience spasticity after a stroke [2]. Spasticity occurs as a result of changes in the mechanical properties of the muscle and the reflex properties following stroke [3]. Although spasticity may improve some functional movements, it is an important disorder that often limits functional mobility in patients with stroke [4].

One of the most important goals of rehabilitation in people with stroke is to restore the function of the upper and lower limbs. Meanwhile, studies have reported that according to the opinion of patients with stroke, rehabilitation protocols are often repetitive, long-term, and monotonous, which can reduce the motivation and participation of patients to participate in rehabilitation treatment programs [5]. In recent years, the use of virtual reality-based treatments has increased as one of the types of interventions in rehabilitation [6, 7]. Virtual reality allows patients to interact with simulated environments that are similar to real environments [8]. Among the various virtual reality devices, non-immersive virtual reality devices are the best for integration into rehabilitation treatment programs, and accordingly, Nintendo Wii is one of the most widely used virtual reality devices in many neurological diseases, including known strokes [9]. Nintendo Wii requires the active participation of the participant in performing various sports and recreational activities in games while standing or sitting and can be adapted to the patient's needs [10, 11]. Nintendo Wii is a useful tool that provides flexibility, balance, strength, and coordination training in safe environments, such as homes or clinical centers, and by using it, targeted training can be done [10, 11]. Many researchers have conducted studies on the effect of Nintendo Wii in improving upper limb function and balance [12, 13]. Saposnik et al. investigated the safety and practicality of using Nintendo Wii to facilitate the upper limb function and found this method to be safe, efficient and has the potential to be used in the rehabilitation of patients with Stroke [14]. In a randomized clinical trial study, Kim et al. investigated the effectiveness of Nintendo Wii on 20 chronic stroke patients and introduced it as an effective method of restoring the function of chronic stroke patients [15]. Some Studies have also described Nintendo Wii exercises in improving balance, performing daily activities, and walking efficiently [16], Meanwhile, Yatar and Yildirim have shown that despite the effectiveness of this method, there was no significant difference between the Nintendo Wii and the Bobat method in the improvement of balance outcomes and activities of daily living in patients with chronic stroke [17].

In previous articles, the positive effect of using Nintendo Wii in improving the balance and movement performance of the upper and lower limbs of patients with stroke has been confirmed; however, according to the gathered information, there is no evidence of the effect of this intervention in reducing spasticity in patients with stroke. For this reason, this clinical trial study compares the effectiveness of conventional physiotherapy alone with the combination of conventional physiotherapy and the use of the Nintendo Wii game console on the outcomes of spasticity, functional mobility, and quality of life in patients with stroke was designed and implemented. The authors of this article assume that adding Nintendo Wii to conventional physiotherapy can have a significant effect on improving the outcomes related to stroke, including reducing the spasticity of the ankle plantar flexor muscles and improving the functional mobility and quality of life in patients with stroke.

Materials and Methods

The present study is a type of parallel single-blind randomized clinical trial, in which patients are randomly assigned to one of the two groups of conventional physiotherapy alone (control group) or the combination of conventional physiotherapy and games with a Nintendo Wii console (experimental group). The target population in this study was male and female with stroke. In the present study, the convenience sampling method was used. All stages of the current study, including clinical evaluations and treatment sessions, were conducted in the physiotherapy clinic of Ayatollah Kashani Hospital in Isfahan City, Iran, between July and December 2022. The patients were assigned to two groups based on the random block method by the clinic secretary who was unaware of the study objectives. Using the appropriate formula and based on a study [18], in addition to considering the significance level of $\alpha=0.05$, and the statistical power of 80%, the sample size of 15 people in each group was estimated.

The flowchart related to the number of people present in each stage of the study is depicted in Figure 1. Accordingly, 55 people with stroke were evaluated and 21 people were excluded from the study due to reasons, such as lack of entry criteria and unwillingness to partici-

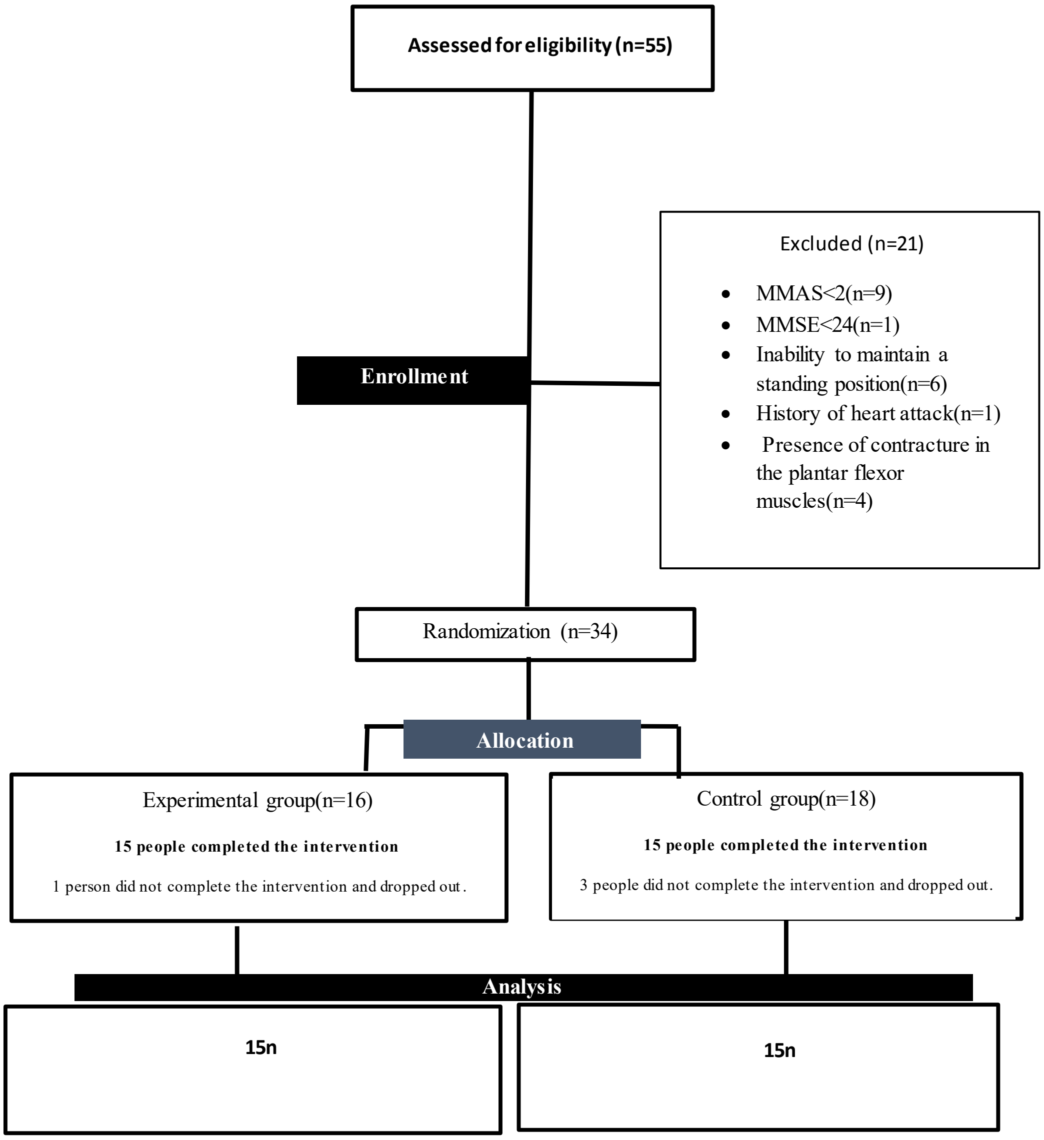

Figure 1. Clinical trial study flowchart (CONSORT flowchart)

MMAS: Modified modified Ashworth scale; MMSE: Mini-mental status exam.

pate in the study. 34 patients with stroke were randomly assigned to one of the control and experimental groups. During the treatment period, a total of 4 eligible people did not complete the treatment period. Finally, the data obtained from 30 people with stroke who completed the treatment course were used for statistical analysis. The inclusion criteria were having 18 to 85 years of age [19], the presence of a history of the first unilateral stroke that has been confirmed by a neurologist diagnosis through computed tomography scan or magnetic resonance imaging [20], the presence of spasticity in the ankle joint 2 or more according to the modified modified Ashworth scale criterion [21], the presence of appropriate cognitive status based on the Persian version of the mini-mental status exam >24 [3], and the ability to maintain a standing position without using aids for at least 30 s [22]. Meanwhile, the exclusion criteria were having a history of heart attack or high-risk heart disease [21], the presence of other neurological disorders, such as neuropathy, epilepsy, convulsions [22], the use of botulinum injection or other antispastic drugs [4], participation in other physiotherapy interventions [3], and the presence of contracture in the plantar flexor muscles [4].

Outcomes measure

The order of measuring the outcomes in this study was random. The primary outcomes were the degree of spasticity and functional mobility, and the secondary

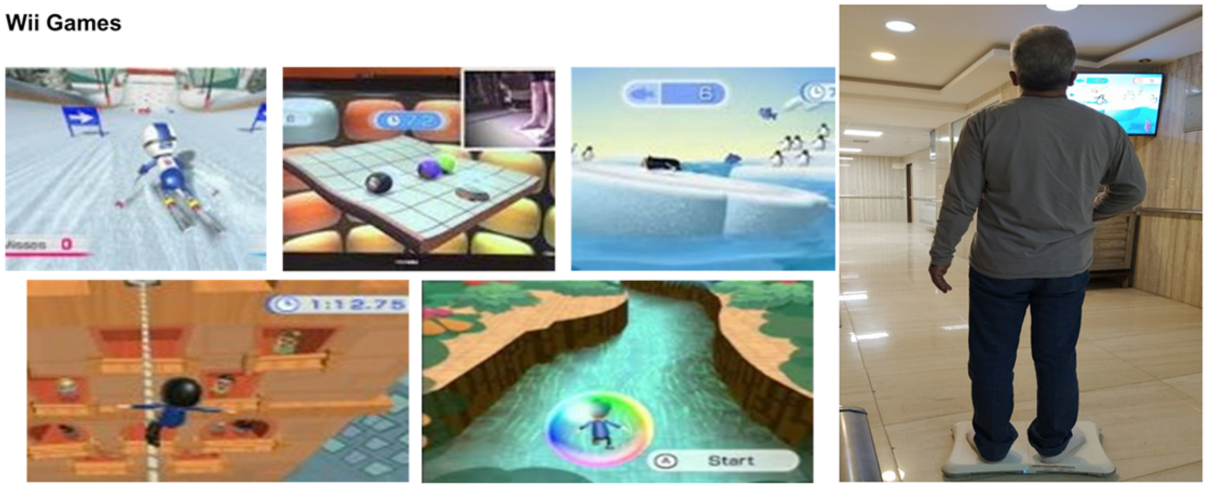

Figure 2. Tasks of the virtual reality and position of the patient on the balance board

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outcome included quality of life. The outcomes of the study were evaluated in two stages before the treatment and at the end of the treatment. The assessor was blind about group assignment.

In this study, the degree of spasticity in ankle plantar flexor muscles was evaluated using the modified modified Ashworth scale. This is a common and reliable tool for measuring the degree of spasticity, which evaluates the amount of resistance to passive stretching of the involved muscles. To determine the degree of spasticity based on the Persian version of the modified modified Ashworth scale, the examiner, unaware of the groups, determines the amount of resistance to passive movement from 0 to 4.

In this study, functional mobility was evaluated using the timed up-and-go (TUG) test. The TUG test is quick and easy with a high reliability [23] and examines the patient's ability to perform sequential motor tasks related to walking and turning. To perform this test, the participant was asked to get up from a chair, walk around a distance of 3 m, and sit on the chair again after returning. The time spent in seconds was recorded by a stopwatch by a physiotherapist unaware of the grouping.

In this study, the quality of life was measured using the 36-item short-form survey instrument (SF-36) questionnaire. The SF-36 has 36 questions and consists of 8 subscales, and each subscale consists of 2 to 10 items.

Treatment protocol

After initial evaluations, both groups were treated for 12 sessions over 4 weeks. Meanwhile, both groups received the exercise therapy protocol under the supervision of a physiotherapist three times a week for 4 consecutive weeks and a total of 12 sessions [24]. Exercise therapy protocol, including stretching exercise, dynamic weight shifting, and step training in the parallel bar. In the experimental group, in addition to therapeutic exercise, the people of this group also received the use of the Nintendo Wii console three times a week for 4 consecutive weeks and a total of 12 sessions. Using the Nintendo Wii console, the games were played while the patient stood on the balance board. The patients had already received the necessary training from the physiotherapist and were controlled by him during the game. In each session, three games out of five games were selected with the physiotherapist's opinion and the patient's preference, and there was a 5-min break between games. Each session lasted 30 min. The games included ski slalom, table tilt, penguin slide, tight rope, and balance bubble. People were at a distance of three meters from the screen (Figure 2).

Data analysis

All statistical analyses were performed using the SPSS software, version 20. To evaluate the distribution of data, the Shapiro-Wilk test was used. Mann-Whitney test was used for inter-group comparison of the degree of spasticity and the Wilcoxon test was used for intra-group comparison. For other outcomes with normal distribution, an independent t-test was used to compare two groups before starting treatment. The one-way analysis of variance/covariance was used to compare the two groups after the start of the study. In the variance/covariance analysis, the results have been reported once without controlling the values before the treatment (raw) and once with the control of the values before the treatment (corrected). In this study, the final model is the corrected model. Paired t-test was used for intragroup comparisons. Cohen's d

Table 1. Stroke subject characteristics (n=30)

Groups	Age (Years)	Weight (kg)	Height (cm)	Duration of Disease (Months)	Stroke Type	Stroke Side	Gender
Experimental	57.07±12.21	66.80±9.89	169±8.24	17.33±13.15	H=5 I=10	R=9 L=6	M=11 F=4
Control	60.33±12.97	67.60±10.43	164.53±9.27	25.73±13.53	H=5 I=10	R=9 L=6	M=8 F=7

Abbreviations: H: Hemorrhagic; I: Ischemic; R, Right; L: Left; M: Male; F: Female.

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effect size was used to examine the magnitude of intergroup differences and determine the effectiveness of the test (using the Nintendo Wii console). The level of significance in the present study was considered 0.05.

Results

A total of 30 stroke patients with lower limb spasticity completed this clinical trial study. The demographic variables of both groups are shown in Table 1. Accordingly, the mean age of the participants in the experimental group was 57.07 years and the mean age of the participants in the control group was 60.33 years. In addition, there was no statistically significant difference between the two groups in quantitative background variables (P>0.05).

Descriptive and analytical statistics of primary and secondary outcomes are presented in Table 2. The median degree of spasticity before the start of treatment in the test and control groups was 3 and 2, respectively, and after the end of the treatment, the median degree of spasticity in both groups was 2. In the analytical statistics section, except for the result of spasticity degree which did not have a normal distribution and non-parametric tests were used, other results had a normal distribution.

Intergroup and intragroup analysis of the degree of spasticity

Before the treatment, there was no statistically significant difference in the median of spasticity between the two groups (P>0.05). The comparison of the mean de-

Table 2. Descriptive and analytical statistics of primary and secondary outcomes in experimental (n=15) and control (n=15) groups

Variables	Mean±SD/Median (Mode)			
	Experimental Group		Control Group	
	Baseline	After Intervention	Baseline	After Intervention
Spasticity level (score)	3 (1)	2 (1)	2 (1)	2 (1)
Timed up and go test (s)	44.29±32	33.43±25.66	56.28±37.48	44.53±27.8
Quality of life (%)	54.13±17.42	69.38±14.54	44.39±16.71	53.44±18.94

Variables	Between Two Groups					Within Group	
	P		Z Index/F Index		Cohen's d	P	
	Baseline	After Intervention	Baseline	After Intervention		Experimental	Control
Spasticity level (score)	0.72	0.21	-0.36	-1.26	-	0.001	0.096
Timed up and go test (s)	0.37	0.26* 0.48**	0.92	1.29* 0.5**	-0.41* -0.26**	0.001	0.04
Quality of life (%)	0.13	0.015* 0.06**	0.13	6.69* 3.76**	0.94* 0.72**	<0.001	0.068

Notes: * shows the raw model and **indicates the corrected model.

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SD: Standard deviation.

gree of spasticity between the two groups after treatment was not statistically significant (P>0.05). Comparing the degree of spasticity before and after the treatment within each group showed that in the experimental group, the degree of spasticity decreased significantly (P<0.05), while in the control group, no statistically significant difference was observed in the degree of spasticity (P>0.05).

Intergroup and intragroup analysis of functional mobility

Before the treatment, no statistically significant difference was observed in the mean time of the TUG test between the two groups (P>0.05). The results of a one-way analysis of variance/covariance show that with and without controlling the baseline values, after the treatment, there is no statistically significant difference in the mean of the TUG test between the two groups, and the difference between the two control and experimental groups after the treatment was not reached statistical significance (P>0.05). In addition, based on the size of the Cohen d effect, the magnitude of the difference between groups for the functional mobility outcome was in the insignificant to small range. The results of the intragroup comparison showed that in both the experimental and control groups, after the treatment compared to before the treatment, the duration of the TUG test was significantly reduced and the functional mobility improved (P<0.05).

Intergroup and intragroup analysis of quality of life

Before the treatment, there was no statistically significant difference in the quality-of-life score between the two groups (P>0.05). Without controlling the baseline values, after the treatment, the experimental group had a higher quality of life score compared to the control group, and this difference was statistically significant (P<0.05). In addition, the Cohen d effect size index showed the high effectiveness of the experimental compared to the conventional treatment. By controlling the baseline values, no significant statistical difference was observed between the two groups (P>0.05). In terms of the numerical value, the P was close to the threshold of statistical significance and the effect size was in the medium range. The quality-of-life score in the experimental group increased significantly after the treatment period compared to before the treatment (P<0.05), while in the control group, there was no statistically significant difference in the quality-of-life score between before and after the treatment (P>0.05).

Discussion

According to the results, there was a considerable difference in spasticity and quality of life after completing the treatment in the experimental group compared to before the treatment, while in the control group, there was not a statistically significant difference between before and after the treatment. After the treatment period, there was no statistically significant difference in the spasticity score and quality of life between the two groups. Intragroup comparison in functional mobility showed that in both groups, after the treatment period, it improved compared to before treatment. In addition, no significant difference was observed between the two groups.

Spasticity after stroke can cause pain, impaired hand movements, limited range of motion, impaired walking and daily activities, and finally, a severe decrease in the quality of life of affected people [25]. There are many pharmacological and non-pharmacological therapeutic interventions aimed at reducing spasticity and improving function in stroke patients. Among conservative treatments, botulinum injection, acupuncture, and dry needling can be mentioned [26]. Exercise therapy is a key and cheap treatment for reducing muscle tone and improving function in people with a history of stroke. Among the types of exercise therapy, stretching exercises are the most common and widely used conservative treatment test to increase the range of motion and manage spasticity, which is prescribed as a basic component in rehabilitation and treatment protocols [4, 27]. The results of a systematic review and meta-analysis of 8 clinical trial studies that examined the effects of stretching on stroke-related outcomes showed that a significant effect of stretching exercises compared to other conservative interventions for improving spasticity was not observed. Two studies stated that stretching is more effective compared to control groups [28]. In the present study, both control and experimental groups received gastrocnemius muscle stretching and walking on a parallel bar. The results within the group showed that in the control group after the end of the treatment, the performance based on the TUG test improved significantly compared to before the treatment and in this group, the duration of the test went from 56.28 s to 44.53 s. This improvement was also seen in the experimental group, and the duration of the test went from 44.29 s to 33.43 s; however, no significant difference was found between the two groups. In the study of Hung et al., they used this test to compare the effect of weight shift exercises and Nintendo Wii exercises in people with stroke and showed that similar to the results of the present study, despite the improvement within the group, there was no significant difference between the groups [29]. In two other studies, participants showed a significant increase in walking speed after 4 weeks of balance training and balance training using Nintendo Wii, but there was no significant difference between the two groups [17, 30]. Contrary to the results of the present study, in the study conducted by Marques-Sule et al., the performance based on the TUG test in the Nintendo Wii group plus conventional physiotherapy improved more than the conventional physiotherapy group alone [31]. It may be because ankle spasticity affects gait efficacy in chronic stroke patients [32]. Ankle plantar flexors are necessary for gait. The absence of push-off majorly reduces the forward propel, swing initiation on the same side, and swing phase on the contralateral side [33]. The results of a systematic review and meta-analysis of 6 articles showed that adding Nintendo Wii to conventional treatments can improve performance based on the TUG test. In other outcomes, no effect was observed in favor of Nintendo Wii [34].

The quality-of-life parameter in the present study showed a 10% increase in the overall score of the SF-36 questionnaire in the control group, but statistically, this difference was not considerable, while this difference was considerable in the experimental group. The results of Şimşek and Çekok's study showed that the amount of improvement in the quality of life in the Nintendo Wii group was similar to that of the Bobat exercise group [35], and another study also showed that the quality of life between the two groups of recreational activities and Nintendo Wii did not differ significantly after treatment [14]. Da Silva et al. also evaluated the quality of life of stroke patients with the help of the SF-36 questionnaire and showed that despite the improvement of the quality of life in both conventional physiotherapy groups and physiotherapy using the Nintendo Wii device, there was not a significant difference between the two groups [36]. Also in Adie et al.'s study, there was no difference between the two groups of Nintendo Wii and therapeutic exercise in the improvement of people's quality of life [37].

Conclusions

Considering that after the treatment in the Nintendo Wii group, the spasticity was reduced and the functional mobility and quality of life improved compared to before treatment, but in the control group only the functional mobility outcome had a noticeable improvement. Intergroup comparisons did not show a considerable advantage in favor of the use of Nintendo Wii on spasticity, functional mobility, and quality of life compared to conventional treatment alone. Considering these results, it is possible to suggest the use of Nintendo Wii along with conventional physiotherapy in people with a history of stroke.

Study limitations

The limitations of the present study were the low number of treatment sessions and the lack of follow-up, which were not considered in this trial due to time constraints. Other limitations of the study include the lack of assessment of adherence and the degree of acceptability of the treatment by the participants.

Ethical Considerations

Compliance with ethical guidelines

The protocol of this study was approved by the Ethics Committee of Isfahan University of Medical Sciences (Code: IR.MUI.RESEARCH.REC.1399.309) and prospectively registered in the Clinical Trials Center of Iran (IRCT Code: IRCT20200101045970N3).

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Authors' contributions

Conception and design: Ehsan Ghasem; Funding acquisitions: Ehsan Ghasemi; Administrative, technical, or logistic support: Ehsan Ghasemi and Saiedeh Farahmand; Provision of study materials or patients: Keivan Basiri and Majid Ghasemi; Data collection: Ehsan Ghasemi, Keivan Basiri, and Majid Ghasemi; Data analysis and interpretation: Ehsan Ghasemi and Saiedeh Farahmand; Critical revising of the article for important intellectual content: Ehsan Gasemi, Saiedeh Farahmand, Keivan Basiri, and Majid Ghasemi; Final approval of the article: Ehsan Ghasemi.

Conflict of interest

The authors declared no conflict of interest.

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