Research Paper: Reliability of Semmes-Weinstein Monofilaments and Tuning Fork on Pressure and Vibration Sensation Measurements in Diabetic Patients

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Objectives: Sensory neuropathy is the major cause of ulceration in diabetic patients. Periodical sensory examination is an appropriate method to detect neuropathy and decrease the risk of diabetic foot ulcer. Semmes–Weinstein Monofilaments (SWM) and tuning fork on/off test are widely used to assess pressure and vibration sensitivity. The present study evaluated the inter- and intra-rater reliability of SWM and tuning fork to measure pressure and vibration sensations in diabetic patients.

Methods: Following ethical approval, 34 diabetic patients without foot ulceration were recruited. Feet kit SWM and tuning fork were used for pressure and vibration sensation evaluation, respectively. Measurements were performed twice on the first session with an hour interval to assess within-day reliability and the third one was demonstrated 7 days later to assess between-days reliability.

Results: Within-day Intra-class Correlation Coefficient (ICC) analysis indicated excellent levels of inter- and intra-rater reliability (ICC>0.75) for feet kit SWM in all foot regions and 128 Hz and 256 Hz tuning forks. Excellent between-days intra-rater reliability (ICC>0.75) was also obtained for SWM; however, the ICC of tuning fork was moderate. Between-days inter-rater reliability of SWM and tuning fork were high and poor, respectively.

Discussion: The obtained results indicated that SWM and tuning fork seemed to be highly reliable to measure pressure and vibration sensations in diabetic patients. However, further studies are required to support the results of current study.

Keywords: Pressure sensation, Vibration sensation, Observer variations, Diabetes Mellitus
Highlights

- Semmes–Weinstein monofilaments are reliable to measure pressure sensation in diabetic patients.
- The tuning fork is reliable to measure vibration sensations in diabetic patients.

Plain Language Summary

Sensory neuropathy is one of the main causes of foot ulcer in diabetic patients. Thus, diabetic patients should be regularly evaluated for sensory perception. One of the simplest ways of sensory evaluation is to examine the pressure sensation by monofilaments and vibration sensation by tuning fork. These two tools (monofilaments and tuning fork) should have sufficient accuracy and reliability to evaluate sensory perception in diabetic patients. In this study, the reliability of these two tools was evaluated for sensory evaluation of diabetic patients and the results showed that they have sufficient reliability in several sessions (intervals of about 7 days). Also, these tests were performed by several experts that showed no significant differences in the obtained results.

1. Introduction

Peripheral Sensory Neuropathy (PSN) is the main risk factor for foot ulceration and lower extremity amputations in diabetic patients [1]. Peripheral neuropathy involves sensory, motor and autonomous systems and causes decreased pressure sensation, increased vibration perception threshold, foot deformities, and dry skin [1].

Previous research recognized sensory neuropathy as the major cause of ulceration in diabetic patients [1, 2]. Approximately 50% of diabetic patients experience peripheral neuropathy and more than 50% of them experience symptomatic neuropathy [3]. Early diagnosis of PSN is important in diabetic patients to prevent diabetic foot problems. Periodical sensory examinations are appropriate to detect neuropathy and decrease the risk of diabetic foot ulcer. According to the Polish Diabetes Society, diabetic patient’s feet should be examined at every medical visit [4].

Nerve conduction velocity is a gold standard test to detect neuropathy [5]. This test is a complex, costly, and time consuming method and not suitable for clinical evaluations [6]. The ideal instrument for neuropathy examination should be easily accessible, simple to use, and reliable with high sensitivity and specificity. Several instruments are frequently used to screen peripheral neuropathies such as monofilaments, tuning fork, and biothesiometry [3, 6].

Previous studies demonstrated that Semmes-Weinstein Monofilament (SWM) and tuning fork are appropriate tools for the clinical evaluation of pressure and vibration sense, respectively [1, 3, 5-8]. Monofilaments and tuning fork are non-invasive, available and easy to use instruments [5, 6, 9]. Monofilaments, often called SWM, are calibrated, single fiber nylon threads, identified by values ranging from 1.65 to 6.65 that generate reproducible buckling stress. The higher the value of the monofilament, the stiffer and more difficult it is to bend [5]. Monofilaments are used to detect the pressure sensation in neuropathic patients [10]. Reliability of SWM in healthy and elderly people was evaluated by the previous studies [4, 11-13].

The graduated tuning fork and tuning fork on/off tests are available in every dialectology clinic. Tuning fork test determines the ability of subjects to discriminate vibration sensation. Limited studies evaluated the reliability of graduated tuning fork for the detection of fracture- and immune-mediated polyneuropathies; however, the tuning fork on/off test reliability was overlooked [14, 15]. Previous studies demonstrated that SWM and tuning fork are appropriate tools to clinically evaluate pressure and vibration senses, respectively [1, 3-7]. Reliability of SWM and tuning fork on/off tests are important in the evaluation of periodic clinical sensation. The present study aimed to determine the within- and between-subject intra- and inter-rater reliability of pressure and vibration senses measurements with SWM presented with a 6-piece foot kit and 128 and 256 Hz tuning fork in diabetic patients.

2. Methods

Study participants

Thirty-four patients with type 2 diabetes, aged 40-60 years were recruited from Taban diabetic center, Tehran City, Iran. Participants with skin ulcer or scar in the test-
ing site, vascular diseases (absence of at least one foot pulse) and other causes of neuropathy such as alcoholism, thyroid disease, lumbar or cervical radiculopathy, inflammatory and infection diseases were excluded [16]. Neuropathy severity was assessed by the Toronto Clinical Neuropathy Score (TCNS) to maintain the patient’s condition during the two test sessions.

TCNS consists of 13 items; 6 items focusing on symptoms, two items testing reflexes and 5 items assessing sensation. Symptom and sensation items answered as yes or no are given scores 0 and 1, respectively. Normal reflex item is scored 0, reduced reflex item is scored 1 and the lack of reflex item is scored 2. The maximum achievable score is 13 [17]. Participants’ demographic data were recorded at the first session. The study was approved by the Medical Ethics Committee of the University of Social Welfare and Rehabilitation Sciences, Tehran, Iran. All subjects provided their informed consent and signed the consent form.

Equipment

Six feet kit SWM (North Coast Medical Inc.; USA) consisting of sizes 2.83, 3.61, 4.17, 4.56, 5.07, and 6.10 was used to evaluate the pressure sensation of foot plantar surface [18]. Four regions of both feet including heel, medial and lateral of forefoot and hallux were examined by SWM [18]. Moreover, 128 Hz and 256 Hz tuning fork (Surgicon; Germany) were employed to evaluate vibration sensation in the hallux region of both feet [9, 19].

Study procedure

Each participant was examined twice on the same day with an hour interval by one examiner in respect of inter- and intra-rater reliability. The third measurement was demonstrated 7 days later to assess between-days reliability [4, 18]. First and second examination sessions were conducted in the same room and under the same condition. The testing protocol was described briefly for all participants and a simple test was performed on the patient’s hand to become familiar with monofilament and tuning fork test in the first session.

The patients were requested to remove shoes and socks, lay on the bed and close eyes; then, they were instructed to say “yes” each time they felt the pressure of monofilament. Both examiners randomly selected SWM size and foot region for pressure sensation test. Examiners placed the monofilament on the plantar surface of the foot and pressed it to bend into a C-shape for approximately 11/2 seconds. Pressure sensation tests were repeated three times at each foot region with each monofilament [20, 21]. After an hour interval, the second measurement was performed using SWM and tuning fork.

Vibration testing by 128 Hz and 256 Hz tuning fork on/off method was applied to the hallux of both feet. The patient was requested to report the lack/existence of vibration [5]. Vibration sensation test was repeated three times for both tuning fork frequencies, while vibration was randomly off in one test. To evaluate the between-days reliability of kit SWM for feet and tuning fork, a similar protocol was performed with a 7 days interval.

Statistical analysis

Descriptive statistic were used to describe the demographic data. Intra-class Correlation Coefficients (ICC) and Standard Error of the Mean (SEM) were calculated to evaluate within- and between-subject inter- and intra-rater reliability of SWM and tuning fork test. Based on Rosner’s classification, ICC≥0.75 represent excellent, 0.4≤ICC<0.75 indicate fair to good, and <0.4 demonstrate poor reliability [22]. Statistical analyses were performed using SPSS.

3. Results

Thirty-four patients (11 men and 23 female) were included in the study. The study participants’ demographic data are listed in Table 1. Neuropathy severity was similar in both sessions among all study participants based on TCNS (P>0.05). The ICC analysis results suggested excellent levels of inter- and intra-rater reliability (ICC≥0.75) with respect to SWM in all regions of feet and both tuning fork frequencies (Tables 2 and 3).

Between-days intra-rater reliability of SWM was excellent, except for right medial forefoot and left lateral forefoot (ICC=0.73) (Table 2). Between-days intra-rater ICC of both tuning fork frequencies were moderate (0.4≤ICC<0.75) (Table 3). Between-days inter-rater reliability of SWM was high, except for medial forefoot of both feet (ICC=0.62 and 0.46, respectively) (Table 2), and it was poor by tuning fork (Table 3).

Within-day intra-rater ICC values of pressure sensation with all sizes of SWM were 0.93 (right heel, medial forefoot and hallux) to 0.89 (left lateral of forefoot); withinday inter-rater reliability were 0.92 (right hallux) to 0.79 (right Heel). Between-days intra-rater reliability range were 0.91 (left heel) to 0.73 (right lateral forefoot and left medial forefoot) and inter-rater ICC were 0.84 (left heel) to 0.46 (left medial forefoot).
Within-day intra-rater reliability range of vibration sensation with both tuning fork frequency was 0.92 (256 Hz in right hallux) to 0.82 (128 Hz in right hallux), and inter-rater ICC was 0.92 (256 Hz in left hallux) to 0.76 (128 Hz in right hallux). Between-days intra-rater reliability range was 0.71 (128 Hz in right hallux) to 0.46 (128 Hz in left hallux) and inter-rater ICCs were 0.47 (256 Hz in left hallux) to 0.18 (128 Hz right hallux).

4. Discussion

High levels of within- and between-days inter-rater reliability were detected for the SWM in the present study. Our result was in line with other studies that reported high inter-rater reliability [11, 12, 18, 23]. However, it was in contrast with Rozental et al. and Collins et al. studies that documented low inter-rater reliability [13, 24].

Examiner professionalism was important in measuring pressure sensation by SWM and affected the level of data reliability [12, 25]. Robert et al. study demonstrated that a professionally trained examiner positively affected inter-rater reliability. Examiners of the current study (M.B, A.M) were expert to evaluate pressure and vibration sensation by SWM and tuning fork and were trained by a professional neurologist [25].

| Variable                      | Mean±SD    | Minimum | Maximum |
|-------------------------------|------------|---------|---------|
| Age, y                        | 51.64±6.52 | 40      | 60      |
| Weight, kg                    | 72.67±8.85 | 56      | 93      |
| Height, cm                    | 166.55±7.64| 155     | 180     |
| Body mass index, kg/m²        | 26.22±2.98 | 21.46   | 32.37   |
| Disease duration, y           | 11.70±5.80 | 3       | 30      |

### Table 2. ICC and SEM for inter-and intra-rater reliability of measuring pressure sensation with Semmes–Weinstein monofilaments

| Reliability  | Right Foot | Left Foot |         |
|--------------|------------|-----------|---------|
|              | Heel       | Medial Forefoot | Lateral Forefoot | Hallux    | Heel       | Medial Forefoot | Lateral Forefoot | Hallux |
| Within day   | ICC        | SEM       | ICC      | SEM      | ICC        | SEM       | ICC        | SEM     | ICC        | SEM      | ICC        | SEM      | ICC        | SEM      |
| Intra-rater  | 0.93       | 0.151     | 0.93     | 0.427    | 0.91      | 0.550     | 0.93      | 0.702    | 0.91     | 0.866     | 0.90     | 1.168     | 0.91     | 0.980     | 0.91     | 0.876     |
| Inter-rater  | 0.79       | 2.012     | 0.88     | 1.154    | 0.83      | 0.999     | 0.93      | 0.191    | 0.86     | 0.317     | 0.80     | 2.096     | 0.83     | 2.108     | 0.88     | 1.095     |

| Between days | ICC        | SEM       | ICC      | SEM      | ICC        | SEM       | ICC        | SEM     | ICC        | SEM      | ICC        | SEM      |
| Intra-rater  | 0.89       | 1.687     | 0.73     | 0.54     | 0.75       | 0.92      | 0.78      | 0.812    | 0.90     | 0.727     | 0.78     | 0.703     | 0.73     | 1.08      | 0.89     | 0.574     |
| Inter-rater  | 0.78       | 1.842     | 0.62     | 2.136    | 0.83      | 0.924     | 0.75      | 0.807    | 0.84     | 0.646     | 0.46     | 2.971     | 0.76     | 0.339     | 0.78     | 2.113     |
The participant’s individual variation affected the reliability [26]. All studies that reported low inter-rater reliability of SWM have examined healthy people [13, 24]. Individual variation was low in healthy people; however, other studies that examined the reliability of SWM in elderly [11] or patients [12, 18, 23] reported high levels of inter-rater reliability. The present study evaluated the diabetic patients with and without neuropathy and the ICC revealed a high inter-rater reliability.

A number of monofilament, test location and examiner may affect the level of reliability. A prolonged period of the test may lead to fatigue and decrees participant’s concentration. Although long-time participant’s immobilization for testing decreased lower limb blood circulation and foot temperature. Decreased skin temperature is affected by plantar sensation [27].

Furthermore, increased number of tests and examiners enhanced participant’s learning. Anderson et al. [12] and Roberts et al. [25] performed test-retest assessment by 5 and 9 expert and trained examiners, respectively. These studies reported high inter-rater reliability; however, Collins et al. [13] evaluated inter-rater reliability by two examiners and reported a low reliability. In the present study, 6 sizes of SWM were tested in the 4 areas of both feet by the first examiner and retested after 5 minutes by the second examiner.

A maximum time lasted approximately 5 minutes for all tests performed by each examiner. Moreover, temperature, room condition and participant’s position were similar in all tests.

Test location may affect the reliability score [13]; Collins et al. indicated stronger reliability for some sub-tests [13]. Heel, metatarsal head and the plantar surface of toes (especially hallux toes) are evaluated for testing plantar sensation in diabetic patients [28]. Previous studies argued that heel, hallux and metatarsal head were reliable testing regions [18]. In the current study, within- and between-days inter-rater reliability were excellent in all areas except for medial forefoot of both feet in between-days inter-rater reliability that was moderate.

The intra-rater reliability demonstrated high ICC in within- and between-days examination, similar to previous studies [13, 18, 23]. Only the reliability of right medial forefoot and left lateral forefoot were moderate. Collins et al. assessed the between-days intra-rater reliability in healthy people and reported good reliability for the right foot and poor-to-moderate reliability for the left foot. Individual’s variation and examiner proficient affected the reliability [25, 26]. Studies demonstrated that vibration sensation test is appropriate for neuropathy diagnosis in diabetic patients [28]. Reliability of graduate tuning fork was assessed in diabetic and polyneuropathy patients [14].

There is no data available on the reliability of on/off method of tuning fork for vibration sensation evaluation in diabetic patients. Results of the present study demonstrated that within-day intra-and inter-rater reliability of tuning fork were excellent. However, between-days intra- and inter-rater reliability were moderate and poor, respectively.

An analysis of 3 cohort studies indicated that disagreement in tuning fork result was associated with age, height and the area of vibration test. In addition, the vibration sensation test by tuning fork results depended on examiner experience and were highly subjective [28]. In our study, both evaluators were expert and only the vibration sensation of hallux wax examined. Percentage of the correct answer on total on/off test of each tuning fork was calculated and the personal opinion of the examiner did not affect the results.

| Reliability       | Frequency | Right Foot |         |         | Left Foot |         |         |
|-------------------|-----------|------------|---------|---------|-----------|---------|---------|
|                   |           | 128 Hz     | 256 Hz  | 128 Hz  | 256 Hz    |         |         |
|                   |           | ICC        | SEM     | ICC     | SEM       | ICC     | SEM     |
| Within day        | Intra-rater| 0.82       | 0.587   | 0.91    | 0.623     | 0.91    | 0.587   | 0.90    | 0.657   |
|                   | Inter-rater| 0.76       | 1.697   | 0.86    | 1.296     | 0.83    | 2.286   | 0.90    | 0.784   |
| Between days      | Intra-rater| 0.71       | 2.986   | 0.46    | 2.546     | 0.52    | 5.763   | 0.66    | 2.021   |
|                   | Inter-rater| 0.44       | 3.743   | 0.18    | 2.512     | 0.42    | 5.279   | 0.47    | 1.193   |
5. Conclusion

The current study was demonstrated to investigate reliability of within- and between-days inter- and intra-rater reliability in diabetic patients by SWM and tuning fork test. The between-days inter- and intra-rater reliability of the tuning fork were low. The sensation of diabetic patients must be periodically evaluated to understand whether SWM is a reliable tool for this reason.

Ethical Considerations

Compliance with ethical guidelines

All procedures performed in studies involving human participants were in accordance with the ethical standards of the University of Social Welfare and Rehabilitation Sciences research committee and with the 2013 Helsinki declaration. Informed consent was obtained from all patients included in the study.

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Authors contributions

Designing and performing tests: Masumeh Bagherzadeh Cham and Akbar Biglarian; Collecting the data and co-writing the paper: Masumeh Bagherzadeh Cham and Saeed Kalbasi; Performing the analysis: Akbar Biglarian; and Supervising the research: Mohammad Ali Mohseni-Bandpei and Mahmood Bahramizadeh.

Conflict of interest

The authors declare no conflict of interest.

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Research Paper: Training Mothers to Improve Gross Motor Skills in Children With Cerebral Palsy: A Randomized Controlled Trial

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ABSTRACT

Objectives: The present study examined the effect of home-based handling training of mothers on the improvement of gross motor function of children with Cerebral Palsy (CP).

Methods: In this randomized control trial, 42 children with CP (5-12 years old) were randomly assigned into the intervention and control groups. Data were collected using the Gross Motor Function Classification System and Gross Motor Function Measure.

Results: Gross motor function suggested significant improvement in the intervention group, in comparison with the control group (P<0.01).

Discussion: Handling training of mothers could be advised as a complementary and helpful intervention for gross motor function improvement in children with CP.
Highlights

● Training mothers of children with cerebral palsy is a part of occupational therapy intervention to improve children’s gross motor functions.

● Neurodevelopmental treatment plus mother training can be more effective improving motor abilities of children with cerebral palsy.

● Proper handling and suitable positioning during activities of daily living can lead to gross motor function improvements.

Plain Language Summary

Mothers of children with Cerebral Palsy (CP) have an essential role in their children’s therapy, should they receive proper training in this regard. Mothers spend a lot of time with their children. However, care of a child with CP should not create problems for instance musculoskeletal pains for the mother. In handling the training program, mothers learn to treat their children during activities of daily living so that not only help the CP child to improve her or his motor functions but also assist themselves to care for children in a more convenient way. In this study, we provided a kind of education for mothers in our intervention group. They participated in a workshop to learn how to handle their children at home or in other settings. Children with CP were all received neurodevelopmental treatment as their ordinary occupational therapy intervention. After the study, the children whose mothers received our training program reported that their children had shown improvement with their gross motor functions compared to the control group. This finding shows that children with CP could achieve better results when their mothers have enough information about how to handle them.

1. Introduction

Cerebral Palsy (CP) is the most prevalent physical disability in children [1]. Its incidence is 2-4 per 1000 live births [2]. Children with CP often have postural and movement disorders as well as problems in the development of fine and gross motor functions [3]. Dysfunction in gross motor skills is among the main characteristics of CP that can affect their participation in daily life activities [3].

Gross motor function includes the ability to control head, roll, and sit and walk independently [4, 5]. Gross motor skills in children with CP can be strong predictors of self-care and social function [6]. Occupational therapists and the family of children with CP need up-to-date and accurate information about gross motor skills [7]. Occupational therapy interventions try to enhance clients’ abilities to perform their daily activities. Some of the children’s activities are related to their gross motor skills. They need to run and walk to gain high quality experiences.

Development in gross motor skills had been considered in most approaches, such as Neurodevelopmental Treatment (NDT), conductive education and sports therapy like hippotherapy [6, 8, 9]. Sterba et al. examined horseback riding therapy on gross motor function in children with CP [8]. They used the Gross Motor Function Measure (GMFM) as the outcome measurement. Their results indicated that this intervention may improve gross motor function in children with CP.

In approaches like NDT and hippotherapy, the techniques can be performed by therapists at clinics and because of their long-term nature, may impose a huge financial burden to the clients’ families [10]. Moreover, children with disabilities need opportunities to practice their newly learned tasks. Therapists believe that home-based programs are crucial for improving children’s functional and motor performance [11]. Handling training can be a part of home-based programs. Handling as a caregiving method for children with CP, facilitates self-care, mobility and social skills in them [12].

In occupational therapy, training has been identified as a type of intervention in which the occupational therapist instructs the client on how to use her skills in real life [13]. Handling training in children with CP is demonstrated to smoothing movement, correcting posture and precluding deformities and contractures [14]. It could be
conducted by therapists or parents. Primary studies have argued that this training program could be helpful to provide care for children at levels 3-5 of the Gross Motor Function Classification System (GMFCS) [15]. In other words, it is hypothesized that handling training is more helpful in children with a severe physical disability than those with mild disabilities.

Johari et al. examined the effects of handling training on fine motor skills of children with CP. The participants in the intervention group showed improvement in their skills, compared to the control group members [16]. However, data are scarce on the effects of handling training on the development of gross motor function in children with CP. Most studies have focused on the parents’ emotional domains, including satisfaction with this training method or interactions between parents and their children [6, 10, 17, 18]. The present research examined the effect of home-based handling training applied by children’s mothers on the gross motor function of children with CP aged 5 to 12 years.

2. Methods

This single blind randomized controlled trial was part of a larger study [16]. Mothers in the intervention group participated in a 5-hour training workshop including proper positioning, carrying, transferring and lifting children during Activities of Daily Livings (ADLs). There were no important changes in the applied methods after trial commencement.

We recruited children with CP and their mothers from the occupational therapy clinics affiliated to the University of Social Sciences and Rehabilitation Sciences (Figure 1). After assessing 118 children, the eligible participants were included in the study. The inclusion criteria were children with a diagnosis of CP, 5 to 12 years of age, levels III to V of Motor Function Classification System expanded and revised (GMFCS E&R) [19]. Inclusion criteria for mothers were literacy, not taking care of other persons with disabilities, and no history of participating

| Enrollment | Enrolled =118 |
|------------|--------------|
|            | Not meeting inclusion criteria=62 |
|            | Remaining children= 56 |
| Allocation | Randomization =42 |
|            | Intervention =21 |
|            | Control =21 |
| Follow up  | Withdraw*= 1 |
|            | Completed study=20 |
| Analysis   | Completed study=20 |

Figure 1. Study flowchart

*Causes of withdrawal: parents’ problems including the lack of time and work-related problems.
in similar training programs [see the details [16]. Finally, 42 mothers and their children participated in the study.

A research assistant randomly assigned the eligible participants (n=42) into the intervention and control groups. The study participants were determined by drawing out a number from an envelope. When the drawn number was even, the participant was allocated to the intervention group. The number of mothers in each group was similar. All the study participants signed an informed consent. Then, the study children were assessed with respect to GMFM and GMFCS (E&R) by an occupational therapist blinded to the groups (pre-test).

Children in both groups continued receiving NDT during the study, which was conducted by 3 occupational therapists. All of the study therapists followed NDT (Bobath) approach principles in the therapy sessions and the first author had checked these principles with them prior to the intervention sessions.

To estimate the number of participants, a confidence interval of 95% and power of 80% were considered [6, 10]. Fifteen participants were needed. The GMFM was used to measure changes resulting from the intervention. GMFM is a criterion-referenced tool developed to assess children with CP. GMFM was used to assess children’s rolling, crawling, sitting, standing and walking, as well as running and jumping functions. The evidence suggests that the GMFM is a valid and reliable instrument [19, 20].

GMFCS (E&R) was used to classify the children. It is a 5-level classification system that categorizes children and youth with CP, based on their gross motor ability, limitations and needs for assistive technologies and devices [19]. Children in level I are more capable than those in the other levels are and children in level V are more dependent in terms of their gross motor functions. This classification disregards judgment about the movement quality or improvement prognosis [21]. The validity and reliability of the Persian version of the GMFCS (E&R) have been examined by Dehghan et al. [22].

Interventions

A training session was held to train mothers about the handling principles by a qualified occupational therapist (see the details [16]). Booklets were provided to the parents at the same session which included the following topics: the problems of the mothers of children with CP; self-care; carrying; rest and sleep; leisure time; and social participation and playing with the child [23].

After initiating the proper handling by mothers at home, one of the researchers (first author) called the mothers in the intervention group once a week for 3 months (the main phase of intervention). During these phone calls, the researcher and parents tried to manage and solve the problems faced while implementing the proper handling. After the completion of intervention, all children were assessed in terms of gross motor function by the same occupational therapist assessing them at the Pre-test. After conducting the post-test, the same workshop was held for the mothers in the control group; they received a booklet of handling training as well, and if they faced problems, they were able to call to the researcher.

Data analysis

Significance level was considered at P>0.05. The baseline measurements and demographic variables were compared using the Chi-squared test and t-statistic. There were no significant differences in any variables between the groups (P>0.05). To identify the effects of handling training on gross motor skills, Analysis of Variance (ANOVA) and Paired Samples t-test were employed.

3. Results

Participant’s gross motor skill ranged from 6 to 87 and the mean score of these skills was 51. Gender was the only variable with a statistically significant difference between the two groups (P<0.05). Forty mothers and their children finished the intervention. Table 1 presents the demographic characteristics of participants at the base line. Gross motor skills significantly improved in both groups at 3 months after the intervention (Table 2); however, the one-way ANOVA results revealed that the improvement in the intervention group was significantly greater than the control group (Table 3).

4. Discussion

This study suggested a significant improvement in gross motor skills in both groups. It may be due to the received occupational therapy services in the two groups. Participants in both groups have been receiving NDT during the study period. NDT could impact children’s motor skills [15]. Children with CP at the levels of III to V of GMFCS could reach their maximum GMFM score at 5 to 7 years of age [24]. The obtained results indicated that if the children and their family receive a proper in-
### Table 1. Demographic data of children with CP and their mothers

|                   | Intervention  | Control     |
|-------------------|---------------|-------------|
| **Age, y (Mean±SD)** | 33.60±4.54    | 34.41±5.72  |
| **Marital status**  |               |             |
| Divorced: 1(5%)     |               | Divorced: 2(10%) |
| Married: 19(95%)    | Married: 18(90%) |
| **Occupation**      |               |             |
| Part time: 8(40%)   | Part time: 6(30%) |
| Full time: 4(20%)   | Full time: 4(20%) |
| **Gender**          |               |             |
| Female              | 2(10%)        | 6(30%)      |
| Male                | 18(90%)       | 14(70%)     |
| **Type of CP**      |               |             |
| Quadriplegia        | 11(55%)       | 12(60%)     |
| Diplegia            | 9(45%)        | 8(40%)      |
| III                 | 6(30%)        | 9(45%)      |
| GMFCS E&R*          |               |             |
| III                 | 6(30%)        | 9(45%)      |
| IV                  | 7(35%)        | 5(25%)      |
| V                   | 7(35%)        | 7(35%)      |
| **Gross motor skills** | 40.70±24.45 | 32.3±18.347 |

* Gross Motor Function classification system expanded and revised

### Table 2. Mean±SD of the mean scores of gross motor skills within the two groups using paired samples t-test

| Group   | No. | Pre-Test Mean±SD | Post-Test Mean±SD | t  | P       |
|---------|-----|------------------|-------------------|----|---------|
| Intervention | 20  | 40.70±24.45      | 60.10±25.57       | 7.46 | 0.001   |
| Control  | 20  | 32.38±18.34      | 41.90±19.51       | 5.56 | 0.001   |

### Table 3. Mean±SD of gross motor skill of the participants in two groups, at 3 months after the intervention using ANOVA

| Group   | No. | Post-Test Mean±SD | CI (95%) | P    | Effect Size |
|---------|-----|-------------------|----------|------|-------------|
|         |     |                   | Lower    | Upper|               |
| Intervention | 20  | 60.10±25.57       | 48.13    | 72.06| 0.016        | 1.2        |
| Control  | 20  | 41.90±19.51       | 32.76    | 51.03|              |            |
tervention, they could improve their gross motor function even after this age range. Occupational therapy services working with children with disabilities focus on improving their performance and interaction with social and physical environments. Home-based programs are often used to achieve such goals [11]. Handling training focuses on the natural environments of child like home and school; thus, it can be considered as a functional and generalizable program [6].

Trained mothers by handling training, prevent secondary conditions including deformities and abnormalities. This condition can limit the children’s motor skill development. In this study, the intervention group displayed statistically significant advancement in comparison with the control group. Novak et al. investigated a home-based program in children with CP [18]. The program had a positive effect on participants’ motor function. However, this study lacked a control group. To eliminate this issue, they conducted a double-blind randomized controlled trial [6]. They used the Canadian Occupational Performance Measure [25] to measure the changes. Eight weeks of home-based occupational therapy program has focused on parent-selected goals. Findings revealed that home-based programs could be beneficial for children with CP. Behzadi et al. reported that home-based programs that focus on improving gross motor function can be more beneficial than NDT [26].

Handling training used in this study is different from other home-based programs in terms of considering simpler care provision for children with CP who have severe motor impairments. The interventions for children with the highest level of GMFCS are limited. Lowing et al. used goal-directed functional therapy on children with CP. The participants were classified according to GMFCS at levels I-IV. Improvements in the GMFM scores were detected after the intervention and at follow-up [27]. However, they did not include children at GMFCS Level V. Another study found that a home-based occupational therapy program including training of daily living activities, environment adaptation and parent training was promising in caring of children with CP [28].

Creating opportunities and offering adapted activities based on the child’s gross motor function level and proper handling and suitable positioning during ADLs can lead to gross motor function improvements by performing exercises and making activities easier. These exercises induce abnormal reflexes inhibition, facilitating normal motor patterns and postures, and reciprocal muscular function adjustment [29]. Intervention implementing is performed based on usual daily care activities by caregivers in the absence of home-based programs and does not impose additional works on caregivers.

Many caregivers are concerned about the correctness of program implementation. However, this program addresses their questions and eliminates their concerns. Moreover, this program increases parents’ participation; the higher the parents’ participation through intervention, the better the development in a child’s motor function will be [6]. Children have received different interventions; controlling this issue as a confounding variable was so difficult. Setting individual programs based on the special needs of each child was an ideal situation that could not be achieved in this study.

5. Conclusion

The obtained results indicated that the handling training for the mothers of children with CP could significantly improve their gross motor skills. Therefore, it can be used as a complementary method of occupational therapy services.

Ethical Considerations

Compliance with ethical guidelines

This study was approved by ethics committee of University of Social Welfare and Rehabilitation Sciences.

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Authors contributions

Conceptualization: Sahar Johari, Mina Ahmadi Kahjoogh, Mostafa Daemi; Methodology: Sahar Johari, Mina Ahmadi Kahjoogh; Investigation: Sahar Johari, Mina Ahmadi Kahjoogh, Fatemeh Sanei, Naser Havaei, Mostafa Daemi; Writing- original draft: Sahar Johari, Mina Ahmadi Kahjoogh; Writing–review & editing: Sahar Johari, Mina Ahmadi Kahjoogh, Fatemeh Sanei, Naser Havaei, Mostafa Daemi; and Supervision: Sahar Johari, Mina Ahmadi Kahjoogh.

Conflict of interest

The authors declare no conflict of interest.
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Research Paper: Effect of Ankle Brace on the Activity and Co-Contraction of Ankle Muscles During Single-Leg Landing

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Objectives: The results of a few studies about the effects of ankle brace on muscles function during the performance of different tasks are contradictory. Moreover, the effect of brace on the co-contraction of ankle muscles is undiscovered. Therefore, the present study investigated the effect of brace usage on the ankle muscles activity and co-contraction during single-leg landing.

Methods: Fifteen non-athletic males aged 22.3±1.09 years without any traumatic injury and abnormality of the lower limb participated in this study. Electromyography activity of the ankle muscles (tibialis anterior, lateral gastrocnemius, medial gastrocnemius, peroneus longus and soleus) and muscle co-contraction in the anteroposterior and mediolateral directions were compared between two single-leg landing conditions, in respect of braced and unbraced ankle. The subjects landed from a 60-cm height bench. For the normalization of electromyography amplitudes, maximum voluntary isometric contractions were recorded for each muscle. Paired Samples t-test was used to compare muscle activities and co-contractions between the two conditions of landing.

Results: In general, the activity of selected ankle muscles was reduced in braced condition, compared to the unbraced condition (P<0.001). This reduction was not significant in the gastrocnemius lateralis muscle. In addition, the muscles co-contraction decreased in both directions during landing in braced condition (P<0.05).

Discussion: According to the obtained results, ankle brace reduces the activity and co-contraction of ankle joint muscles during landing. These findings can be considered as advantages of using brace, because it could reduce the load imposed on joint and muscles.

ABSTRACT

Objectives: The results of a few studies about the effects of ankle brace on muscles function during the performance of different tasks are contradictory. Moreover, the effect of brace on the co-contraction of ankle muscles is undiscovered. Therefore, the present study investigated the effect of brace usage on the ankle muscles activity and co-contraction during single-leg landing.

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Discussion: According to the obtained results, ankle brace reduces the activity and co-contraction of ankle joint muscles during landing. These findings can be considered as advantages of using brace, because it could reduce the load imposed on joint and muscles.
Highlights

- Wearing an ankle brace reduces the activity of the ankle joint muscles during landing.
- Wearing an ankle brace reduces the co-contraction of the ankle joint muscles during landing.

Plain Language Summary

Athletes use braces to protect them from injuries. One of the popular kinds of braces is ankle brace. It is important to know why athletes are greatly satisfied while using an ankle brace. The present study revealed that ankle brace decreases activity and co-contraction of ankle muscles during intense activities like single-leg landing. This finding can be considered an advantage of using an ankle brace because it could reduce the load imposed on joint and muscles.

1. Introduction

Studies revealed that 15% of all sports injuries occur in the ankle joint, and 85% of these injuries are ankle sprains [1]. Moreover, joint stabilization by external protectors can reduce the odds of injury and sprains; thus, therapists recommend athletes to use braces [2, 3]. Although brace as a supportive tool has been accepted by athletes, researchers are still investigating the mechanism by which brace affects the function of supporting structures of the joint.

In this regard, the mechanism of the bracing effect on the ankle muscles activity has been evaluated. Few researchers have investigated the effect of bracing on the ankle muscles during different tasks [4-7] and reported contradictory results. Hopper and et al. investigated the effect of bracing on the selected muscle activity in netball players in jump landing. They concluded that the electromyographic activity of gastrocnemius and peroneus longus muscles significantly decreased when subjects were braced [7].

Feger et al. determined the effect of bracing on electromyography amplitudes in participants with chronic ankle instability during various tasks. According to their findings, the activity of some ankle muscles reduced during the forward lunge and anterior reach of star excursion balance; while no differences were observed between braced and unbraced conditions during the single limb eyes-closed balance, the postromedial reach of star excursion balance, or lateral hop exercises [5].

Cardoso et al. indicated that ankle bracing cannot affect the muscles activity during vertical jumping and lateral shuffling [4]. Tesuchida et al. reported the effect of bracing on the activity of selected muscles during landing from 30 cm and 50 cm height movements. Their findings suggested that wearing a brace significantly decreased the activity of medial gastrocnemius muscle during landing from a 50 cm height [6].

Although muscle co-contraction is an important protective mechanism for joints [8], the impact of brace on it has been overlooked by previous researches. Therefore, the present study investigated the effect of brace on the ankle muscles activity and co-contraction in healthy individuals during single-leg landing. Among different tasks, single-leg landing imposes the greatest force on the ankle joint. Thus, this task was considered as an independent variable to determine the effect of ankle brace on muscles function in one of the most difficult dynamic conditions.

2. Methods

Fifteen non-athletic male volunteers (Mean±SD age: 22.3±1.09 years, height: 179.6±6.64 cm, weight: 74.6±4.48 kg, and BMI: 23.7±2.67 kgm²) were recruited. Inclusion criteria were ≥19 years of age, a normal BMI, not being an athlete. Exclusion criteria were health problems such as traumatic injuries, abnormalities, surgical history, and pain in the lower limb. The Research Council of the Islamic Azad University, Boroujerd Branch, in agreement with the Declaration of Helsinki, approved all the study procedures prior to the onset of study.

For the electromyographic acquisition, Electromyography (EMG) (Biomonitor ME6000 T-16, Finland) was used. Muscle activity was sampled at 1000 Hz via a 16 bit DAQ-516 A/D card and recorded in a laptop computerizing MegaWin (Mega Electronics Ltd, Kuopio, Finland). The signal-to-noise ratio was set at 110 db.
Pairs of 10-mm diameter Ag/Ag Cl electrodes in dipole array were located on the skin of Tibialis Anterior (TA), Peroneus Longus (PL), Gastrocnemius Lateralis (GL), Gastrocnemius Medialis (GM), and Soleus (S) muscles with an inter-electrode distance of 20 mm (Figure 1). For reducing the skin impedance, the skin was shaved and cleaned by alcohol 70% (ethanol-C\textsubscript{2}H\textsubscript{5}OH) before placing the surface electrodes. The electrodes were fixed at the abdominal muscles according to the European concerted action Surface EMG for a Non-Invasive Assessment of Muscles (SENIAM) [9]. The right leg was randomly selected for the placement of electrodes. After electrode placement and warm-up, at trials, three Maximum Voluntary Isometric Contractions (MVIC) were recorded for each muscle to normalize SEMG amplitudes. Every participant was trained to perform 2 second maximum contraction against the resistance. The resisted movements were as follows: dorsiflexion-tibialis anterior, pronation-peroneus longus, plantarflexion—medial and lateral gastrocnemius and soleus [9, 10].

The participant sat on a bench while performing the MVICs in respect of tibialis anterior and the peroneal muscles. In the gastrocnemius and soleus MVICs, to ensure that the participant would not slide backward during the contraction, the participant sat on the floor with their back against a wall. Three consecutive maximum efforts were separated by a 1 min recovery period to avoid fatigue. For calculating average Root Mean Square (RMS) from three trials, a 600 ms window in the middle of the 2 s recording period was applied. After performing the normalization test, the electrical activity of the muscles was recorded while performing single-leg landing tests on a 60-cm height bench both unbraced and braced (ankle brace) (Figure 1). This study used the ankle support brace by an elastic strap (model 1009).

Three balanced single-leg landing in each condition (braced and unbraced) were recorded for every participant. Muscle activity was considered from the moment of landing to one second after landing. The moment of landing was determined by a single electrical footswitch. To measure the amount of muscles electrical activity, the average root mean square of every three trial was computed and normalized while considering corresponding MVIC trials for each muscle.

To reduce electrical interferences from external sources, the signals were filtered by a bandwidth Butterworth fourth-order filter of 10-500 Hz and a band-stop filter of 50 Hz. The Co-Contraction Index (CCI) [11] was used to represent ankle-dorsiflexor and extensor (TA and GL), and ankle invertor and evertor (TA and PL) muscles co-contraction.

$$CCI = 2 \times \frac{EMG_{AG}}{EMG_{AG} + EMG_{ANT}} \times 100$$

To measure the CCI, the antagonistic muscle activity (the average of root mean square) was divided by the mean score of agonistic (EMG\textsubscript{AG}) and antagonistic (EMG\textsubscript{ANT}) muscles activations.

The average RMS values of the co-contractions and muscles activities between the two conditions of landing were compared using the paired samples t-test.

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**Figure 1.** Electrode placement over the ankle muscles and experimental setup with and without a brace.
Statistical analysis was carried out using SPSS and P<0.05 was considered as statistically significant.

3. Results

As shown in Figure 2, brace reduces the activity of all selected ankle muscles. This decrease in muscle activity was statistically significant except for the GL (P<0.001). In general, brace usage reduced the average activity of selected muscles by 15.82%, which was statistically significant (P<0.001) (Table 1).

The results of the effect of brace on the ankle muscles co-contraction are presented in Figure 3. These results suggested that using brace reduces the co-contraction rate of ankle muscles (P<0.05) in anteroposterior (plantarflexor and dorsiflexor muscles), and mediolateral (evertor and invertor muscles) directions.

4. Discussion

The obtained results suggested that using brace decreased the ankle muscles activity, in general. The results of some studies are in-line with the current research [5, 7], while others [4] are inconsistent with the present study. The reduced ankle muscle activity by a brace, can be associated with two other effects of brace on the joint. Previous studies have argued that brace controls the joint range of motion [12]. By controlling the joint’s range of motion, the brace can partly reduce the amount of load imposed on the joint muscles, thereby reducing muscle activity [13]. Additionally, brace increases the joint’s mechanical stability [14]. By increasing the passive mechanical stability, the brace reduces the need for the active mechanical stability of the joint caused by muscle intervention. Reducing muscle intervention in stabilizing the joint leads to decreased muscles activity.

The most important finding of the present study was reduced ankle muscle co-contraction, both in the plantarflexors and dorsiflexors muscles as well as evertor and invertor muscles after using a brace. Based on the literature review, this issue has not been assessed in previous studies. Co-contraction is among the functional mechanisms of agonist/antagonistic muscles to increase joint stability during motion performance [8]. However, because the brace produces passive stability in the joint, [15] the requirement of active stability for the joint will reduce. It can be considered as a benefit of using brace; as active stability derived from co-contraction has the potential to increase the compressive forces within the joint [16].

The selection of the right leg for the experiment without paying attention to the dominant and non-dominant

| Percent Reduction | TA       | PL       | GL       | GM       | S        | Total    |
|-------------------|----------|----------|----------|----------|----------|----------|
| Mean±SD           | 22.00±16.57 | 17.57±9.76 | 7.45±33.22 | 19.86±11.3 | 13.65±13.83 | 15.82±9.75 |

Figure 2. Mean±SD scores of ankle muscles activity during two single-leg landing conditions

Figure 3. Percentage of the anteroposterior and mediolateral ankle muscles co-contraction during two single-leg landing conditions
leg was a limitation to this study and it is recommended for consideration in future studies.

5. Conclusion

According to the present study, using ankle brace reduced the ankle muscles activity and co-contraction. It can be speculated as a functional mechanism of the brace; thus, such use of brace is recommended for athletic rehabilitation procedures.

Ethical Considerations

Compliance with ethical guidelines

The Research Council of the Islamic Azad University, Boroujerd Branch, in agreement with the Declaration of Helsinki, approved all the study procedures prior to the onset of study.

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Authors contributions

Study concept and design: Farnaz Mobini, Mehrdad Anbarian; Data collection: Farnaz Mobini, Leila Ghazaleh; Interpretation of data: Mehrdad Anbarian; Supervision: Mehrdad Anbarian; and Writing-review and editing: Leila Ghazaleh, Mehrdad Anbarian.

Conflict of interest

The authors declare no conflict of interest.

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Research Paper: Effectiveness of a Combined Training Package on Strengthening Visual Perceptual Skills in Preschool Children

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Objectives: Paper and pencil exercises are extensively used to enhance children’s visual perceptual skills, while exercises involving volumetric shapes have been neglected. The present study aimed to develop a combined training package, including volumetric shapes and paper and pencil exercises, and to investigate its effectiveness in strengthening the visual perceptual skills of preschool children.

Methods: This was a quasi-experimental study with pre-test post-test and a control group design. The statistical population of the study consisted of preschool children (n:30; age: 5-6 years), who were randomly assigned to the control and experimental groups. In the experimental group, the training package reinforcing visual perceptual skills was presented in ten 45-minute sessions in a play and paint framework. In the pre-test and post-test phases, the Frostig developmental test of visual perception was completed by children.

Results: The results suggested that the post-test pre-test differences between the experimental and control groups were significant in terms of the following components: differentiation between object and background, understanding shape stability, the perception of position in space, and the total score of visual perception.

Discussion: Considering the effectiveness of combined training package in strengthening visual perceptual skills, it can be used to facilitate learning in preschool children and reduce visual perceptual deficits in children with learning disabilities.

ABSTRACT

Objectives: Paper and pencil exercises are extensively used to enhance children’s visual perceptual skills, while exercises involving volumetric shapes have been neglected. The present study aimed to develop a combined training package, including volumetric shapes and paper and pencil exercises, and to investigate its effectiveness in strengthening the visual perceptual skills of preschool children.

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Discussion: Considering the effectiveness of combined training package in strengthening visual perceptual skills, it can be used to facilitate learning in preschool children and reduce visual perceptual deficits in children with learning disabilities.
Highlights

- The combined training package reinforces the visual perceptual skills of preschool children.

Plain Language Summary

Children should receive sufficient visual perceptual skills in order to be successful in their education. Visual perception allows a person to accurately analyze the size, shape, color, and spatial relations of objects. Children with poor visual perceptions are more likely to develop learning problems at elementary school. The current training packages for reinforcing visual perception are purely composed of paper-pencil exercises or motor programs. The combined training package use paper-pencil exercises alongside tactile and objective materials to enhance visual perceptual skills. In the combined training package, the children perform visual perceptual exercises through games. These games include an assortment of cards, volumetric puzzle patches, nail boards, and model rulers. Such visual perceptual gaming exercises can improve perceptual capacity and vision in children. Children during visual perceptual and motor games learn a lot about shapes, colors, and causal relationships, which assists their cognitive development. After doing exercises and games in this package, the preschool children can differentiate between objects and background, understand shape stability, and the perception of position in space.

1. Introduction

Children use visual information processing skills to examine and understand shapes and visual symbols, like letters and numbers. Deficits in cognitive and information processing skills are one of the most important causes of learning disorders [1]. In general, visual perception is a process through which visual information is analyzed [2]. It occurs in the right brain hemisphere and detects the position and form of objects, as well as their spatial relations with the observer [3].

Visual perception allows a person to accurately analyze the size, shape, color, and spatial relations of objects [2]. Visual perceptual skills include the reception and recognition of visual stimuli. Visual reception is the process of extracting and organizing information from the environment [4], while the recognition aspect of visual perception is the ability to interpret and use visual information [5]. Generally, the recognition of visual cues requires effective visual representation [4], including visual attention, visual memory, and visual distinction [5].

There are two types of visual perception; the perception of shape and the perception of space. The perception of shape is defined as recognizing an object which consists of 3 components of shape stability, visual completion, and differentiation between shape and background [6]. Furthermore, space perception is the ability to identify the position of an object in space, including its orientation in space, spatial relations, and the perception of its direction.

Frostig, Whittlesey, and Lefever [7] proposed that visual perceptual skills include differentiation between shape and background, the perception of spatial relations, visual coordination, the perception of object stability, and the perception of object position in space.

Mash and Barkley [8] similar to Aminzadeh and Hassan Abadi [9] emphasized that children with poor visual spatial or visual motor perceptions are more likely to develop math problems at primary-school level. Generally, children with reading impairments are unable to focus on the stimuli. They are misled by the background stimuli, and differentiation between visual cues is difficult for them. They fail to realize that changes in the position of letters in a word do not change their pronunciation (shape stability); in fact, they fail to pay attention to the form of letters in words [10-12].

Recent studies have suggested that defects in visual perception reduce letter and number recognition through vision, resulting in reduced reading speed. Young children with visual impairments are at an increased risk of reading difficulties [13]. Additionally, children with mathematical learning disabilities have mild developmental delays in visual perception, visual motor integration, and motor coordination [14].

Perceptual motor programs are effective in the perceptual development of children. Perceptual motor games, through strengthening spatial processing, can help children have a more accurate perception of what they see and read; this is in fact one strategy to develop perception in children [15]. Therefore, the direct training of visual perceptual skills can be a reliable method to...
eliminate problems associated with learning disabilities. Torman and Takala [16] examined the effects of audio-visual matching training on the rehabilitation of reading skills in dyslexic children. This intervention was effective and could strengthen visual discrimination, visual recognition, visual stability, discrimination between shape and background, spatial relations, visual memory, sequencing, and visual completion.

Hossinkhanzade et al. confirmed the effects of exercise on visual perceptual skills to improve the visual skills of primary school students with reading disorders [17]. Moore reported improvements in the attention process of children with Attention Deficit Hyperactivity Disorder (ADHD) by performing a series of exercises for attention and eye focus [18]. In addition, Chen et al. found that the multimedia visual perceptual group training program was effective in improving the visual perception of preschool children with developmental delays [19]. Moreover, Nasri and Karimi used Frostig exercises to enhance visual discrimination and visual memory [20]. These exercises facilitated the mental development of children and prepared them for more advanced mental activities.

According to the literature, most studies have applied Frostig visual perception exercises to improve visual perception in children. Therefore, it is important to develop a visual perceptual package to eliminate the limitations of Frostig visual perception exercises. Considering the components of Frostig visual perception exercises, the present study aimed to introduce new exercises, involving volumetric shapes and paper and pencil exercises. Children are not generally motivated enough to perform paper activities and are uninterested to continue continuing these exercises [19], we used a volumetric shapes game to reinforce the visual perception of preschoolers. The present study aimed to reinforce children’s visual perceptual skills by a combined training package, based on the visual components of Frostig test.

2. Methods

This was a quasi-experimental study with pre-test-post-test and a control-group design. The statistical population included all normal preschool children from Bojnord City, Iran, who were selected from a preschool via cluster sampling method. The inclusion criteria were visual, audio, and motor health; and 5-6 years of age. Thirty children in the age range of 5-6 years were randomly selected and divided into the experimental and control groups. The parents of selected children provided consent forms for participation in this study. The number of girls and boys was equal in the two groups (7 boys and 8 girls in each group).

The participants in both groups completed the Frostig Developmental Test of Visual Perception (DTVP) in the pre-test and post-test phases. In the experimental group, the training package of reinforcing visual perceptual skills was presented in ten 45-minute sessions in a play and paint framework, while no intervention was applied for the control group. However, after the end of the study, the training package was also presented to the control group.

Frostig DTVP

This test was presented by Frostig, with 5 major components, including eye-motor coordination, discrimination between shape and background, the perception of shape stability, the perception of object position in space, and the perception of spatial relationships; the subtests are scored from one to 5. The test reliability for teacher grading in classroom evaluation, motor coordination and mental operations were 0.44, 0.50, and 0.50, respectively [7]. In Iran, the reliability of Frostig DTVP has been reported as 0.68-0.74, and its validity has been estimated equal to 0.47 [21].

Training package for strengthening visual perceptual skills

The experimental group received a training package for reinforcing visual perceptual skills in ten 45-minute sessions, as described below:

Session 1: Familiarization with lines; drawing lines to develop eye-hand coordination; Session 2: Recognizing and drawing shapes; Session 3: Exercises for eye-hand coordination by visual cards; Session 4: Painting with lines and finding meaningful images; Session 5: Presenting images on a wooden board to complete the half-finished images on cards; Session 6: Drawing geometric shapes on paper with the help of rulers in multiple directions, painting, and finding shapes in different sizes and textures among images. Session 7: Creating meaningful images using geometric shapes pieces, image card pieces, wooden pieces, and volumetric shapes. Session 8: Drawing an image by looking at a card with the help of arrows on a paper showing directions; selecting the correct image among different cards; Session 9: Creating volumetric shapes in the same direction depicted on the cards; and Session 10: Making cards with the help of flexible strings on wooden boards with nails attached.
3. Results

Data related to Frostig DTVP (e.g. Mean±SD) in the experimental and control groups during pre-test and post-test phases are presented in Table 1. The present study compared the two experimental and control groups in terms of visual perception and its dimensions. To select suitable parametric or nonparametric tests, Kolmogorov-Smirnov test was initially applied to examine the normal distribution of scores in the pre-test and post-test phases.

The results showed that in the pre-test, discrimination between shape and background, the perception of shape stability, the perception of shape position in space, and the perception of spatial relationships were normal in both groups. Moreover, in the post-test, eye-motor coordination, discrimination between shape and background, the perception of shape stability, and the perception of spatial relationships were normal in the control group (P>0.05).

Levene’s test was then used to examine the equality of variances in the two groups. The results revealed that variances were significantly similar in the groups in terms of visual perceptual components (P>0.05). Considering the normal distribution of scores and the equality of variances in the two groups, a parametric test was applied. The assumptions of homogeneity of regression gradient and linear relationships between the pre-test and post-test variables were examined to select either Independent Samples t-test or Analysis of Covariance (ANCOVA) for group comparisons.

According to the obtained results, the assumption of regression homogeneity was confirmed for eye-motor coordination (F=1.65; P=0.21) and discrimination between shape and background (F=15.2; P=0.13); therefore, ANCOVA was applied to examine these variables. In addition, in terms of the other dimensions of visual perception, the homogeneity of regression gradient was not confirmed. Moreover, the results indicated that linear relationships between the pre-test and post-test variables were not valid for eye-motor coordination and discrimination between shape and background. Accordingly, based on the assumptions, an Independent Samples t test was used to analyze the obtained data. First, pre-test and post-test differences were determined to control the pre-test effect. Then, differences were compared in the experimental and control groups (Table 2).

Table 1 presents that the experimental group was significantly different from the control group with regards to

| Variables                          | Group          | Mean±SD  |   |   |
|------------------------------------|----------------|----------|---|---|
|                                    |                | Pre-test | Post-test |   |   |
| Eye-motor coordination             | Experimental   | 12.9±3.94| 13.07±2.89|   |   |
|                                    | Control        | 10.07±1.83| 12.00±2.36|   |   |
| Discrimination between shape and background | Experimental | 2.0±0.84 | 3.00±1.41 |   |   |
|                                    | Control        | 2.87±1.12 | 2.53±1.41 |   |   |
| The perception of shape stability  | Experimental   | 2.4±1.84 | 8.33±3.88 |   |   |
|                                    | Control        | 4.13±2.92 | 4.8±3.43 |   |   |
| The perception of shape position in the space | Experimental | 3.7±1.62 | 7.07±0.70 |   |   |
|                                    | Control        | 3.6±2.35 | 4.73±1.98 |   |   |
| The perception of spatial relationships | Experimental | 3.4±1.76 | 4.67±1.29 |   |   |
|                                    | Control        | 2.07±1.79 | 3.60±1.18 |   |   |
| Total score                        | Experimental   | 24.47±6.35| 36.13±8.09|   |   |
|                                    | Control        | 22.73±5.88 | 27.67±7.88 |   |   |
the variables of discrimination between shape and background, the perception of shape stability, the perception of shape position in space, and the total score of visual perception; in other words, the training package was effective in strengthening visual perceptual skills.

4. Discussion

This study presented a combined training package and investigated its effectiveness in strengthening the visual perceptual skills of preschool children. The results revealed that the designed combined training package was effective in strengthening children’s visual perception. This finding is consistent with the results reported by Nasri and Karimi [20], who designed exercises using Frostig test to enhance the visual perceptual skills of children. It was found that 8 sessions of exercise could facilitate the mental development of children and prepare them for more advanced mental activities.

In our developed training package, painting activities were incorporated, including drawing lines and shapes to strengthen visual perception. Generally, painting and drawing lines can help enhance cognitive development and perception skills, like visual accuracy. Zaidel et al. also suggested that painting could increase visual spatial perception by reinforcing the right and left hemispheres of brain [22]. In fact, painting improved learning by strengthening the parietal and right occipital lobes and improving their interactions.

Another type of activity in the designed training package involved games. Children performed visual perceptual exercises through games. These games included an assortment of cards, volumetric puzzle patches, nail boards, and model rulers. Such visual perceptual gaming exercises can improve perceptual capacity and vision in children. Children during visual perceptual and motor games learn a lot about shapes, colors, and causal relationships, which increases their cognitive development.

The present study clarified that the designed training package could not strengthen eye-motor coordination skills in children. Coetzee and Pienaar consistently revealed that eye-motor coordination depends on a coordinated visual system and an accurate eye muscles control [15].

They stated that motor reactions would fail if the perceived visual information was impaired; therefore, children with poor visual coordination show poor responses to visual stimuli. In this training package, drawing lines between two points (with different widths of images in the designed cards) and extracting meaningful images from lines enhanced eye-motor coordination in children; however, it seems that a longer and more diverse training program is required to strengthen eye coordination. Also, the present study revealed that the designed training package was effective in improving discrimination between shape and background. Generally, figure-ground perception is the ability to concentrate on specific forms and find latent shapes in a complicated background [23].

In the designed training package, exercises involving the use of cards with intersecting and hidden geometric shapes, as well as wooden boards containing meaningful images and lines, helped differentiate shapes from the background; this skill can generally help children identify a hidden shape or object in lines or forms. It seems that one’s inability to distinguish an object from its back-
ground is affected by his/her weakness in visual search, overemphasis on details, the negligence of the overall concept of image, and inability to focus on a word or image on a page.

The obtained results indicated that the training package significantly increased the perception of shape stability. Shape stability is one’s ability to identify differences in size, shape, shade, and objects’ orientation [23]. Exercises, such as the identification of geometric shapes with different sizes and textures and an assortment of wooden volumetric shapes, help strengthen the perception of shape stability. Our study suggested that the designed training package could significantly improve the perception of shape orientation in space.

In this training package, children could move and rotate objects and shapes in different situations by assorting wooden volumetric shapes according to the presented pattern. Generally, understanding the position of shapes and objects in space is to determine their spatial association with the observer and other objects or shapes. This skill is related to the awareness of the object position in terms of the observer and understanding the direction in which the object is rotated.

Using this skill, the child can become aware of the object position and understand its relationship to him/herself and the environment. The present study indicated that the training package was not effective in enhancing recognizing spatial relations skill in children. The perception of spatial relations occurs in the right hemisphere, which helps detect the position of objects and shapes in relation to each other and the observer. This skill helps the individual recognize the sequence of letters and numbers in a word or the words’ sequences in a sentence [8].

The designed training package used wooden boards to strengthen spatial relations. In this wooden board, nails were arranged at regular intervals, and children followed patterns according to images on the cards (in the same direction depicted on the board), using colored rubber bands. However, it seems that this exercise is not adequate for strengthening spatial relations, or at least a significant amount of time is required to successfully implement it.

5. Conclusion

The present study indicated that the training package designed based on Frostig test, could significantly strengthen children’s visual perception. The most important limitation of this study is related to the sample, which included normal children aged 5-6 years. Another shortcoming was that the designed package had not been used in clinical or educational situations; therefore, it is recommended to compare the effectiveness of this package with Frostig exercises. Overall, this training package can be used to strengthen the visual perceptual skills of children and to facilitate reading in elementary school students. Also, the present training package can be used to restructure visual perceptual skills in children with learning disabilities.

Ethical Considerations

Compliance with ethical guidelines

The present study was reviewed in terms of ethical considerations by the Research Committee of Islamic Azad University of Bojnourd and approved on February 26, 2017 (Code: 18220705961003).

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Authors contributions

All authors contributed in preparing this article.

Conflict of interest

The authors declare no conflict of interest.

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Research Paper: Exploring the Challenges in Orthotics and Prosthetics Clinical Learning Environments: A Qualitative Study

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Abstract

Objectives: The present study explored challenges in orthotics and prosthetics clinical learning environments in Iran.

Methods: A qualitative content analysis method was used to obtain data on orthotics and prosthetics clinical educator’s experiences. Qualitative data were obtained using semi-structured in-depth interviews involving 7 clinical educators; all selected by the maximum variation purposeful sampling method. Interviews continued until data saturation.

Results: During the interview sessions, notes and ideas were classified and assorted. The study themes were relationships, personal characteristics, facilities, and policies. Analysis of the qualitative data provided insights into the barriers to the desired delivery of clinical education services.

Discussion: The present research contributes to clinical educators’ experiences in respect of the clinical learning process. Clinical learning concerning orthotics and prosthetics education remains crucial. The findings emphasize the importance of listening to educators, and consider how relationships and contexts impact clinical learning. Understanding the challenges in clinical education environments has increased the quality of clinical education in orthotics and prosthetics field.

Keywords: Challenges, Clinical learning environment, Clinical educator, Orthotics, Prosthetics, Qualitative study
Highlights

- Interpersonal and group relationships affect the quality of clinical education.
- Individual and professional characteristics of students and clinical educators influence clinical learning.
- Another important factor is the characteristics of the clinical environment and facilities.

Plain Language Summary

The provision of orthotic and prosthetic services requires the presence of skilled therapists. Clinical education is one of the main pillars of orthotics and prosthetics. Providing educational services to students is done by clinical educators who are responsible for both healthcare provision to clients, and clinical education to students. Clinical education occurs in an environment where the provision of services to clients leads to human resource limitations and fiscal pressure. Therefore, recognizing the experiences of clinical educators from the clinical education process can provide the necessary ground for improving clinical education in the field of orthotics and prosthetics.

1. Introduction

The fulfillment of clinical placements and exercising supervision play a key role in healthcare students’ achievement of desired learning outcomes [1, 2], the growth of their professional characteristics and capability [3], as well as mastering their clinical skills [4]. Clinical education, which is a kind of learning through experience, includes mastering clinical skills at work. Clinical education is the best option for beginners to enhance their clinical reasoning expertise [5].

In clinical teaching, teachers are required to consider the right developmental level of each learner and empower their participation in workplace activities appropriate to their stage of learning [6]. The development of capable rehabilitation therapists like orthotics and prosthetics requires clinical practice experience at the undergraduate level.

Successful clinical education depends on the clinical educators, their capabilities and personal characteristics, and the support and encouragement they receive [7]. Clinical learning involves obtaining clinical experience and practicing the necessary skills through observation, participation, designing the treatment methods and applying it by considering all the clinical aspects, under the supervision of a teacher [8].

In spite of the importance of orthotics and prosthetics clinical education, there is a lack of clear understanding of assisting individuals involved in clinical instruction. When students join the clinical environment, they are faced with patient’s healthcare needs and their learning needs. Learning may improve in an appropriate clinical environment. The clinical environment is ideal for education [9]. Clinical education of orthotics and prosthetics students is conducted at three medical universities and the Iranian Red Crescent Institute (IRCI). Typically, orthotics and prosthetics student’s clinical practice initiates from the fifth and sixth semesters with observation courses. Then, students enroll the internship courses [10].

Several studies have suggested that learning environments greatly influence the clinical education process [11]. The clinical environment includes inpatient centers, as well as hospital outpatient and community settings, with their own specific issues. Researchers have repeatedly emphasized that the quality of clinical education environment is a strong reliable indicator of the overall quality of training courses [12].

Clinical educators are responsible for healthcare provision to clients, and clinical education to students, simultaneously. Clinical education occurs in an environment where the provision of services to clients leads to human resource limitations and fiscal pressures [13]. Therefore, the present research explored orthotics and prosthetics educators’ experiences in clinical learning environments in Iran.

2. Methods

This qualitative study was performed using content analysis method. Qualitative research clarifies the human condition in various contexts [14]. Qualitative
Content Analysis (QCA) is usually used to explain the textual data by applying the systematic coding process. Data analysis characterizes the categories, themes, and patterns [15]. QCA consists of conventional (inductive), directed (deductive) and summative methods [16]. Inductive QCA, which is most favored in data analysis, contributes to the improvement of theories, schematic models or conceptual frameworks [17].

Sampling and data collection methods

For participant recruitment, maximum variation and purposive sampling methods were applied. This purposive sampling technique was specifically selected to ensure that the sample population would represent various factors relevant to the study objectives [18]. The study was performed from September 2016 to May 2017. Semi-structured interviews were performed, recorded and completely transcribed by 7 orthotics and prosthetics clinical educators affiliated to Iran University of Medical Sciences (IUMS), Isfahan University of Medical Sciences (MUI), University of Social Welfare and Rehabilitation Sciences (USWR), and IRCI (Table 1).

All interviews were conducted by the same researcher and continued until data saturation. In addition, the researcher recorded respondents’ body language and verbal information. The inclusion criteria for clinicians were ≥3 years of clinical education experience and providing clinical education services to students, during the research period. Prior to the beginning of each interview, the researcher informed the participants about the purpose of study and their right to withdraw from the study as desired.

The interview included open-ended questions on orthotics and prosthetics clinical educators’ experience regarding their clinical learning environment and factors influencing their clinical learning process. A guide was developed for the semi-structured interviews, and the following questions were asked, which focused on the participants’ experiences as clinical educators: 1. Describe an internship session; 2. What are the positive or negative factors for clinical learning?; 3. What is the most enjoyable moment or event that has been implicated in your mind in the clinical environment?; and 4. What are the factors that can influence the formation of a person as orthotics and prosthetics?

The interviews lasted for 43-65 min, with a mean duration of 52.7 min. Exclusion criterion was the participant’s relinquishment in any step of the study.

Ethical considerations

The study was approved by the Research Ethics Committee of Iran University of Medical Sciences (Code: IR.IUMS.REC 1395.9411531004). The study was conducted following the instructions issued by the Declaration of Helsinki (2008): The participants were briefed on the study both verbally and in writing. The study participants provided written informed consent forms prior to the interviews. To protect their privacy and confidentiality, all data were recorded anonymously.

Data credibility

Activities such as peer debriefing, prolonged engagement, persistent observation, triangulation, negative case analysis, referential adequacy, and member checking can be used to build credibility [19]. The research credibility was checked. Participants’, investigators’ and method triangulations were done to ensure the precision and reliability of this qualitative study.

Data analysis

The semi-structured interviews were tape-recorded and transcribed; then, the transcriptions were analyzed using content analysis method. It is often appropriate that existing theories or literature be limited to the studied phenomenon. The analysis was conducted manually. Due to long-term engagement with the study participants and obtained data, the researchers effectively communicated with the study participants and thoroughly understood the study context. The transcribed interviews were read and re-read to obtain a clear statement by the researchers. According to the study objectives, meaning units were identified, composed and coded. In total, 116 open codes were extracted. The codes were classified into different categories. Finally, as per Table 2, the meaningful themes were obtained by comparing the orthotics and prosthetics clinical educators’ experiences categories.

3. Results

Seven individual interviews were completed. Some characteristics of the study participants and interviews are presented in Table 1. The analysis yielded four themes of relationships, personal characteristics, facilities, and policies (Table 2).

Relationships

This was the first theme extracted from the data and consisted of “relationship between students and clinical
educators”, “relationship between students” and “relationship between students and patients”. All clinical educators reported relationships as a stressor source in clinical environments. The study participants expressed different dimensions of relationships between students and patients and even their companions, effective in clinical learning processes.

A number of contributors mentioned the positive impact of group relationships on the educational process. One of the clinical educators indicated the impact of senior students on junior students, which could negatively affect the educational process in clinical settings: “In the prosthetic section, senior students are together with lower grade students in a course … But, they always disappoint new students!” [CE6, line 3].

The communication and interaction of healthcare center staff with the students are effective in the clinical education process and cause a variety of experiences to students: “some of my colleagues find students disturb-

Table 1. Characteristics of participants and interviews

| Interview | University | Gender | Education History, Y | Time, Min | Codes |
|-----------|------------|--------|----------------------|-----------|-------|
| 1         | IUMS       | Female | 4                    | 65        | 30    |
| 2         | IRCI       | Male   | 11                   | 51        | 23    |
| 3         | IUMS       | Male   | 5                    | 55        | 20    |
| 4         | MUI        | Female | 13                   | 50        | 16    |
| 5         | USWR       | Male   | 13                   | 43        | 13    |
| 6         | USWR       | Male   | 6                    | 45        | 8     |
| 7         | IRCI       | Female | 12                   | 60        | 6     |
|           |            |        |                      | Total     | 369   | 116   |

Table 2. Themes and categories derived from interviews

| Theme                      | Category                                      |
|----------------------------|-----------------------------------------------|
| Relationship between students and clinical educators | Relationship between students and patients |
| Relationships              | Relationship between students                 |
| Personal characteristics   | Individual characteristics of students        |
| Environmental health       | Environmental health                          |
| Environmental safety       |                                               |
| Policies                   | Ministry of health policies                   |
|                            | University approaches                         |
|                            | Educational department approaches             |
ing their work at clinical centers ... they believe their time is wasted!” [CE 5, line 21].

A number of participants objected to the clarity of boundaries of orthotics and prosthetics, compared with other areas of rehabilitation. This can interfere with tasks while performing team work: “e.g. physiotherapists can prescribe orthoses, but not us! now, students are discouraged ...” [CE 3, line 19].

The role of mentor support in the process of clinical education is very important. One of the clinical educators believed that: “… indeed, students must be supported at work. I always prefer to help them. Sometimes, in the middle of the work, I assist them with their work” [CE 6, line 5]

Personal characteristics

This theme consists of three categories, as follows: “the individual characteristics of students”, “the personal and professional characteristics of clinical educators”, and “patient’s characteristics”.

Student motivation significantly impacts the clinical education process. “[students] do not want to do anything. [they] come sit and drink tea ... [laughter]” [CE2, line 5].

One of the educators also mentioned the lack of accuracy among clinical instructors during internships and believed there should be a firm structure: “… we have less accuracy and less stringency than physiotherapist” [CE 7, line 20].

Contributors discussed the negative impact of job conditions on clinical education, as follows: “I'm getting the money for every orthosis I make ... well, naturally. I try to work harder, to earn more! This condition limits my internship attendance” [CE 5, line 3].

In clinical education, the educator should communicate with students to transfer knowledge and skills. Self-esteem and students’ learning identity are preserved: “… when you appreciate the students’ work, their efforts and motivations are reinforced” [CE 6, Line 10]. Constant monitoring of clinical instructors is effective in trainees' performance. This was another matter expressed by a number of contributors: “it is necessary to pay attention to the students’ work …” [CE 2, line 21].

Referring patients to medical education centers as affects the clinical environment with the following conditions and characteristics: awareness level, socio-political status, psychological features and personal hygiene. The personal hygiene of clients referred to rehabilitation centers is important: “the socks of a patient were so dirty! Students could not approach him ...” [CE 6, line 23].

Some participants discussed the impact of socio-political status of patients on the clinical education process: “e.g. if the patient is a mayor, the girls are not allowed to visit him! He says only boys …” [CE 3, line 4]. Mistrust of patients on trainees does not allow them to sufficiently cooperate and disrupt the training process.

Facilities

The characteristics of clinical environment are discussed in various methods by the study participants. This theme is also composed of three categories, as follows: “the physical characteristics of clinical center”, “environmental health”, and “environmental safety”. Unlike other medical sciences, in the field of orthotics and prosthetics, most of the work is demonstrated in technical workshops. Therefore, proper equipment and tools are essential for the supply of qualitative orthoses and prostheses.

Many clinical trainers have reported that the tools of educational centers are outdated: “we lack modern devices in the department! We have a force plate ... which is always broken!” [CE 7, line 12].

In this field, the presence of raw materials for the construction of orthoses and prostheses is among the main components of clinical education process. In some centers, the lack of raw materials or difficulty in obtaining those are students’ challenges in clinical learning. One of the educators complained about the limited space of clinic and the inappropriateness of physical space with the number of students: “the problem is ... the workshop is small ... it is chaotic!” [CE3, line11].

The use of equipment and tools such as sandblast, grinding, and gibson machines, hammers, as well as raw materials such as laminate and carbon, affect the workplace environment. The presence of various tools at orthotics and prosthetics workshops requires the observance of safety principles. However, a number of contributors mentioned the negative attitudes in the use of protective equipment in clinical settings: “… some people tell students that the use of protective devices is ridiculous!” [CE 3, line 3].
Policies

The last theme focuses on the factors impacting the student's learning process despite the high spatial and temporal distance from the clinical education environment. This theme consists of three categories, as follows: “the Ministry of health policies”, “university approaches” and “educational department approaches”.

There are numerous upstream laws and policies that somehow affect the quality and effectiveness of internships and students’ experiences. In the past few years, the Ministry of Health has privatized health and rehabilitation centers. A number of educators emphasized on the negative impact of this approach on clinical education: “now we cannot refer students to hospital centers because they are private…” [CE 7, line 9].

One of the educators also objected to extensive admission of students. “Too many students are admitted. We cannot teach them well” [CE 1, line 25].

The method of allocating financial and non-financial resources among the departments of the university affects the availability of facilities and functions of clinical environments. A contributor expressed his objection as follows: “they do not allocate us enough budget to buy instruments and materials!” [CE 1, line 8].

Educational departments provide high quality educational services to students. Some clinical educators believed that the theoretical units were high and not proportional to practical units. The result is confusion among students in clinical settings: “… some theoretical lessons are not used in the clinical setting!” [CE 4, line 22].

4. Discussion

This study aimed to discuss orthotics and prosthetics clinical educators’ experiences on challenges in clinical environments and settings. The study participants stated that positive relationships between students improve the learning process. Research has also revealed that the peer-assisted learning approach apparently decreases the students’ anxiety, improves their sense of safety in the learning environment, decreases educators’ responsibilities and enhances professional skills like cooperation [20-22]. The negative effects of senior students on other students and their pessimism and disappointment are in line with the results of this study. However, a number of studies have explained how a positive relationship between peers improves the learning process [23, 24].

The current study suggests that appropriate relationships between students and staff is effective in the clinical education process. Previous studies have also highlighted the importance of social dimension of clinical education environments [25]. Teamwork requires clear roles and responsibilities of various professionals. In this study, it was stated that the uncertainty of the boundaries of field is conflicting. Therefore, the knowledge of different professionals from their duties and inter-professional collaboration positively affects the atmosphere of clinical education [26].

In this research, a number of contributors indicated the impact of mentorship and receiving feedbacks from clinical educators during the clinical education process. Mentoring opportunities may be structured for orthotics and prosthetics students to facilitate clinical decision-making and reflection skills [27, 28].

Clinical educators identified a range of characteristics exhibited by their students, including interest, motivation, attitude, and desire to perform technical work affecting the student's active presence in clinical settings. Studies have reported that lack of student motivation to learn, and their irresponsibility and irregularity, affect clinical education [24, 29].

The findings indicate that the status of clinical educators' occupation is one of the challenges in clinical settings. This is because they pay attention to the students’ learning needs and the patients’ needs, simultaneously. This suggestion is likely associated with low salaries in academia and how these low salaries are a disincentive for recruitment and retention [30]. In clinical training, educators’ interaction with students is a significant chance of learning. Based on the obtained data, respecting students’ learner identities in clinical settings increases their effort and motivation [31].

The obtained results suggested that the of patients’ characteristics and relatives may negatively impact the clinical education process. The relatives’ overprotective attitudes and patients’ distrust of students to perform their duties negatively impact their performance.

Clinical educators who participated in the study indicated that the number of students are too high and the available facilities are not adequate for the number of accepted students. Many students would probably assume that clinical instructors might not have enough time for them and being evaluated incorrectly is the issue that worries these students most [32, 33].
Observance of hygiene issues and safety principles are among the necessities of clinical training centers for orthosis and prosthesis courses. This is a result not reported by previous studies. Thus, paying attention to the students’ health should be prioritized. Finally, the lack of coordination between theoretical and practical lessons leads to different perceptions in clinical education environments. The literature review suggests that a significant amount of stress is caused due to the gap between theory and practice during clinical practices [34].

5. Conclusion

Results of this study suggest considering the challenges in orthotics and prosthetics clinical education environments, provides the necessary conditions for improving the quality of educational services and, consequently, providing graduates with effective training. Clinical learning with regards to orthotics and prosthetics education remains crucial. The findings emphasize the importance of listening to educators, considering how relationships and contexts impact clinical learning. In this study, clinical educators could not be gathered at a meeting, simultaneously. As a result, focus group discussions could not be conducted.

Ethical Considerations

Compliance with ethical guidelines

The study was approved by the Research Ethics Committee of Iran University of Medical Sciences (code: IR.IUMS.REC 1395.9411531004). The study was conducted following the instructions issued by the Declaration of Helsinki (2008): The participants were briefed on the study both verbally and in writing; The study participants provided written informed consent forms prior to the interviews; To protect their privacy and confidentiality, all data were recorded anonymously.

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Authors contributions

Conceptualization: Saeed Shahabi and Mohammad Kamali; Methodology: Saeed Shahabi and Narges Shafaroodi; Interviews: Saeed Shahabi; Writing-original draft: All Authors; Writing-review & editing: All authors; and Supervision: Mohammad Kamali.

Conflict of interest

The authors declared no conflict of interest.

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Research Paper: Patient Safety Climate and Its Affecting Factors Among Rehabilitation Health Care Staff of Hospitals and Rehabilitation Centers in Iran-Tehran

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Objectives: Hospitals and clinical centers are concerned about patient safety. Safety climate is a perceived value of safety in an organization that could improve the safety of workers and patients. The present research was conducted to study the safety climate of patients in the hospitals and rehabilitation centers affiliated to the University of Social Welfare and Rehabilitation Sciences.

Methods: This descriptive-analytical study was conducted on 300 nurses and nurse’s aides (healthcare staff) who were selected by stratified sampling method, from two hospitals and three clinics, in 2017. Data collection tools included Patient Safety Climate Scale presented by Kudo and a demographic data questionnaire. The obtained data were analyzed by SPSS using descriptive statistics like frequencies and percentages. Furthermore, Mann-Whitney U test and Kruskal-Wallis test were used to analyze the obtained data and compare the mean scores, respectively.

Results: The Mean±SD age and work experience of study participants were 36.7±6.79 and 9.46±5.8 years, respectively. The patient safety climate sub-factors were significantly different between males and females (P<0.05) except for reporting aspect (P>0.05). Patient safety climate was only different in nursing condition (P=0.013) among studied healthcare centers. Also, only fatigue reduction was different among various studied wards (P=0.035), where intensive care unit had the lowest score (2.12±2.0).

Discussion: Overall, the poor condition of patient safety climate was found in the studied rehabilitation centers. Therefore, it is recommended to improve nurses’ attitudes with the assistance of hospital managers, to enhance patient safety.

ABSTRACT

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Discussion: Overall, the poor condition of patient safety climate was found in the studied rehabilitation centers. Therefore, it is recommended to improve nurses’ attitudes with the assistance of hospital managers, to enhance patient safety.

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Highlights

- The patients’ safety concerns are considered a top priority for the healthcare of rehabilitation centers.
- In studied rehabilitation centers, the patients’ safety climate is only different with respect to nursing condition.
- The patients’ safety climate is good in some areas such as supervisors’ attitude, communication between nurses, communication with physicians, and reporting.
- Fatigue reduction, nursing condition, and opportunities for nursing education are not good enough to preserve the appropriate patients’ safety climate.

Plain Language Summary

According to the World Health Organization, patient’s safety refers to preventing healthcare accidental injuries. The main objective of healthcare systems with respect to patient’s safety is to reduce the incidence and effects of associated complications and improve recovery from such injuries. Safety climate is one of the effective factors on patients’ safety in organizations. There are several factors that affect safety climate. To conduct a safe environment for both patients and practitioners, it is critical to improve the assessment and attitudes on safety among different groups of people in healthcare settings. Considering the above-mentioned points, we conducted a study to evaluate the safety of the patients’ climate in the hospitals and clinics affiliated to the University of Social Welfare and Rehabilitation Sciences. According to findings, all aspects of patients’ safety climate were in appropriate condition. These aspects included feeling sleepy at work, enough time to rest, recreation, physical and mental fatigue in private life, lack of correlation between workload and the number of employees, and an opportunity to understand the patient’s condition; other necessary items were also at a moderate level. The patients’ safety climate in studied hospitals was not appropriate. Because safety climate is a major indicator of safety performance and recognizing its affecting factors is important, the assessment of this situation can be effective in reducing the incidence of medical errors.

1. Introduction

The patient safety concerns are considered as a top priority for healthcare organizations. The patient consequences in care or economic burden could be observed following safety incidents and clinical errors [1]. According to the World Health Organization, patient safety indicates preventing healthcare accidental injuries. The main objective of healthcare systems on patient safety is to reduce the incidence and effects of associated complications and improve recovery from such issues [1]. The occurrence rate of preventable mortality due to the inadequate measures of patient safety was over 97000 in the USA between 2005 and 2007 [2]. Safety climate is one of the effective factors on the safety of patients in organizations [3]. It is often considered as an indicator to determine patient safety because its changes like increased medical errors, can severely and directly affect patient’s safety [1]. The staff perception of safety influence their motivation towards occupational safety behaviors [3].

Nurses are the main caregivers of the patients and responsible for many care activities; thus, they are strongly contributed to medical errors. Therefore, assessing nurses’ attitudes and perceptions on safety may greatly impact the evaluation and safety climate level [4]. Patient safety climate in the hospital is a key element to increase patient safety, representing the perceived level of safety at a particular time and place [5].

Depression and stress are highly prevalent among nurses especially in rehabilitation and psychiatric settings where nurses provide care for patients with special conditions [6]. Stress has psychosomatics effects on all employers, including nurses [7-9]. Moreover, such psychological factors are correlated with safety climate and can affect patient safety [10]. Furthermore, the frequency of patient safety incidents is extremely high [11]. Therefore, it is necessary to explore healthcare staffs’ attitudes about patient safety. Nurses may be aware of their es-
sential role in providing safe care services and that they need to have positive safety attitudes [12].

To conduct a safe environment for both patients and practitioners, it is critical to improve the assessment and attitudes on safety among different groups of people in healthcare settings [13]. Considering the above-mentioned points, this study was conducted in Iran to evaluate the safety climate of patients in the hospitals and clinics affiliated to the University of Social Welfare and Rehabilitation Sciences.

2. Methods

This descriptive and analytical research was conducted on healthcare staff (nurses and nurse’s aides) in Rofeideh Hospital and Razi Hospital and Nezam Mafi Clinic, Asma, and Akhavan affiliated to the University of Social Welfare and Rehabilitation Sciences, which were selected using stratified sampling method. The final sample size was estimated to be 300 persons. Finally, 57 participants from Rofeyide, 203 from Razi, 17 from Nezam mafi, 13 from Asma, and 10 participants from Akhavan clinic were selected.

The main inclusion criterion was being a nurse or nurse’s aide. Respondents completed researcher-made demographic data questionnaire and Patient Safety Climate Scale (PSCS) developed by Kudo et al. [3].

The demographic data questionnaire consisted of age, gender, marital status, educational level, work experience, type of employment, the name of the hospital, and ward. PSCS included 30 items covering safety climate in 7 dimensions, as follows: opportunities for nursing education, communication between nurses, communication with physicians, fatigue reduction, superiors’ attitudes, reporting, and nursing condition with responses in a 5-point Likert type scale format.

Data analyses were performed in respect of the obtained mean scores in each dimension, where the total score of each dimension was divided by the number of questions. Scores less than 2.6 indicated an unfavorable level, 2.6 to 4.3 moderate and greater than 4.3, represented an ideal level. The content validity and reliability of the Persian version of the scale were confirmed and Cronbach’s alpha of 0.832 was achieved as the internal reliability by previous research [14].

Results were collected and reported after approval by the Ethics Committee of University of Social Welfare and Rehabilitation Sciences. Informed consent forms were obtained from all nurses and nurse’s aides; they were also informed that participating and leaving the study was voluntarily. All related information of the study participants were considered confidential.

Obtained data were analyzed using descriptive statistics like frequency and percentage by SPSS. Kolmogorov-Smirnov (K-S) test was applied to assess the normality of data. Then, Mann-Whitney U test and Kruskal-Wallis test were used to compare the mean scores.

3. Results

The Mean±SD scores of age and work experience were 36.7±6.79 and 9.46±5.8 years, respectively. The mean score of daily working time was 8.22 hours. In total, 169 (56.34%) participants were female, and 249 (83%) had a university degree. Moreover, 219 (73%) subjects were officially employed. Also, 207 (69%) participants were married. Furthermore, 79 (26.33%), 62 (20.67%), 57 (19%), 55 (18.33%), and 47 (15.67%) participants were selected from the internal, surgical, emergency, and pediatrics wards, respectively. Distribution of the Mean±SD scores of 7 dimensions of patient safety climate are presented in Table 1.

According to Table 1, all sub-factors of patient safety climate were in appropriate condition. These include feeling sleepy at work, enough time to rest, recreation, physical and mental fatigue in private life, the lack of correlation between workload and the number of employees, and an opportunity to understand the patient’s condition; other items of requirements were also at moderate level.

According to the K-S test results, data were not normally distributed (P<0.05). Thus, non-parametric tests were applied. Distribution of the Mean±SD of the 7 dimensions of patient safety climate is listed in Table 2 according to the subjects’ demographic characteristics.

4. Discussion

It is critical to recognize Nurses’ attitude on the safety of patients in hospitals. Employees’ perception on safety culture are correlated with their performance in clinical centers [15]; thus, the present study was conducted to measure such association. Numerous studies have investigated patient safety climate in general hospitals; however, few studies have addressed rehabilitation and psychiatric settings, in this regard. Therefore, this point can be considered as the novelty and importance of the present study.
According to the obtained results, the level of patient safety climate was not appropriate in the hospitals. Although the study was against Baghaee et al. [16] research, it was similar to some other investigations [4]. Nurses especially in rehabilitation and psychiatric clinics, experience more unusual behaviors and violence by patients [17]. Singer et al. reported healthcare centers with better safety climate had a lower incidence of Patient Safety Indicators (PSIs); also, better safety climate among frontline personnel was associated with the lower risk of facing PSIs [18]. Therefore, lower levels of health outcomes will be expected in the studied organizations [19].

Healthcare organizations with stronger attitudes empower employees and provide psychological safety and comfort to take interpersonal risks, which enables people to prevent, solve, and learn more from problems at the frontlines of care delivery [11]. Mann-Whitney U test results suggested significant differences between males and females. This finding is in line with Vifladt et al. [20], but inconsistent with some others [4, 14].

Kruskal-Wallis test revealed no significant difference between employment status in terms of the mean scores of scale dimensions, except for the healthcare staff conditions (P=0.036). It means females had a better attitude on nursing conditions; in other words, females can better manage different conditions. In addition, nurses in the contract status of employment reported better nursing condition (P=0.034, 2.93). Clinics (except for the clinics of two main hospitals of Rofeyide and Razi) had a better nursing condition in the viewpoints of studied nurses (P=0.013, 3.1).

The obtained results indicated that men had more opportunities to educate in the nursing field (2.96 vs. 2.76). In our study, educational level had no variation effect on any factor (P>0.05). Brasaite et al. illustrated the effects of education on some aspects of patient safety climate like management perceptions but not the safety climate [12]. Females (mean score: 3.28) and males (mean score:3.6) had differences in communication with physicians (P=0.07). It means males can communicate better during nursing duties. Past researches reported that attitudes about patient safety was different among various job groups in hospitals [21].

In terms of wards, nurses working in the emergency department had the lowest mean score (2.34); likewise, Singer et al. reported that emergency department staff perceived lower levels of safety climate than other wards’

| Table 1. Mean±SD and distribution of patient safety climate items in terms of desirability |
|-----------------------------------|-----------------------------------|------------------|-------------------|
| Factor                           | Main Items                         | Mean±SD          | Desirability      |
|-----------------------------------|-----------------------------------|------------------|-------------------|
| Superior’s attitudes              | Courage to error reporting        | 2±1.22           | Moderate          |
| Superior’s attitudes              | Authorities fair reaction in the event of a fault | 3.17±1.2 | Moderate          |
| Superior’s attitudes              | Proper guidance of supervisors    | 3.34±1           | Moderate          |
| Superior’s attitudes              | Valuing the proposed staff about patient safety | 3.17±1.2 | Moderate          |
| Relationships among nurses        | Team work of healthcare staff      | 3.44±1.11        | Appropriate       |
| Relationships among nurses        | Good relations between healthcare staff | 3.66±2  | Appropriate       |
| Relationships among nurses        | Staff cooperating with other sections when required | 3.46±0 | Appropriate       |
| Communications with physicians    | Proper guidance of nurse by physicians | 3.46±2  | Appropriate       |
| Communications with physicians    | Good cooperation between healthcare staff and physicians | 3.2±0 | Moderate          |
| Communications with physicians    | Easy communication with physicians about health issues | 3.24±2 | Moderate          |
| Fatigue reduction                 | Lack of sleep                      | 2.50±1.10        | Inappropriate     |
| Fatigue reduction                 | Enough time to relax               | 2.42±2           | Inappropriate     |
| Factor                                      | Main Items                                      | Mean±SD      | Desirability |
|--------------------------------------------|-------------------------------------------------|--------------|--------------|
| Fatigue reduction                          | Adequate opportunity for recreation              | 2.23±0       | Inappropriate |
| Fatigue reduction                          | Not feeling mental fatigue                      | 2.40±2       | Inappropriate |
| Fatigue reduction                          | Not feeling physical fatigue                    | 2.35±1.70    | Inappropriate |
| Opportunities for nursing education         | Appropriate training programs to improve job skills | 2.88±1.3     | Moderate     |
| Opportunities for nursing education         | Proper role in healthcare provision             | 2.85±1.77    | Moderate     |
| Opportunities for nursing education         | Training programs for new healthcare staff       | 2.77±2       | Moderate     |
| Opportunities for nursing education         | Specific training programs tailored to the needs of each individual | 2.7±1.67 | Moderate  |
| Opportunities for nursing education         | Improving the ability of employees               | 2.72±2       | Moderate     |
| Nursing conditions                          | Healthcare workers election based on ability     | 2.93±1       | Moderate     |
| Nursing conditions                          | Healthcare workers election based on clinical experience | 2.67±1.2  | Moderate     |
| Nursing conditions                          | Sufficient number of health care worker staff    | 2.35±1.13    | Inappropriate |
| Nursing conditions                          | The appropriateness of work load and the number of employees | 2.44±3       | Inappropriate |
| Nursing conditions                          | Sufficient time to understand the patient’s condition | 2.56±0      | Inappropriate |
| Reporting                                   | Positive change in reporting errors              | 4.35±1.12    | Moderate     |
| Reporting                                   | Increased awareness of patient safety in reporting errors | 3.15±1.10 | Moderate     |
| Reporting                                   | Unpredictable nature of the error                | 3.12±1.2     | Moderate     |
| Reporting                                   | Addressing medical errors                        | 2.84±0       | Moderate     |
| Reporting                                   | Quick action by employees informed as soon as the error occurred | 3.19±1.14 | Moderate |

Table 2. Level of the situation of the dimensions of patient safety climate based on average
### Table 3. Comparing the domains of patient safety climate between different groups

| Characters       | Item 1 Mean±SD | Sig. | Item 2 Mean±SD | Sig. | Item 3 Mean±SD | Sig. | Item 4 Mean±SD | Sig. | Item 5 Mean±SD | Sig. | Item 6 Mean±SD | Sig. | Item 7 Mean±SD | Sig. |
|------------------|----------------|------|----------------|------|----------------|------|----------------|------|----------------|------|----------------|------|----------------|------|
| **Gender**       |                |      |                |      |                |      |                |      |                |      |                |      |                |      |
| Female           | 3.12±0.8       | 0.029| 3.9±1.0        | 0.011| 3.28±1.3       | 0.007| 2.4±0.99       | 0.02 | 2.76±0.91      | 0.03 | 2.66±1.15      | 0.036| 2±0.93         | 0.039|
| Male             | 3.32±0.85      |      | 3.24±0.8       |      | 3.6±3.0        |      | 2.6±1.38       |      | 2.96±1.12      |      | 2.5±0.74       |      | 3.25±0.78      |      |
| **Educational level** |            |      |                |      |                |      |                |      |                |      |                |      |                |      |
| Diploma          | 3.25±0.92      | 0.14 | 3.66±0.88      | 0.05 | 3.48±0.91      | 0.011| 2.28±0.88      | 0.02 | 3.0±0.81       | 0.011| 2.76±0.95      | 0.03 | 3.21±0.93      | 0.06 |
| Undergraduate    | 3.14±1.23      | 0.41 | 3.65±1.14      | 0.03 | 3.49±0.92      | 0.007| 2.28±0.87      | 0.02 | 4.0±1.55       | 0.07 | 2.7±0.8        | 0.08 | 4.0±0.95       | 0.06 |
| BA               | 3.11±0.84      | 0.33 | 3.6±1.0        |      | 3.25±1.6       |      | 2.49±1.12      |      | 2.71±0.91      |      | 2.5±1.2        |      | 2.0±0.91       |      |
| MS               | 3.7±2.0        |      | 3.25±0.75      |      | 3.7±0.9        |      | 2.43±1.0       |      | 3.17±0.99      |      | 4.15±2.7       |      | 3.37±0.76      |      |
| **Employment status** |            |      |                |      |                |      |                |      |                |      |                |      |                |      |
| Official         | 3.1±0.94       |      | 3.64±1.0       |      | 3.28±1.53      |      | 2.39±0.97      |      | 2.74±0.93      |      | 2.54±0.2       |      | 3.06±0.96      |      |
| Contractual      | 3.36±0.98      | 0.37 | 3.3±0.96       | 0.05 | 3.4±0.92       | 0.007| 2.47±0.001     | 0.02 | 2.7±0.2        | 0.011| 2.5±0.87       | 0.034| 3.15±0.94      | 0.4  |
| Contract         | 3.23±0.73      | 0.14 | 3.37±0.87      | 0.02 | 3.4±1.5        | 0.06 | 2.55±1.28      | 0.02 | 2.91±0.95      | 0.013| 2.93±1.24      | 0.02 | 3.02±0.77      | 0.06 |
| **Marital status** |            |      |                |      |                |      |                |      |                |      |                |      |                |      |
| Single           | 2.97±0.79      | 0.02 | 3.37±0.95      | 0.06 | 3.17±0.97      | 0.06 | 2.45±0.001     | 0.02 | 2.84±0.95      | 0.07 | 2.5±1.27       | 0.06 | 2.87±0.83      | 0.039|
| Married          | 3.22±0.9       |      | 3.59±0.89      |      | 3.37±1.6       |      | 2.43±1.2       |      | 2.77±0.94      |      | 2.64±0.2       |      | 3.12±0.93      |      |
| **Hospital**     |                |      |                |      |                |      |                |      |                |      |                |      |                |      |
| Rofeyide         | 2.97±0.2       |      | 3.56±0.98      |      | 3.32±1.8       |      | 2.2±0.88       |      | 2.9±0.12       |      | 2.4±0.78       |      | 2.96±0.94      |      |
| Razi             | 3.22±0.72      | 0.09 | 3.47±0.85      | 0.06 | 3.23±1.4       | 0.06 | 2.44±1.24      | 0.08 | 2.83±0.87      | 0.07 | 2.5±0.8        | 0.013| 3.14±0.9       | 0.39 |
| Other clinics    | 3.03±0.83      |      | 3.56±0.84      |      | 3.53±0.83      |      | 2.68±0.94      |      | 2.94±0.87      |      | 3.1±1.71       |      | 3.1±0.92       |      |
| **Unit**         |                |      |                |      |                |      |                |      |                |      |                |      |                |      |
| Internal         | 3.37±0.85      |      | 3.49±0.84      |      | 3.4±1.8        |      | 2.7±1.35       |      | 2.86±0.001     |      | 2.69±0.9       |      | 3±0.8          |      |
| Pediatrics       | 2.98±0.75      |      | 3.53±0.9       |      | 3.85±2.7       |      | 2.5±0.001      |      | 2.83±0.73      |      | 2.6±0.9        |      | 2.98±2.0       |      |
| Intensive care   | 2.87±0.001     | 0.07 | 3.7±2.0        | 0.06 | 2.0±1.1        | 0.06 | 2.12±2.0       | 0.05 | 2.52±1.0       | 0.06 | 2.4±0.97       | 0.42 | 3.14±0.96      | 0.27 |
| Surgical         | 3.28±0.87      |      | 3.6±0.91       |      | 3.24±0.92      |      | 2.27±0.7       |      | 2.9±0.9        |      | 2.74±1.36      |      | 3.24±0.89      |      |
| Emergency        | 2.22±0.6       |      | 3.38±0.8       |      | 3.23±0.91      |      | 2.65±0.92      |      | 2.9±0.96       |      | 2.65±1.26      |      | 2.7±0.81       |      |
staff. This finding recommends that the higher levels of risk and complexity, and faster-paced work environment in emergency departments require relatively more consideration to safety issues than other wards [22].

Experience of healthcare staff in a particular ward, type of task, work experience and daily work hours made significant differences in patient safety [23]. Among the 7 items of questionnaire, fatigue reduction differed based on the ward. The internal ward reached the highest score (P=0.035, 2.7). In other words, nurses in internal ward were more aware of their fatigue state and got more time to rest. Meanwhile, the Intensive Care Unit (ICU) had the lowest score (2.12) that probably was due to the higher levels of workload among staff. In addition, married nurses reported more problems than singles (P=0.039, 3.12 vs. 2.87).

It can be explained by their family-related responsibilities and so, report near misses and accidents in the work. Married nurses also had higher scores in the supervisor’s attitude aspect (P=0.022, 3.22 vs. 2.97).

Overall, with respect to the vital situation of nursing groups in healthcare, all factors influencing their performance and those leading to errors occurrence need to be identified and controlled. Both organizational and individual factors, such as safety climate, complexity in the organization, work schedule, stress and frustration, must be taken into consideration [24-26]. Furthermore, training healthcare staff in terms of patient safety climate and culture, as well as various structure interventions may improve patient safety and the quality of care [27].

Supervisor’s attitude

The attitude of managers and supervisors is critical to have high levels of safety for both patients and staff. Snijders et al. found that reporting behavior in the neoNatal Intensive Care Unit (NICU) could be promoted by the management support of patient safety, a nonpunitive manner towards mistakes, and the perception of patient safety [28].

Communication between nurses

Good communication can highly affect the process of patient care and improve patient safety. Open communication should be established among healthcare system personnel to prevent errors by the means of the team work ability of supervisors [29].

Communication with physicians

Patient care can be improved through appropriate professional relationships. The mutual effect can be observed among the staff due to the dynamic process of relationships. Professional relationships are considered to be important factors to prevent risk; thus, communication plays a principal role in medical practice, which is necessary for patient safety [30].

Fatigue reduction

Sufficient sleep and rest as well as healthy entertainments are necessary. There was a correlation between sleep deficiency and working at home and having the second job, shift working and excessive working hours [31-35].

Nursing condition

Importance of suitable proportion between a number of patients, healthcare workers, and nurses’ workload to provide adequate time to perform duties is obvious. An insufficient number of workforce in hospitals could lead to a heavy workload in healthcare staff [36]. Inadequate time to manage the patient significantly influenced the performance of hospital personnel [37].

Opportunities for nursing education

The purpose of educational opportunities is updating clinical information and be aware of changes in healthcare workers’ problems and create opportunities to improve their skills. Quality management is effective in determining the educational needs of healthcare workers. In a hospital where total quality management is performed, healthcare workers make efforts to upgrade their knowledge by learning new training techniques and try to succeed in providing healthcare [38, 39].

Reporting

This part refers to the continuous and accurate reporting of employee’s activities and occurred errors. Reasons for the lack of reporting errors were the lack of positive feedback from healthcare staff superiors, focusing on malpractice, lack of other possible factors involved in causing the error (management factors), and fear of the legal issues (fear of the consequences of reporting) [40].

5. Conclusion

Patient safety climate in studied hospitals was not appropriate. Considering the fact that safety climate is a major indicator of safety performance and recognizing
its affecting factors; the assessment of situation can be effective in reducing the incidence of errors.

The studied centers need to consider patient safety climate in the daily functioning of the organizations and the routines of individuals. It is recommended to improve nurses’ attitude through hospital managers’ efforts to increase patient safety. Attention to personnel training is important in patient safety. In spite of the high levels of academic education among the studied subjects, patient safety climate was not desirable. Therefore, it is recommended to provide them safety training courses. However, improving culture is a time-consuming process.

Ethical Considerations

Compliance with ethical guidelines

This study was according to general ethical guidelines, and participants were assured of the confidentiality of their information.

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Authors contributions

All authors contributed in preparing this article.

Conflict of interest

The authors declare no conflict of interest.

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Research Paper: Binary Regression With a Misclassified Response Variable in Diabetes Data

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ABSTRACT

Objectives: The categorical data analysis is very important in statistics and medical sciences. When the binary response variable is misclassified, the results of fitting the model will be biased in estimating adjusted odds ratios.

The present study aimed to use a method to detect and correct misclassification error in the response variable of Type 2 Diabetes Mellitus (T2DM), applying binary logistic regression.

Methods: Data from the Diabetes Screening test in the Health Center of Zahedan City, Iran, were explored. It included 819 Iranian adults with a binary response variable (T2DM). By a new method, the misclassification parameters and the estimated parameters in logistic regression were validated. Statistical analysis was performed using SAS, and P<0.05 were considered as statistically significant. Results are presented as Odds Ratio (OR) and 95% Confidence Interval (CI).

Results: Increased age (OR=1.04, 95% CI=1.02-1.06), hypertension (OR=3.06, 95% CI=1.80-5.21), and obesity (OR=1.99, 95% CI=1.26-3.15), all elevated the odds of T2DM.

Discussion: The method provided adjusting for bias due to misclassification in logistic regression, and using it is recommended.

Keywords: Logistic regression, Diabetic, Odds ratio

Highlights

● We proposed a model implemented within a logistic framework to analyze binary data subject to misclassification.

● Using our approach, we achieved a significant reduction in bias.

Plain Language Summary

A logistic model was used to explain the relationship between one dependent binary variable and one or more independent variables. Errors in misclassification of data tend to bias the inference. Using this method, we found that age, hypertension, and obesity are associated with type 2 diabetes mellitus. Our results show that obesity and a sedentary lifestyle can increase the risk of type 2 diabetes.

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1. Introduction

Outcome misclassification is prevalent in epidemiology and has important impacts on parameter estimates and statistical inference. The issue of misclassification in 2×2 tables has first been considered by Bross [1-4] and a review study was conducted by Chen on this subject [5].

Neuhaus analyzed the bias size of misclassification error correction in the response variable and reported except for when the sensitivity and specificity are both large, ignoring the misclassification correction leads to a biased estimate of the effect of exposures [6]. Researchers often use logistic regression to estimate the effect of exposures on the binary response variable. Tang et al. used logistic regression to correct misclassification in estimating the coefficients and the maximum likelihood estimation [7].

Davidov et al. used logistic regression to correct the coefficients of the models with misclassification error [8]. In medicine and epidemiology, the classification issue is of particular importance with respect to the stage of the disease or the condition of exposure to the risk factor. In these studies, after classifying the subjects, based on the status of exposure and infection, the data are classified to create some statistical indicators (e.g. odds ratio and relative risk) for measuring the relationship between the predictor variables and the response variable [9].

This cross-sectional study with a misclassified binary outcome used a method proposed by Lyles et al. [10]. We applied the maximum likelihood method to identify and correct misclassification in binary variables [6].

2. Methods

Data from the Diabetes Screening test in the Health Center of Zahedan City, Iran, were investigated in this cross-sectional study. It included 819 Iranian adults with the binary response variable of Type 2 Diabetes Mellitus (T2DM). The main purpose of the analysis was to model the association between T2DM and hypertension, obesity, and age. However, in practice, T2DM may be diagnosed by error-prone test and the misclassification in diagnoses compromises the adjusted OR estimation and statistical inference.

Using a method proposed by Lyles et al. [10], we examined the relationship between age, hypertension, obesity, and T2DM in 819 Iranian adults. Statistical analysis was performed using SAS and P<0.05 were considered as statistically significant. T2DM was defined as a binary outcome variable. Age: Information about the respondent’s age was obtained based on their self-reported birth year and was considered as a continuous covariate. Hypertension: The study participants were diagnosed with hypertension if their systolic blood pressure was >140 mmHg, or if their diastolic blood pressure was >90 mmHg. Obesity: Individuals with a Body Mass Index (BMI) ≥30 kg/m² were considered obese and <30 kg/m² as non-obese.

3. Results

The Mean±SD age of subjects was 47.65±12.23 years. Of participants, 462(56%) were men and 190(23.2%) were obese. Among participants, 15.8% and 15.5% were diabetic and had high hypertension, respectively. Logistic regression model was used in the new model. The regression coefficients and odds ratios are presented in Table 1. The odds ratio of people with hypertension equaled to 3.06 (95% CI=1.80-5.21), compared with those without hypertension. The estimated OR for age is 1.04 (95% CI=1.02-1.06). This means that increased age enhances the odds of T2DM occurrence. The estimated OR for obese people is 1.992 (95% CI=1.260-3.149), compared with non-obese ones.

4. Discussion

Specific motivation for these developments is provided by cross-sectional data on the assessments of T2DM and hypertension status and covariates measured in the Diabetes Screening test. We specified likelihood functions corresponding to main/internal validation study designs to solve the prob-

| Variable       | Coefficient | OR  | 95% CI for OR |
|----------------|-------------|-----|---------------|
| Hypertension (yes) | 1.120       | 3.064 | 1.802 - 5.213 |
| Age, y         | 0.038       | 1.039 | 1.021 - 1.057 |
| Obesity        | 0.689       | 1.992 | 1.260 - 3.149 |

*Odds Ratio; **Confidence Interval
lem of outcome misclassification in logistic regression [11, 12]. Thus, we incorporated validation data and covariates into misclassification models. Although validation data based on maximum likelihood methods are outlined in the comprehensive text of Carroll et al. [13], a study generalized the logistic regression-based approach [7] which only outcome misclassification was addressed. It also makes AIC calculations available and the AIC indicator was used to select the appropriate model [14]. Consistent with some studies, our results revealed a positive association between age and T2DM.

Age is generally a critical factor of developing diabetes [15, 16]. In line with some studies, we also found that T2DM was almost 3 times as likely to develop in subjects with hypertension as in subjects with normal blood pressure. Other concerning factors may exist; e.g. reducing blood pressure decreases albuminuria in T2DM. In a randomized controlled trial, the management of blood pressure was considered a high priority in the treatment of T2DM [17]. Consistent with some studies, our results supported that obesity plays a major role in T2DM [15]. Increasing physical activity and improving nutritional diet can reduce obesity and T2DM.

We failed to establish a causal association between factors and T2DM, or specify the direction of such association. Although we adjusted our analyses for confounders, our model has not included other factors associated with T2DM, such as longer diabetes duration, family history, and ethnicity.

5. Conclusion

The method provided adjusting for biases due to misclassification in binary response in logistic regression, and using it is recommended. Logistic regression methods with misclassified data are appropriate choices to estimate the correct odds ratio in potential misclassified response variable. Using logistic regression for misclassified data validation suggested that blood pressure has a significant effect on diabetes. It is suggested that the logistic regression method be used to correct the odds ratio in terms of the probability of misclassification error in the screening data.

Ethical Considerations

Compliance with ethical guidelines

The study was approved by the Research Ethics Committee of the University of Social Welfare and Rehabilitation Sciences (IR.USWR.REC.1397.30).

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Authors contributions

Conceptualization and methodology: Enayatollah Bakhshi; Investigation: Maryam Raštégar; Writing original draft: Maryam Raštégar and Sammaneh Hoseinzadeh; and Writing review & editing: All authors.

Conflict of interest

The authors declare no conflict of interest.

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Research Paper: Developing the Persian Version of Infant-Toddler Meaningful Auditory Integration Scale

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Objectives: Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) is a useful tool for the quantitative evaluation of auditory behaviors in different situations. The present study aimed to develop the Persian version of IT-MAIS.

Methods: There was 4 main steps in the translation and validation of the scale, as follows: forward translation, synthesis, backward translation, and expert committee discussion. Then, the final Persian version of the scale was analyzed in terms of reliability and validity. The scale was studied on the parents of 17 hearing impaired and 17 normal hearing children.

Results: There was a significant difference in the mean score of scale between hearing impaired and normal hearing children (P≤0.001). The internal consistency of the items was satisfactory. The Cronbach’s alpha for the overall score was 0.93.

Discussion: This study suggested that IT-MAIS-F can be a reliable and valid tool for the evaluation of the auditory function of children. However, the sample size of the study was small. Thus, studies with larger sample sizes are recommended. In addition, test-retest reliability of the scale was not studied.
Highlights

- There are subjective and objective methods to evaluate hearing loss in infants and toddlers.
- It is difficult to monitoring auditory responses in infants and toddlers who have assistive hearing aids.

Plain Language Summary

A lot of children suffer from hearing loss or impairments. Many children have a hearing loss since birth or develop it during their first years of lives. There are several subjective and objective tests for early hearing loss diagnosis that help us to manage the disorder as early as possible. However, checking children's auditory responses after receiving hearing aid or cochlear implant is hard due to their lack of cooperation in behavioral tests. The Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) is a useful tool for checking hearing-impaired infants and toddlers via an interview with their parents and can help us determine if everything is alright. This scale was not available in Farsi so this study was conducted to evaluate its Farsi version that was proved to be valid and reliable.

1. Introduction

Hearing loss is a prevalent disorder among infants and toddlers. The average incidence rate of hearing loss in newborns in the USA is approximately 1.1 per 1000 infants [1]. This prevalence is higher in infants suffering from one or more risk factors for hearing impairment. The prevalence of hearing loss in neonates with low risk extends from 0.09% to 2.3%; however, in the high-risk infants, it is estimated to range from 0.3% to 14.1%. The prevalence rate of hearing loss is as high as 11% in neonates with very low birth weight [2]. Iran lacks a nationwide estimation about hearing loss prevalence; however, based on some studies, it seems to be highly prevalent especially due to the high rate of consanguinity in Iran [3, 4].

The severity of hearing loss can range from mild to profound and can be monaural or bilateral. Hearing loss, in general, has adverse effects on speech and language development. The negative consequences of hearing loss increase with the severity of hearing loss, the involvement of both ears, and prelingual hearing loss [5, 6]. The first three years of infant’s life (especially the first year) is a golden time for exposure to auditory stimuli as the brain is most plastic for learning speech and language skills [7, 8]. The rich language environment and perfect auditory access are vital components for a developing child [9].

To provide good auditory access, there is an absolute need for providing a suitable sensory aid (hearing aid or cochlear implant) as early as possible. Good auditory access is a key component prior to any successful auditory rehabilitation or early intervention [10]. Evaluating auditory access and auditory skills of infants and toddlers can be challenging. Their behavioral test results may be inconsistent [11]. In addition, pure tone audiometry and speech recognition tests in quiet overlook auditory function in real-world situations; thus, may not be good predictors of child’s auditory behavior [12].

Infant-Toddler Meaningful Auditory Integration Scale (IT-MAIS) is useful for the quantitative evaluation of auditory behaviors in different situations. IT-MAIS (Zimmerman-Phillips 2000) is a Modification of the original scale (Meaningful Auditory Integration Scale; MAIS) [13]. This scale is actually a structured interview with parents. It consisted of 10 main probes that assess three areas: vocalization behavior; alertness to sounds; and deriving meaning from sound. For scoring, 0 (lowest) to 4 (highest) points can be designated to each question including never, rarely, occasionally, frequently, and always. The total score (20 questions for 10 probes) is calculated, ultimately.

Since the introduction of IT-MAIS, numerous studies have used this scale for determining hearing aid benefits, cochlear implant candidacy and cochlear implant outcome measures. In general, it is considered as a useful tool for evaluating audiological outcomes in children younger than 3 years of age [14-21]. It is translated and validated in many languages including Arabic, Italian, Chinese, German, Polish, and British English [21-23].
IT-MAIS test-retest reliability, Intraclass Correlation Coefficient (ICC), internal consistency (Cronbach’s alpha), and content validity (Pearson’s correlation coefficient) were 0.92, 0.89, 26.84 and 0.84, respectively [13].

The present study aimed to translate and validate IT-MAIS in Persian speakers. The forward-backward translation method was applied. This study was conducted with the assistance of one of the main developers of the original scale and under her official permission.

2. Methods

After contacting with the third author who is one of the main developers of the scale, and obtaining her permission, the scale was translated from English to Persian by 4 professionals including two audiologists and two speech-language pathologists (step 1: Forward translation). These professionals comprised the expert committee throughout the study. In translation, there was a need for some cultural adaptations such as changing the probes’ examples. The translated scale was discussed with two audiologists and two speech-language pathologists familiar with the research method for improving these versions (step 2: Synthesis). After final approval, the resultant version was provided to a professional translator and a bilingual (Persian-English) speech-language pathologist who was not familiar with the original scale, to translate it into English (step 3: Backward translation). The expert committee compared the newbackward translation with the original one to ensure that it has the same semantic value as the original scale (step 4: Expert committee discussion).

The translation was forwarded to the author and she approved the scale. Then, the Persian-IT-MAIS was distributed among 5 audiologists, 6 speech-language pathologists, and 5 mothers of hearing impaired children for evaluating its face validity. The explored factors included clarity, simplicity, and relevance. Their comments were taken into consideration and were cross-checked by the author. Finally, 17 Persian infants and toddlers with normal hearing (10 males and 7 females with a Mean±SD age of 28.29±7.37 months) and 17 hearing aid user Persian infants and toddlers with a profound hearing loss (10 males and 7 females, with a Mean±SD age of 23.23±5.93 months) were enrolled in the pilot study (step 5: testing the pre-final version).

Only children with native Persian speaking parents were enrolled. All the normal hearing children were recruited from those who had passed the universal newborn hearing screening and their hearing status were considered normal based on audiological documents. Moreover, children with hearing impairment risk factors based on the Joint Committee on Infant Hearing (JCIH) were excluded from the study.

Research ethics based on the Declaration of Helsinki were observed. All evaluations were non-invasive. Informed consent was obtained from the mothers of hearing-impaired children, and other subjects. In the normal hearing children, only 9 items out of total 10 probes of IT-MAIS were demonstrated. This was because the first item, ‘is the child’s vocal behavior affected while wearing his/her sensory aid (hearing aid or cochlear implant)?’ was not included and inapplicable to the normal hearing children. Children with profound hearing loss had the auditory thresholds of ≥90 dBHL in behavioral audiology tests and Auditory Brainstem Response (ABR) based on the records.

They did not have any additional disabilities. The test items were asked by the mothers as a structured interview. The Mean±SD age of children’s mothers was 45.5±5 years and all of them had at least 12 years of academic education. The interviewer was a trained speech-language pathologist with 16 years of experience in the field of auditory rehabilitation. The interviews were conducted in a room without distracters. The children’s mothers had no time limit to think, ask questions and respond, during interviews.

The test terminology was altered based on the mothers’ suggestions and the final version of the scale was formed. The three main areas of the scale (vocalization behavior; alertness to sounds; and deriving meaning from sound) were analyzed concurrently. Internal consistency indicates to what extent each item measures the same underlying construct. For this evaluation, the IT-MAIS-F scores in 17 normal hearing infants and toddlers were investigated.

3. Results

The Mann-Whitney U test was performed on items 2 to 10 of the scale, because probe 1 was only used in children with hearing loss. There was a significant difference (P<0.001) between the two groups in all items (Table 1). Cronbach’s alpha confidence was applied for evaluating the internal consistency of the scale. Cronbach’s alpha from 0.7 to 0.9 were considered in the range of acceptable internal consistency. The overall score Cronbach’s alpha was 0.93. The results of inter-item reliability were acceptable (Table 2).
### Table 1. Mann-Whitney U test for probes 2 to 10 of IT-MAIS-F

| Status | Mean±SD | P     |
|--------|---------|-------|
| Probe 2 | Profound | 3.00±1.22 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 3 | Profound | 2.71±1.16 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 4 | Profound | 2.12±1.16 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 5 | Profound | 2.53±1.17 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 6 | Profound | 2.35±1.16 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 7 | Profound | 2.29±0.10 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 8 | Profound | 2.44±1.36 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 9 | Profound | 2.41±1.06 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |
| Probe 10| Profound | 2.47±1.12 | ≤0.001 |
|         | Normal   | 4.00±0.00 |        |

### Table 2. Internal consistency of IT-MAIS-F items

| Question | Scale Mean (If the Item Was Deleted) | Cronbach's Alpha (If the Item Was Deleted) |
|----------|--------------------------------------|-------------------------------------------|
| Question 2 | 19.80 | 0.91 |
| Question 3 | 19.38 | 0.94 |
| Question 4 | 20.06 | 0.92 |
| Question 5 | 19.63 | 0.92 |
| Question 6 | 19.75 | 0.92 |
| Question 7 | 19.81 | 0.91 |
| Question 8 | 19.63 | 0.91 |
| Question 9 | 19.69 | 0.91 |
| Question 10 | 19.50 | 0.92 |
4. Discussion

In this study, IT-MAIS-F was translated and validated into Persian and examined on 17 hearing impaired and 17 normal hearing children. The results revealed that IT-MAIS-F is a reliable scale applicable in Persian speaking children. In face validity examination, all items were clear, simple, understandable, and relevant to the scale initial aim. All of the studied children’s mothers were comfortable answering the probes. Based on the experts’ report, the scale was easy to administer and its completion took about 20 to 30 minutes.

IT-MAIS-F internal consistency was acceptable (α=0.93 for the total score and 0.92, 0.91 for detection and recognition subscales, respectively). In a study on the development of Italian IT-MAIS, internal consistency satisfactorily extended from α=0.87 for the detection to α=0.92 for the recognition category [24]. In another study on the IT-MAIS on a Chinese population, Cronbach’s alpha was obtained as 0.96 for the total score. Zhong et al. studied the reliability and validity of the Chinese version of IT-MAIS in 300 children with a cochlear implant and Cronbach’s alpha coefficient equal to 0.836 for the total score [13].

These results suggest that this scale is a reliable and valid tool. The internal consistency and item reliability of the Chinese version of IT-MAIS was comparable to the German, Polish, and British English versions of IT-MAIS scale. These similar results among different cultures and languages might be attributable to the same development course of the early pre-lingual auditory function in all infants. All items of the original scale were kept in the cross-language version of IT-MAIS [21].

In the present study, there was a significant difference between the mean scores of the scale in normal hearing and hearing impaired children. The significant differences in IT-MAIS scores in children with profound hearing loss and in normal hearing children suggest that the IT-MAIS-F could potentially be a useful tool in assessing auditory performance and monitoring sensory device benefits in hearing impaired children. This result is in agreement with the Italian version of IT-MAIS [24].

IT-MAIS can clarify normative auditory skill development and be used as an outcome measurement tool for the evaluation of early hearing intervention, hearing aid and cochlear implant [14]. IT-MAIS is the most frequently used parental questionnaire in the USA, and widely used in different parts of the world to help determine cochlear implant candidacy and monitoring listening development after cochlear implant surgery in children with hearing loss [24]. This scale has been widely used in assessing the progress of auditory performance in very young children [25].

This study suggested that IT-MAIS-F can be a reliable and valid tool for the evaluation of the auditory function of children. However, the sample size of the study was small. Studies with larger sample sizes are recommended on this subject. In addition, test-retest reliability of the scale was not studied.

5. Conclusion

The Persian versions of IT-MAIS (IT-MAIS-F) has a high internal consistency and validity which make it a reliable and useful tool for evaluating auditory functions among infants and toddlers.

Ethical Considerations

Compliance with ethical guidelines

This study followed ethical guidelines of Helsinki declarations.

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Authors contributions

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Conflict of interest

The authors declare no conflict of interest.

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Research Paper: Increasing Prevalence of Methamphetamine Use Among Women: Implication in Suicide Attempt

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Objectives: This study aimed to compare the ratio of suicide attempts between female opium and Methamphetamine (MA) users to determine the relationship between the increased prevalence of MA and suicide risk.

Methods: In this cross-sectional study, 136 drug dependent females were randomly selected from Tehran. Data gathering was performed by a demographic questionnaire and Beck Scale for Suicidal Ideation. Data were analyzed by Chi-squared test and Independent Samples t-test.

Results: There was no significant different in suicidal ideation between the two groups; however, the suicide attempt was significantly higher in the MA users compared to opium users (P<0.001).

Discussion: Suicide attempt is much higher in females who use crystal MA, compared to female opium users. This could be a warning to prevent associated risks.

Highlights
- The probability of suicide attempt among women is increased due to methamphetamine use.

Plain Language Summary

All family members of a crystal meth user who lives with the family need to know that the possibility of a suicide attempt may increase in them. So, they must be careful to make it harder to do. They must get things that may be used for suicide away from the patient and be prepared for relief efforts.
1. Introduction

Drug use disorder is a major health concern globally. According to the world drug report of 2017, about 5% of the world's adult population have consumed drugs at least once in 2015 and 0.6% of the world total adult population suffered from drug use disorders [1]. Same values were calculated equal to 8.3% and 2.4%, in Iran, respectively [2, 3].

In recent years, the rate of drug consumption has increased more rapidly in women than men around the world [1]. A similar trend has also been reported in Iran, the ratio of male to female drug consumers has decreased from 19 in 2007 to 11 in 2011. This ratio was much lower-about 8%- for Methamphetamine (MA) abuse [4] which reflects increased use of MA among women [5]. Suicide attempt was estimated 17.43% among people with drug use disorders [6-8] which is much higher than the general population (less than 3%) [9]. Mood disorders such as depression and anxiety are recognized as critical risk factors for suicide attempt among women with drug use disorders [8]. In addition, psychotic symptoms, anxiety, depression and suicide are prevalent among MA dependents [10].

In Iran, there is a high incidence of depression and anxiety among MA dependent females [11] which can be a potential suicide risk among them and requires appropriate evaluation and attention. To our knowledge, no previous research has investigated the suicide attempt among female MA users in Iran. On the other hand, opium is the most prevalently used drug in Iran (in both males and females) [2-4]. Therefore, this study aimed to compare the ratio of suicide attempts between female opium and MA users to determine the relationship between the increased prevalence of MA abuse and suicide risk.

2. Methods

This study was part of a larger cross-sectional survey on women with drug use disorders in Tehran City, Iran (2015).

Study participants

One hundred forty women with drug use disorders participated in this study. One hundred twenty of them were selected from outpatient treatment centers for substance use, a self-help Non-Governmental Organization (NGO) group, short term residential treatment centers, harm-reduction centers (DIC), imprisoned women, and those under compulsory treatment (clause 16) by simple random sampling method. Moreover, 20 female drug users under no treatment were selected by snowball sampling method. Twenty participants were selected from each 7 mentioned sub-groups. Inclusion criteria were opium or MA use and being diagnosed with drug dependence based on Diagnostic and Statistical Manual of Mental Disorders, 5th Edition: DSM-5 (DSM-V). Exclusion criteria were poly-drug use, psychosis or any psychiatric condition affecting the participant’s responses.

Measurements

Survey data were collected by a researcher-made data gathering form. A pilot study was conducted to evaluate the validity and reliability of the tool, and Kaiser-Meyer-Olkin (KMO) and Cronbach’s alpha of 0.722 and 0.726 were obtained, respectively. Additionally, Beck Scale for Suicidal Ideation (BSSI) was used to investigate suicidal ideation [12].

Its concurrent validity with Beck Depression Inventory (BDI) has been reported as 76% and its reliability was calculated as 95% by Cronbach’s alpha [13]. After the completion of data gathering, 136 questionnaires were recognized eligible for statistical analysis.

Data analysis

The obtained data have been analyzed by descriptive and inferential statistics using SPSS. Mean±SD have been used to describe the achieved data. Independent Samples t-test was used to compare the BSSI results between the two groups and the Chi-squared test was used to compare nonparametric variables.

3. Results

The Mean±SD age of opium and MA users were 36±10 and 31±7 years, respectively. Findings suggested no statistically significant difference between the two groups of study, in respect of their level of education (P=0.664), ethnicity (P=0.822), family monthly income (P=0.119), type of occupation in the past year (P=0.524), parent’s level of education (P=0.632), parent’s occupation (P=0.588), and housing status (P=0.464). In conclusion, there was no significant difference in demographic, socio-economic, and cultural variables between the two groups of study.
The Mean±SD total score of BSSI among opium users (n=54) were 29.6±6.2 which fell in the range of 6 to 34 and these values for MA users (n=82) were 27.8±7.5 (range=5-33). There was no significant difference in suicidal ideation between the two groups (P=0.825). Two groups of study were compared in respect of their suicide attempt. As per Table 1, suicide attempt was significantly higher in MA users than opium users (P<0.001).

4. Discussion

This research compared suicide attempt between female MA (glass or crystal MA) users and female opium users in Tehran City, Iran. Considering the increasing MA use among women [5], unfamiliar complications are expected in this population. According to the obtained data, the rate of suicide attempt was higher in crystal MA users. Self-injury behaviors aiming to end one’s own life are considered as suicidal behavior. A complicated condition of current psychiatric disorders along with stress may lead to suicide which is associated with numerous affecting factors, including childhood experiences, impulsivity, pessimism, familial/genetic factors, and aggression [14].

There were differences between the two groups of study in terms of personality traits, cognitive issues and complications associated with the use of each substance. Impairments in cognitive-emotional processing are prevalent in drug use disorders. This is because chronic substance use may lead to long-term degeneration in the brain and impairment in its functions [15]. Dopamine release in reinforcing normative behaviors leads to behavioral activation and behavioral responses to instinctual human needs [16]. Moreover, substance abuse evokes dopamine release in dopaminergic pathways. MA use is associated with higher dopamine release, in comparison with opium [17].

MA users suffer from widespread deficits in neurocognitive skills, as a result of alternations in the neurotransmitter system, especially at dopamine terminals. Such alternations lead to impairments in cognitive, emotional, and behavioral functions [18, 19]. In addition, cognitive defects in MA users seem to be greater than that of the opium users [20]. Furthermore, cognitive deficits were associated with suicidal behavior [21, 22]; thus, we can expect higher odds of suicide attempt among crystal meth users, compared to opium users.

Some personality traits can well distinguish between substance users and their tendency toward a specific substance [23, 24]. Moreover, prior research reported a correlation between personality disorders and the type of abused substance [23, 25]. Interestingly, there is an association between the data suggested by such investigations and studies on personality disorders and suicide attempt, which suggests the odds of a higher incidence of suicide, consequent to the use of some types of drugs.

Previous investigations highlighted the role of sensation seeking in tendency toward drug use [26] and impulsivity in the development of drug use and its relation with the dopaminergic pathways [27]. In addition, some studies revealed the effect of impairments in dopaminergic pathways; especially an increase in dopamine, upon the occurrence of violence and uncontrolled behaviors [28].

The impulsivity and aggression are highly correlated with suicidal behavior [29]; therefore, more incidence of suicide attempt are expected among MA users. Severe neurotransmitter and brain impairments occur in MA abuse [30]. Thus, the consequences of such impairments (e.g. suicide attempt) are expected to be higher in MA users, compared to the opium users. No studies have directly compared the consequences of neurotransmitter disturbances resulting from MA and opium use. However, the above-mentioned points could be inferred from the literature review and individual investigations [31].

A study explored the prevalence of high-risk sexual behaviors and self-harm among the users of all types of drugs in Tehran. The greatest rate of high-risk sexual behaviors was reported by MA and cocaine users which reflects great risk-taking among them. The same study

| Group          | History of Serious Suicide Attempt (%) | P  |
|----------------|----------------------------------------|----|
|                | Yes                          | No |    |
| Opium users    | 5(9.25)                      | 49(90.75)                     | <0.001 |
| MA users       | 34(41.46)                    | 48(58.54)                     |    |

Table 1. Comparing suicide attempt between female opium and MA users in Tehran (Chi-Squared test)
also reported the higher rates of self-harm in MA users, compared to opium users. This finding could explain the higher frequency of suicide attempt among female MA users, compared to female opium users [32].

5. Conclusion

Suicide attempt is much higher in females who use crystal MA, compared to female opium users. This could be a warning to prevent associated risks. Thus, it is necessary to establish preventive plans and manage to deliver emergency interventions, when required.

The main concern about the findings of current study is that the data were obtained by a cross-sectional survey on females’ drug dependence in Tehran. Thus, the research was not initially designed in accordance with the achievements of the investigation. As a result, further research is suggested to be conducted with the same purpose, applying more appropriate research methods. Another limitation in the present study involves the lack of similar investigations, both in Iran and internationally, which made it impossible to directly compare the obtained results with prior data.

Ethical Considerations

Compliance with ethical guidelines

This article was part of a research project (Code: 801/93/10355/1) approved by the Ethics Committee of University of Social Welfare and Rehabilitation Sciences.

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Authors contributions

Developing the study concept, design and the definition of intellectual content: Ali Farhoudian, Omid Massah and Bahman Bahman; Searching the literature: Omid Massah and Naslara Rafiee; Conducting the study procedures and data collection: Elaheh Ahounbar, Seyed Hadi Mousavi and Mohsen Roshani; Data analysis: Omid Massah and Seyed Hadi Mousavi; Writing the manuscript: Omid Massah and Naslara Rafiee; Editing and reviewing the manuscript and take responsibility for the integrity of the research as a whole from inception to published article: All authors.

Conflict of interest

The authors have no conflict of interest to declare.

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Research Paper: Recognition of Barriers in Physiotherapy Clinical Education From Students’ Perspectives: A Content Analysis

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Objectives: Clinical education in medical sciences is essential, because of its important role in the education of specialist skills. Physiotherapy specialization is among the main branches of medical sciences, which requires high academic and professional skills. One of the most important and effective methods to assess the quality of clinical education in physiotherapy is to review it from a student’s perspective. Therefore, this study attempted to recognize the barriers of clinical education in physiotherapy students from their own perspective.

Methods: This qualitative study used content analysis method. Data were collected using semi-structured interviews and the samples were selected by purposeful sampling method. We have considered maximum variation (gender, semester, educational level, place of residence) of persons in the sample selection. The data collection continued until saturation was reached. Participants included 13 physiotherapy undergraduate students who had completed at least 6 clinical education units.

Results: We extracted 182 original codes from interviews analysis. By eliminating and matching the data, we finally developed 4 categories, as follows: 1. Personal and professional characteristics of clinical educators; 2. Personal characteristics of students; 3. Inadequate education system; 4. The inappropriate clinical education environment.

Discussion: Clinical incompetency, inadequate clinical skills, and failure to observe professional ethics are the most frequent problems of clinical supervisors. Moreover, student’s irresponsibility, inadequate participation, the lack of self-esteem in some students, and inappropriate planning and the implementation of clinical education of PT department and inappropriate interpersonal communication and facilities in clinical settings, can be considered as barriers for clinical education. Considering the obstacles and attempts to resolve them, reviewing the clinical education process can improve its quality. Reviewing the clinical education process seems to help recognize its barriers and attempt to resolving them. It seems to improve the quality of clinical education.

ABSTRACT

Objectives: Clinical education in medical sciences is essential, because of its important role in the education of specialist skills. Physiotherapy specialization is among the main branches of medical sciences, which requires high academic and professional skills. One of the most important and effective methods to assess the quality of clinical education in physiotherapy is to review it from a student’s perspective. Therefore, this study attempted to recognize the barriers of clinical education in physiotherapy students from their own perspective.

Methods: This qualitative study used content analysis method. Data were collected using semi-structured interviews and the samples were selected by purposeful sampling method. We have considered maximum variation (gender, semester, educational level, place of residence) of persons in the sample selection. The data collection continued until saturation was reached. Participants included 13 physiotherapy undergraduate students who had completed at least 6 clinical education units.

Results: We extracted 182 original codes from interviews analysis. By eliminating and matching the data, we finally developed 4 categories, as follows: 1. Personal and professional characteristics of clinical educators; 2. Personal characteristics of students; 3. Inadequate education system; 4. The inappropriate clinical education environment.

Discussion: Clinical incompetency, inadequate clinical skills, and failure to observe professional ethics are the most frequent problems of clinical supervisors. Moreover, student’s irresponsibility, inadequate participation, the lack of self-esteem in some students, and inappropriate planning and the implementation of clinical education of PT department and inappropriate interpersonal communication and facilities in clinical settings, can be considered as barriers for clinical education. Considering the obstacles and attempts to resolve them, reviewing the clinical education process can improve its quality. Reviewing the clinical education process seems to help recognize its barriers and attempt to resolving them. It seems to improve the quality of clinical education.

Keywords:
Clinical clerkship, Physical therapy specialty, Qualitative research

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1. Introduction

Universities have an important role in educating specialist therapists, who are responsible to provide healthcare services for the community [1]. Clinical education is an integral part of educational programs, which combines both theoretical and practical education and plays an important role in developing and enhancing students’ skills [2]. Bachelor’s students of Physio Therapy (PT) have the opportunity to participate in various clinical fields and rehabilitate patients with the various conditions of orthopedics, neurology, cardiology, rheumatism, and so on. For being successful and effective, it is essential to monitor the current situation and recognize the strengths and modify weaknesses [3-5]. Therefore, it is essential for universities to provide continuous monitoring and evaluate clinical education to improve education quality.

Previous studies on the quality of clinical education in different courses, explored some problems such as clinical incompetency, inadequate clinical skills, and failure to observe professional ethics for clinical supervisors. Indeed, irresponsibility, inadequate participation, the lack of learning motivation and self-esteem in some students and inappropriate planning and the implementation of clinical education of PT department and inappropriate interpersonal communication and facilities in clinical settings are main problems in this regard [4-9].

Due to cultural and political changes over time, it is necessary to periodically assess the status of clinical education. Furthermore, the students are the main education recipients. Thus, it is necessary to use their experiences to identify the deficiencies and barriers. Therefore, the present study aimed to identify the barriers of clinical education in PT because of its importance and limited studies on this subject.

2. Methods

In this qualitative study, content analysis method (contractual type) was used. All clinical practice courses were presented during the last two years of undergraduate program; it was decided to conduct interviews with students in their last year of studies. Therefore, 13 undergraduate PT students who were in their last year of studies participated in the study. They were studying at the Rehabilitation Schools of Iran University of Medical Sciences, University of Tehran, Shahid Beheshti University, and University of Social Welfare and Rehabilitation Sciences. Students were enrolled into the study if they had passed at least 6 units out of the total 24 clinical units, during their studies.

They were selected for the interviews by purposeful sampling method, with a maximum variation in terms of the location of university, gender, semester, and residential place (far from family or with family). The interview process initiated after making the necessary arrangements. An appropriate place for conducting the interviews was arranged (a quiet place with good lighting), and consent forms were obtained from the study participants. Initially, two interviews were conducted as a trial run, to complete the questionnaire. Then, the interview initiated with a couple of open questions.

During the interview, the study participants’ body language, facial expressions, non-verbal reactions, pauses, and statements that were emphasized by them, and voices were recorded. In the interviews, questions leading to...
“yes” and “no” answers were not used. In case of ambiguity, the researcher asked the interviewees to provide further explanations. Semi-structured interviews were used for data collection; thus, the entire conversation was recorded and transcribed. Afterwards, using data analysis, the important states were extracted and encrypted.

Conducting interviews and collecting data continued until a new code was added to the previous codes. Finally, data consisted of a sample of 13 PT students. To prevent interference with interviewee perspectives and paradigms, in addition to bracketing, peer checking and member checking were performed. Therefore, two co-authors and participants confirmed the validity of findings. To validate the data, the triangulation method was used in which one faculty member and one graduate student with 2 years of work experience, were both interviewed. The data analysis of these two interviews confirmed the codes received from previous interviews. Each interview lasted 25-53 minutes.

3. Results

We extracted 182 original codes from interviews analysis. By eliminating and matching the data, we finally developed 4 categories (Table 1).

Table 1. Categories and sub-categories derived from interviews with PT students

| Category                                      | Sub-Categories                                      |
|-----------------------------------------------|-----------------------------------------------------|
| Personal and professional characteristics of clinical educators | Clinical incompetency                               |
|                                              | Inadequate clinical skills                          |
|                                              | lack of observing professional ethics                |
| Personal characteristics of students         | Student’s irresponsibility                          |
|                                              | Inadequate participation                            |
|                                              | The lack of self-esteem                             |
| Inadequate education system                  | Inappropriate planning                              |
|                                              | The inappropriate management of clinical education courses |
| Inappropriate clinical education environment  | Inappropriate interpersonal communication            |
|                                              | The lack of facilities                              |

Table 2 presents the study participants’ characteristics. This part includes three sub-categories, as follows: clinical incompetency, inadequate clinical skills, the lack of observing professional ethics. For example, one of the participants described the lack of responsibility in clinical supervisors: “Sometimes during working with the patient, we face a question, but there is no one to ask and we can’t solve our problem without guidance” (A.A).

Another participant stated about the low level of supervisor’s clinical skills: “Some clinical educators respond to student’s questions or practice clinical skills based on their old knowledge. They don’t update their information” (N.S). Observance of professional ethics is an important task for a clinical supervisor. One of the students discussed the lack of ethical considerations: “Sometimes, during working with a patient, the instructor enters the room and asks questions or shares comments in the presents of patient and humiliates us by this behavior” (F.K).

Personal characteristics of students

This part includes three sub-categories, as follows: student’s irresponsibility, inadequate student participation in education, and the lack of self-esteem. One of the participants described the lack of student’s responsibility: “Some students fail to follow the rules of clinical education, they have irregular entrance and exit time, and due to the lack of motivation or interest, they try not to involve in this process. They usually scape from work” (H.M).
The students also are not attentive. Their participation in the practice is inadequate. One of the participants stated: “Some students are not interested. This lack of motivation and interest negatively affects the time and quality of clinical education process” (S.F). To illustrate the lack of self-esteem, a participant explained: “Some students, despite adequate theoretical knowledge, have poor clinical performance, because they are not self-confident and they are afraid of making mistakes” (N.M).

Inadequate education system

Educational system problems include the following sub-categories: inappropriate planning and the poor management of clinical education programs. One of the participants described inappropriate planning: “Most of us must repetitively practice in various clinical centers that are not specialized” (A.M). To explain the poor management, another participant explained: “The education group of PT department disregards a proper assessment of the clinical education and supervisor’s performance. In fact, clinical education in each center varies, depending on the interests of the supervisors and their own viewpoints” (M.M).

The inappropriate clinical education environment

This category includes two subsets; inappropriate interpersonal communication, and the lack of facilities in clinical settings. Lack of facilities and therapeutic equipment can affect the quality of clinical education. For example, a participant stated: “Some centers lack complete therapeutic equipment; e.g. there are not enough cabins in some centers, so the patients and students have to wait for a while” (A.A).

Most of the student’s clinical experiences are environment-related. Inappropriate interactions of the center staff with students can turn clinical education into an unattractive environment. Another contributor talked about inappropriate interactions: “Sometimes during the work a nurse comes to our room, shows an aggressive behavior and forces students to stop their clinical work, to record a clinical report” (N.M).

4. Discussion

By categorizing, eliminating and matching the data, we finally developed 4 categories, as follows: 1. Personal and professional characteristics of clinical educators; 2. Personal characteristics of students; 3. Inadequate education system; and 4. The inappropriate clinical education environment

| No. | Age | Gender | Semester | University                        |
|-----|-----|--------|----------|----------------------------------|
| 1   | 24  | Female | 8        | Iran University                  |
| 2   | 23  | Male   | 7        | Iran University                  |
| 3   | 23  | Female | 7        | Iran University                  |
| 4   | 23  | Female | 8        | Tehran University                |
| 5   | 22  | Male   | 7        | Tehran University                |
| 6   | 21  | Male   | 6        | Tehran University                |
| 7   | 22  | Female | 7        | Tehran University                |
| 8   | 22  | Female | 7        | University of Social Welfare and Rehabilitation Sciences |
| 9   | 21  | Female | 7        | University of Social Welfare and Rehabilitation Sciences |
| 10  | 24  | Male   | 8        | University of Social Welfare and Rehabilitation Sciences |
| 11  | 22  | Male   | 7        | Shahid Beheshti University       |
| 12  | 22  | Female | 6        | Shahid Beheshti University       |
| 13  | 22  | Male   | 8        | Shahid Beheshti University       |
environment. In the learning-education process, the students and educators are in close contact. Undoubtedly, their inadequate interaction negatively impact students’ performance [10-12]. Studies have revealed that accompanying students with clinical supervisors has the greatest impact on the quality of clinical education [13-15].

The present study suggested that the characteristics of clinical supervisor such as irresponsibility, insufficient clinical skills and the lack of paying attention to professional ethics, are barriers to the effectiveness of clinical education. Chiang and Sloan in similar studies have argued that clinical proficiency, the ability to transfer skills to students, responsibility, effective communication with students, and adherence to the clinical ethics, are facilitators of clinical education [10, 16]. To make the clinical education more effective, students also need to have features like willingness to learn, responsibility, high self-confidence, a sense of compassion and sympathy, sufficient information and a spirit of partnership with the supervisor [1, 4, 5, 11].

In this study, the participants’ experiences suggested that laziness, the lack of motivation and self-esteem in students prevent the achievement of educational goals. Lack of interest in the field of study, considering the clinical education as an unimportant period, as well as the inappropriate training environment with respect to student’s expectations are the main reasons for this issue. Other studies also reported that lack of self-confidence leads to depression and anxiety among students and affects their clinical performance [17, 18].

Taheri et al. in a descriptive study, argued that the individual characteristics of clinical supervisor and students, had the most significant effects on the clinical education of rehabilitation students [19]. From the perspective of contributors, the inappropriate planning and implementation of clinical education system programs are another hindrance to the process of clinical training. Abdi et al. also reported that the condition of clinical settings and undergraduate PT curriculum are undesirable [3, 4]. In this study, the students acknowledged that despite the wide range of PT skills, they lacked a specific program for managing various cases in different clinical settings, such as orthopedics, neurology, and so on. According to them, clinical practice courses are tedious and repetitious.

It could be explained by the limited number of hospitals affiliated to the university, as well as the lack of specialized centers of clinical education. Moreover, the study participants complained about the lack of adequate opportunities to learn important clinical skills such as the interpretation of radiological images, manual techniques, dry needles, kinesiology tape, and so on. Kamali et al. also documented that undergraduate PT curriculum does not provide enough opportunities to learn clinical skills [5].

Perhaps the conversion of a bachelor’s degree in PT to a professional doctorate can greatly compensate for the lack of required clinical skills. Another barrier to the efficiency of clinical education was the lack of adequate supervision over the performance of clinical educators and the implementation of training programs in clinical settings. Other studies have also reported that monitoring and evaluation is an important indicator in the measurement of achievement to educational goals, because it determines the strengths and weaknesses of training program [1, 3, 5, 20, 21].

The most significant part of student’s clinical experiences is formed in the context of the environment. Papathanasiou stated that the characteristics of learning environment are among the important and influential factors in clinical education [22]. The study participants acknowledged the lack of facilities and inappropriate interpersonal communication, as the most important environmental barriers. It seems that the unfair distribution of training spaces due to organizational policies and the lack of funds allocated for equipping the PT settings are among reasons for students’ dissatisfaction with the training environment. Consistently, Dashtgeibi, Kamali, Gard and Dunn, highlighted the role of environmental factors such as the availability of suitable space, appropriate facilities and equipment [4, 5, 23, 24].

It is suggested that the quality of clinical education be assessed through periodic evaluations, to improve the quality of clinical education by empowering the strengths and defeating barriers.

5. Conclusion

Clinical incompetency, inadequate clinical skills, and failure to observe professional ethics are the most frequent problems among clinical supervisors. Furthermore, student’s irresponsibility, inadequate participation, the lack of self-esteem in some students, inappropriate planning, the implementation of clinical education of PT department, and inappropriate interpersonal communication and facilities in clinical settings, can be considered as barriers for clinical education. Considering the obstacles and attempts to resolve them, reviewing the clinical education process can improve the quality
of clinical education. It seems to improve the quality of clinical education.

Participants of this research were selected from Medical Sciences universities in Tehran. Therefore, the results cannot be generalized to other rehabilitation schools in other cities.

**Ethical Considerations**

**Compliance with ethical guidelines**

The ethics code was received (IR.IUMS.REC 1395.9311340008).

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**Authors contributions**

All authors contributed in preparing this article.

**Conflict of interest**

The authors declare no conflict of interest.

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**Research Paper:** Proximal Interphalangeal Joint Flexion Contracture Treatment by Serial Casting Method and the Use of Thermoplastic Tape

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**Objectives:** Flexion contractures of the Proximal Interphalangeal joint are the most frequent complications resulting from surgical procedures and traumatic events. Orthotic interventions for the treatment of contractures may include serial splinting, serial casting, dynamic or static progressive orthoses, or a combination of these orthoses. This study aimed to determine the effects of serial casting methods using thermoplastic tape in the Proximal Interphalangeal (PIP) joint flexion contracture treatment.

**Methods:** Thirty-one patients with flexion contracture of the PIP joint (mean: 32.5°, range: 10-65°) were treated by serial casting method using thermoplastic tape. Flexion contracture, total active motion, extension lag and flexion gap were evaluated in the first session. The affected joint was casted after hand therapy interventions. Patients were requested to visit the clinic every other day for recasting and receiving exercises.

**Results:** After one month, the mean range of flexion contracture decreased from 32.5° to 10.7°. The mean range of flexion gap decreased from 3.2 cm to 1.8 cm. The mean range of extension lag decreased from 2.04 cm to 0.86 cm, and the mean range of total active motion increased from 81.67° to 128.81°. All of the aforementioned changes were statically significant (P<0.05).

**Discussion:** The use of thermoplastic tape for serial casting is an effective and reliable method for the treatment of PIP joint flexion contracture.

**ABSTRACT**

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**Discussion:** The use of thermoplastic tape for serial casting is an effective and reliable method for the treatment of PIP joint flexion contracture.
Highlights

- Flexion contracture of fingers is treated with a casting method.
- Casting with plaster of Paris is effective in reducing contracture but it may produce some complications.
- Thermoplastic materials are new casting materials that have benefits for serial casting.

Plain Language Summary

Flexion contracture of proximal interphalangeal joints of hand is a common condition resulting from injuries and trauma to hand. Sports injuries, finger and hand fractures, and tendon injuries might result in fixed flexion contracture. There are several ways to treat finger flexion contracture. One of the most effective treatments is serial casting. Serial casting with Plaster of Paris (PoP) material was used commonly in the past. Most recently with the improvement of available material for orthotic interventions, thermoplastic materials are more popular among therapists.

Using PoP causes a wide range of complications, such as skin lesions, limiting patient’s performance in the activity of daily living, lack of patient’s adherence to treatment, and so on. Thermoplastic material due to its antibacterial feature could resolve these problems. In this study, we decided to use thermoplastic tape instead of PoP to see if it is a good substitute for PoP. The results of this study revealed that using thermoplastic material is as effective as PoP in reducing flexion contractures of the finger. Furthermore, the patient’s limitation reduces by the use of this type of material. The study patients were also satisfied using this kind of orthosis and report fewer skin complications. Therefore, thermoplastic material is a good choice for patients and therapists.

1. Introduction

The stiffness of finger joints is a prevalent complication following surgical procedures or traumatic events. The Proximal Interphalangeal (PIP) joints are particularly prone to stiffness and often develop flexion contractures [1]. This may be due to injuries to the joint surrounding tissues, the joint, edema, and poor positioning during immobilization after surgical procedures [2].

Significant improvements in regaining the range of motion in joints are often achievable through exercises and orthotic interventions [3]. Orthotic interventions vary from cylindrical serial casting method to dynamic orthotics. Modified Weeks Test (MWT) is a reliable method for therapists to decide which type of splint/orthotic is suitable for patients based on the joint responses to therapeutic interventions [4].

Dynamic orthoses with the use of traction devices, such as rubber bands or elastic threads, provide an extension in an affected joint and facilitate its flexion. Dynamic orthoses produce plastic deformation through creep. If the tissue is unloaded before failure occurs, it remains permanently lengthened as a result of its viscoelastic properties [5]. Serial static (serial casting) or static progressive splints through the prolonged, constant load, can cause plastic tissues deformation via different processes [6] (stress relaxation).

The use of Plaster of Paris (POP) for serial casting method was first introduced by Paul Brand in India in the 1960s for treating stiff joints. As described by Brand, the technique is not a progressive stretching, but an advancement. The cells of contracted tissue are stimulated to grow and become internally rearranged or modified by being held in maximum extension [7]. This process is time-consuming and the position of stiff joint must be held constant until remodeling occurs [8, 9].

The current research investigated the efficacy of serial casting method, using thermoplastic material instead of POP, in treating fixed PIP joint flexion contractures (regardless of the specific precipitating event). We also hypothesized that this intervention can increase the flexion range of motion and consequently decrease flexion contracture and flexion gap.

2. Methods

A power analysis indicated that a total sample size of 27 participants would provide 80% power with the alpha level of 0.05 to detect a medium effect size. To account...
for an expected loss of 20% to 25% of patients, we enrolled 35 patients into this intervention.

The patients who gained 5-10° increase in passive ROM after therapeutic interventions in one session (heat, stretching and exercises) were included to be treated by serial casting method based on MWT [10]. The patients whose range of motion in the PIP joint increased more than 10° after the intervention or were unable to complete the therapeutic sessions or refused to participate in the study were excluded.

Finally, 31 adult patients with a flexion contracture of the PIP joint completed the study between May 2015 and February 2016. All individuals provided a written informed consent form prior to conducting the study. The Medical Ethics Committee of the University of Social Welfare and Rehabilitation Sciences approved the study protocol. Thirty-one patient with the Mean±SD age of 33.94±15.20 years participated in the study. Eleven (35.5%) patients were women and 20 (64.5%) were men (Table 1).

The mean measure of active PIP motion was 81.6°; (ranging from 10-179°). The average level of flexion contracture was 32.5° (ranging from 10-65°), and the average flexion gap was measured as 3.2 cm (ranging from 0.5 cm to 8.0 cm).

All patients with flexion contracture in their fingers were evaluated for an active and passive range of motion, as well as the degree of flexion contracture and flexion gap in the first session. After conducting a 45-minute therapeutic intervention, the patients were reevaluated, and those who gained ≤10° in the extension of PIP were enrolled into the study. Patients were visited every other day. After conducting the therapeutic interventions (paraffin wax, oil massage and passive and active joint exercises), PIP joint was casted in the newly gained range of motion.

Orficast thermoplastic tape was used instead of POP. The material was activated in hot water (68°C) for about one minute. During molding the material for casting the PIP joint, patients were requested to keep their hands in plus position to facilitate intrinsic muscles activities, to gain the most extension range of motion. After removing the Orficast from the hot water, it was gently dried with a towel and, molded on the patient’s finger by wrapping and overlapping each layer to cover 50% of the previous layer (Figure 1).

The affected finger was positioned in maximum possible extension with the MCP joint held in flexion. After 1 minute, the material was sufficiently hardened and could be removed for trimming as needed. The finger’s skin color and circulation were evaluated at this time. If the splint was too tight, a new one was fabricated. All orthotic interventions were performed by an experienced occupational therapist.

After one month, the patients were reevaluated in terms of the range of total active motion, the contracture degree, extension lag and flexion gap. The range of motion was measured by a handheld Jamar goniometer placed on the dorsum of the finger. Flexion gap was measured using a ruler as the vertical distance from the tip of the finger to the distal palmar crease while the patients tried to make a fist.

Continuous variables (the active PIP range of motion, the degrees of contracture, flexion gap and extension lag) were compared before and after conducting the intervention by Paired Samples t-test. Spearman’s correlation coefficient was used to detect the relation between dependent variables and independent categorical variables. Pearson’s correlation coefficient was also used to detect the relation between continuous variables. Analysis of Variance (ANOVA) was applied to detect the differences between outcome measurements in the three groups of patients based on their referral time. SPSS was used for data analysis.

3. Results

The pre-test Mean±SD score of flexion contracture was 32.5±14.3. After conducting the intervention, it decreased to 11.6±8.2. The mean range of flexion gap decreased to 1.43° (from 3.29±1.71 to 1.86±1.07). The difference in the active range of motion was statistically significant before and after the treatment (P=0.001, effect size: d=1.09) (Table 2). The difference in TAM (P=0.001),
 flexion contracture ($P=0.001$, effect size: $d=2.23$), extension lag ($P=0.000$) and flexion gap ($P=0.000$) were statistically different before and after casting (Table 3).

There were no difference in TAM before and after interventions with regards to gender ($P=0.5$, Spearman’s rho=-0.12), age ($P=0.7$, Pearson’s Rho=-0.15), and time past from injury ($P=0.7$, Spearman’s Rho=-0.5) in all patients. The difference in flexion contracture was statistically significant ($P=0.001$, effect size, $d=2.23$). Outcome measurements were independent from time passed from injury based on ANOVA results ($P>0.05$).

Table 1. Demographic characteristics of the patients

| Variables                        | N (%)     |
|----------------------------------|-----------|
| Gender                           |           |
| Men                              | 20 (64.5) |
| Women                            | 11 (35.5) |
| Injured hand                     |           |
| Right                            | 14 (45.2) |
| Left                             | 17 (54.8) |
| Time passed from injury (months) |           |
| 0-6                              | 2 (6.5)   |
| 6-12                             | 7 (22.6)  |
| ≥12                              | 22 (71)   |
| Total active motion at the baseline |       |
| Excellent                        | 2 (6.5)   |
| Good                             | 3 (9.7)   |
| Fair                             | 6 (19.4)  |
| Poor                             | 20 (64.5) |

Table 2. Frequency of TAM after the treatment based on strickland criteria

| Variables              | %         |
|------------------------|-----------|
| Before                 | After     |
| Total active motion    |           |
| Excellent              | 6.5       |
| Good                   | 9.7       |
| Fair                   | 19.4      |
| Poor                   | 64.5      |

Table 3. Differences between variables at pre-test and post-test

| Variables                | Mean±SD     | P     |
|--------------------------|-------------|-------|
|                          | Before      | After |
| TAM                      | 81.67±39.85 | 128.81±38.35 | 0.001 |
| Flexion gap              | 3.29±1.71   | 1.86±1.07  | 0.000 |
| Extension lag            | 2.04±1.22   | 0.86±0.71  | 0.000 |
| Flexion contracture      | 32.52±14.36 | 11.61±8.20 | 0.001 |
4. Discussion

Flexion contractures can be treated by various kinds of orthotic or exercises, regardless of their causes. When the soft tissue is responsible for the contracture, it can be treated with orthotics. When the major problem is in the joints, it is suggested to use total end range time to keep the joint in its maximal tolerable range with continuous stress in the long term [11]. Cylindrical serial static method is among the treatment choices of this condition. The issue is always irritation of skin by POP during the long-time immobilization needed for treatment [12](one month). Finding a substitution method to overcome this problem can help the patients and clinicians.

Our findings suggest that holding the contracted tissue over time can reduce contracture [13], which is consistent with previous studies [14, 15]. Many authors believe that long-term immobilization should be avoided due to the risk of losing motion. This idea does not hold merit with regards to the stiff joints and adherent tissues of hand and fingers. When live tissue is held under constant stress, more collagen will be produced; the tissue will overcome the adherence, and improvements in the range of motion will be noticeable [8].

A study on using plaster casts for the elbow, wrist, and finger flexion contractures, reported significant improvements in the range of motion [15]. Serial casting in the PIP joint was also reported to be beneficial in patients with rheumatoid arthritis, leading to improvements in their range of motion and decrease in their contractures [16]. Use of casting for 8 weeks, to manage crush injuries significantly improved the range of motion and decreased flexion contracture [17]. The benefit of using casting instead of dynamic orthosis was also reported [18]. This theory claims that the increased range of passive motion in a stiff joint is proportional to the amount of time the joint is held at its end range position, or total end range time.

Increasing joint flexion range of motion and decreasing contracture suggested the effectiveness of using this method for treating fixed contractures. Our results supported that this method can be used for the patients regardless of the time passed from their injury. Findings of this study confirmed that this method can be used on all genders and age categories. Besides the measured variables, we received no report of skin irritation. Moreover, patients were able to perform their Activities of Daily Living (ADL) with minimal limitations and precautions. The patients were also able to wash their hands during the day. There are some reports on the limitations and problems with using POP [19], which can be eliminated with the use of Orficast.

The obtained results declared that cylindrical serial casting method with the use of thermoplastic tape is effective in the treatment of PIP joint flexion contractures, as well as using POP with fewer limitations.

We disregarded any criteria to evaluate satisfaction and skin irritation in the patients. The lack of a functional evaluation fails to provide important patient information on how the contracture interferes with ADL and how the use of an orthosis contributes to improvements. The lack of a control group or a parallel treatment group using POP was another limitation to this study.

5. Conclusion

Cylindrical serial casting can be considered in treating flexion contractures. Thermoplastic materials are appropriate substitutions for POP, without causing any long-term skin irritations.

Ethical Considerations

Compliance with ethical guidelines

The Medical Ethics Committee of the University of Social Welfare and Rehabilitation Sciences approved the study protocol.

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Authors contributions

All authors contributed in preparing this article.

Conflict of interest

The authors declare no conflict of interest.

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Research Paper: The Effects of Virtual Reality on Upper Limb Function in Chronic Stroke Patients: A Clinical Trial

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ABSTRACT

Objectives: Stroke is one of the main causes of disability and mortality worldwide. Most survivors experience impairments in their upper limb motor function.

Methods: This experimental study was performed as a clinical trial on 30 chronic stroke patients who experienced stroke from 6 to 96 months ago. Patients were non-randomly divided into the intervention (Virtual Reality besides conventional occupational therapy) and control (conventional occupational therapy) groups. Each treatment session lasted for one hour which was divided into conducting conventional occupational therapy techniques and Virtual Reality (VR) for the intervention group, and routine techniques for the control group. The intervention effectiveness was evaluated by the Fugl-Meyer Upper Extremity Scale, Stroke Impact Scale, Chedoke Arm and Hand Activity Inventory, Motricity Index, Modified Ashworth Scale and goniometer. Results were analyzed by SPSS and one-sample Kolmogorov-Smirnov, Shapiro-Wilk test, Independent Samples t-test and Mann Whitney U test were applied to assess the normality of data and to detect significant differences between study variables.

Results: The results suggested that investigated parameters such as upper limb motor function, muscle tone and the range of motion were significantly different in the intervention group, compared to control group; however, there was no significant changes in none of the group’s daily living activities.

Discussion: VR-based computer games in combination with routine occupational therapy interventions could improve upper extremities functional impairments in chronic stroke patients. However, it seems the mechanisms behind the effectiveness of video games and their impact on brain cortex as well as upper limbs function need to be further investigated.
1. Introduction

Stroke is one of the vascular neurological diseases where vascular damage impairs the brain’s blood supply leading to damage and dead of brain cells and tissues [1, 2]. Common stroke consequences are hemiplegia, sensory impairment, visual, perceptual and cognitive impairments, motor deficits and difficulty in performing targeted movements, and depression [1]. Only 10% of those surviving from stroke may return to their previous functional level; almost 50% of them may have desirable functionality with limited help and about 40% would need help and support for rehabilitation [3].

Studies demonstrated that about 85% of stroke patients suffer from upper limb impairments. Among this huge number, 40-60% can use their hands in daily activities and 15% will regain their functional abilities after a while [4]. Upper limb impairments include impairments in the movement and coordination of arms, hands and fingers and usually limit activities like eating, dressing and washing [5, 6]. Each of the mentioned disabilities might occur in anyone. Therefore, improving upper limb impairments is a fundamental aim of any rehabilitation program, specially for occupational therapists who specifically work on promoting upper limb function in daily living activities [5-7].

Most of the methods including neurodevelopmental techniques and task-oriented approaches which emphasis on increasing the range of motion, power and endurance are not equipped with measurable and gradable tools [8]. These long-term and repetitive programs could be tedious for patients and cause the lack of adherence, decrease motivation and attention to pursue therapy program, leasing to reduce their efficacy [4, 8]. All of the mentioned shortcomings have made therapists to replace traditional methods with modern therapeutic computer games.

Virtual Reality (VR) interventions such as video games, which are part of biofeedback techniques, have emerged into the rehabilitation field [9]. VR games can improve upper limb impairments, due to their repetitive activities, voluntary movements performed in various directions and speeds as well as the need to react precisely [10]. Therefore, VR games can successfully lead to motor learning facilitation [11]. Entertaining VR videogames provide feedbacks that encourage patients to participate more in treatment and benefit from their residual functional capacities to achieve success [12].

Nintendo Wii video game has been represented as a secure, accessible and proficient choice for rehabilitation purposes and recovering post-stroke upper extremity impaired functioning. Moreover, VR and videogame applications are groundbreaking impressive technologies that can be efficiently mixed with conventional rehabilitation methods of upper limb impairments after stroke [13, 14]. Upper extremity scores have significantly improved by the use of a Wii device [15].

Nintendo Wii has been suggested as an easily accessible complementary device for improving conventional therapy specially in the subacute stage of stroke rehabili-
tation in subjects with moderate strength and upper limb functional limitations [15-17]. In addition, VR training could be advantageous in improving the voluntary function of the arm during the acute stage of stroke in subjects participating in an intensive training program [17].

Unlike Nintendo VR system, E-Link device has the capacity for measuring as well as analyzing upper extremity function. Additionally, it has various handles that enable the practitioner to train and rehabilitate the patients for operating more diverse movements [18]. Despite the extensive use of the computer in human life, its application is very limited in rehabilitation. The majority of studies in this field have not described a precise protocol or have used commercial devices which are not designed specifically for therapeutic purposes. To our knowledge, no study has investigated the efficacy of using VR (E-Link) in stroke patients in Iran. Thus, we investigated the effectiveness of VR on upper arm functioning in chronic stroke patients.

We assumed that the unique characteristics of this technology could be used as an impressive tool for improving upper limb functioning in the subjects with motor deficits. The therapeutically designed system experimented in this study was adopted for the first time to provide intervention and evaluation, concurrently. In this study, we compared 12 sessions of Traditional Occupational Therapy (TOT), with the same number of sessions combining TOT with VR E-Link on the upper extremity functioning in stroke patients to realize which could be more beneficial.

2. Methods

Study design

The present study was a non-randomized controlled trial. The samples were selected among patients referring to the occupational therapy laboratory of Iran University of Medical Sciences. Patients were divided non-randomly and according to their sequence of referring to the lab. There were 15 subjects (10 right hemiplegia and 5 left hemiplegia) in the intervention group (traditional occupational therapy methods accompanied by VR) and 15 (10 right hemiplegia and 5 left hemiplegia) in the control group (only traditional occupational therapy methods). This clinical trial was registered (IR.IUMS.REC1395.9411355008) and approved by the Ethics Committee of the Rehabilitation Center of Iran University of Medical Sciences. Written informed consent was obtained from all participants before their enrollment to the study.

Study participants

This study was implemented in the School of Rehabilitation Sciences (Iran University of Medical Sciences) in 2017. All study participants suffered from stroke for a minimum time of 6 months to a maximum time of 96 months. The inclusion criteria were suffering from stroke for at least 6 months due to the diagnosis of a neurologist, Brunnstrom’s upper limb function of ≥4, a cognitive function score of 21 by Mini Mental Status Examination (MMSE), the lack of any other neurological disorders according to their medical records, their family or their physicians report, achieving maximum score of 1+ in Modified Ashworth Scale and having normal vision (not having any visual impairments such as hemianopsia).

Study procedure

Assessment tools

The Fugl-Meyer Upper Extremity (FMUE) Scale is a performance-based scale broadly used to measure impairments in stroke patients. Reflex activity, movement control and muscle strength of upper extremity are the main parameters assessed in post-stroke hemiplegic patients by this tool. The FMUE includes 33 items. Each item is scored 0 if the participant fails to perform it, 1 if the subject partially performs the function and 2 for fulfilling the task, ideally. The whole test takes almost 30 minutes to be completed and has revealed acceptable reliability, validity and responsiveness in stroke evaluations. A distinguished feature of this test is no needs for specialized equipment or preparation and could be administered in a variety of occasions as well as long lasting assessments [19].

The Chedoke Arm and Hand Activity Inventory (CA-HAI) has been used for assessing the recovery of post-stroke upper limb function since 2004 when Barreca et al. first developed it to investigate the recovery of paretic limb in this category of patients. Fundamental objectives of the test are as follows: to discriminate between various dysfunctions of upper limb, predict functional recovery in the affected upper limb, quantify upper limb functional changes, determine the critical results of these changes in stroke survivors and be a valid tool for guiding treatment. The test comprises of 13 real life functional tasks. Scoring of all 13 tasks is based on a 7-point quantitative scale. The total scale would be at a minimum amount of 13 to a maximum amount of 91, which higher scores reveal greater abilities. The total amount of time required for test administration is 25 min [20].
The Stroke Impact Scale (SIS) is a stroke-specific self-report scale with 2 versions. The second version has 64 items that are categorized into 8 domains (strength, hand function, Activities of Daily Living (ADL), communication, emotion, mobility, memory and thinking, and participation). Maximum achievable point for each item is 5. The scoring is based on the level of difficulty experienced by patients while performing each task in the previous week. The higher total score is representative of performing the task without any difficulties [21]. We used items 7 (SIS 1) and 9 (SIS 2) of this questionnaire which assess daily living activities, to evaluate our results.

The Modified Ashworth scale was originally invented to investigate the impact of an anti-spastic drug on Multiple Sclerosis patients. The scale is rated by the examiner to assess the amount of perceived resistance or muscle tone while moving the limb through the full range of motion. The original version consisted of 5 grades from 0 to 4; however, in 1987, the scale was reworded to enhance the sensitivity of it and one grade (1+) was added [22].

The Mini-Mental State Examination (MMSE) was first designed as a screening tool to quantitatively investigate cognitive impairments and record its changes over time. The MMSE has 11 simple questions or tasks, classified in 7 cognitive categories. These 7 domains are orientation to place and time, registration of 3 words, attention and calculation, recall of 3 words, as well as language and visual construction. The test completion takes about 10 minutes provided that it is conducted by an expert interviewer. The test explores patients' cognitive performance and has a total score of 30. A score of 23 or 24 is generally accepted as the cutoff point which indicates cognitive impairment presence. Impairment levels are classified as none (24 to 30), mild (18 to 24), and severe (0 to 17) [23].

The Motricity Index is applied for grading muscle strength based on patients’ ability to activate a muscle group, to move a limb segment within the range of motion, as well as resist against examiner’s force. The validity of this index for upper limb function is confirmed by the close interrelation between its components and its correlation with grip strength and upper extremity function [24].

The Goniometer is a useful instrument to measure joints’ angle and the range of motion for either active or passive movements [25].

Intervention

A 4-week continuous program was designed for all of the study participants. Both of the control and intervention groups received 1-hour sessions of three times per week with the exception that the control group only received TOT for the 1-hour sessions; however, the time was divided for the intervention group to 40 minutes of VR E-Link and 20 minutes of TOT. All the interventions and data collections were performed by one trained examiner to increase the accuracy. Our intervention was mainly focused on the function of the distal part of the upper extremity.

VR E-link

The VR system used in the current study was E-Link (Evaluation and Exercise, Biometrics Ltd systems, version 6). The advantage of this computer system is the capacity to evaluate several times and applies treatment exercises within defined games with the purpose of specific usage in rehabilitation. The loading and resistance rates are also adjustable in accordance with the patients’ disabilities. Additionally, this system has the capacity to evaluate the active and passive ranges of motion for every single functional movement.

The E-link categorizes training games for desired movements as follow: forearm supination/pronation and wrist flexion/extension in the vertical and horizontal planes. All the practices in this study were simple, colorful and exciting, such as driving, playing basketball, space shooting and so on. The difficulty and complexity levels of games were different and adjusted based on the individuals’ ability. At the beginning of each session, movement functions were explained and patients learnt how to play and work with the system, depending on the functionality of hand, joystick and games.

Catch balls, Find space, Load ship and Solar eclipse were played by cylindrical joysticks and games like Maze, Wipe out, Driving and Space shooting were played by spherical joysticks for improving wrist extension and forearm supination, respectively. The video-games were run at various times according to patients’ interest and movement restrictions. If needed, participants were given a break during playing. The mentioned movements were selected to achieve specific task-based goals in real life situations by visual feedback. The comfortability of all parts like joysticks have been medically tested and approved.
The TOT intervention included strengthening, the range of motion, table top activities and training activities of daily living for the more involved limb. TOT interventions included the similar movements of the distal part of upper extremity in VR E-Link group, to maximize the integrity between the two groups. The difficulty of the intervention was changed considering the level of participant’s performance in each group, as well.

Finally, the functionality of the upper limb, muscle strength, movement range, and the quality of the daily activities were reassessed after the completion of intervention.

Statistical analysis

Statistical analysis was performed by SPSS after the obtained data were encoded. Data normality was examined by the Shapiro-Wilk test, and Mann-Whitney U test was used to compare the efficacy of interventions.

3. Results

The mean age of the control and intervention groups were 55.26 and 55.23, with the maximum age of 80 and 72 and a minimum of 39 and 36 years, respectively. The maximum and minimum time passed after the stroke was 50 and 11 months for the control group and 96 and 7 months for the intervention group. The MMSE average scores were 27.09 and 28.20 in the control and intervention groups, respectively. A maximum score of mental status testing for both groups was 30; the minimum score for the control group was 22 and for the intervention group was 23. Qualitative demographic variables are presented in Table 1.

Table 1. Qualitative demographic variables

| Variables           | Intervention | Control |
|---------------------|--------------|---------|
|                     | No. | Frequency (%) | No. | Frequency (%) |
| Gender              |     |               |     |               |
| Male                | 11  | 73.33         | 9   | 60            |
| Female              | 4   | 26.66         | 6   | 40            |
| Affected side       |     |               |     |               |
| Right               | 10  | 66.66         | 10  | 66.66         |
| Left                | 5   | 33.33         | 5   | 33.33         |
| Marriage status     |     |               |     |               |
| Married             | 14  | 93.33         | 15  | 100           |
| Single              | 1   | 6.66          | 0   | 0             |
| Dominant side       |     |               |     |               |
| Right               | 13  | 86.66         | 13  | 86.66         |
| Left                | 2   | 13.33         | 2   | 13.33         |

Regarding the intervention group, Fugl-Meyer wrist part (P<0.001) and Fugl-Meyer hand part (P=0.001) were statistically significant, compared to the control group. The forearm supination/pronation and wrist flexion/extension movement ranges measured by goniometer were significantly different with the P<0.001 for both variables. The measures of daily activity revealed no significant difference in any group (P>0.05). The data on daily living activities reviewed by the Stroke Impact Scale suggested no significant difference between the
study groups (P>0.05). Chedoke Test and Motricity Index had normal data distribution, while others had not (Tables 2 and 3).

4. Discussion

The present study examined the effect of VR technology (by the use of E-Link) on the upper limb function in stroke patients. Our results revealed that VR technology could improve upper extremity function in chronic stroke patients. Patients reported no pain or discomfort after the intervention. Despite their lack of experience in working with VR, they could learn to make neces-

Table 2. Analytical statistics of variables with non-normal distribution

| Variables               | Group    | No. | Mean Differences | Difference Changes | Z   | P   |
|-------------------------|----------|-----|------------------|--------------------|-----|-----|
| MAS forearm supination  | Intervention | 15  | 0.33             | 0.16               | 1.7 | 0.001|
|                         | Control  | 15  | 0.16             |                    |     |     |
| MAS wrist extension     | Intervention | 15  | 0.33             | 0.16               | 1.7 | 0.001|
|                         | Control  | 15  | 0.16             |                    |     |     |
| SIS1                    | Intervention | 15  | 0.00             | 1.66               | 2.40| 0.01|
|                         | Control  | 15  | 1.66             |                    |     |     |
| SIS2                    | Intervention | 15  | 0.80             | 2.26               | 2.11| 0.03|
|                         | Control  | 15  | 1.46             |                    |     |     |
| FMA (wrist)             | Intervention | 15  | 1.33             | 1.93               | 3.66| <0.001|
|                         | Control  | 15  | 1.40             |                    |     |     |
| FMA (hand)              | Intervention | 15  | 3.20             | 0.73               | 1.61| 0.001|
|                         | Control  | 15  | 2.46             |                    |     |     |
| FMA (total score)       | Intervention | 15  | 6.53             | 2.66               | 3.16| 0.001|
|                         | Control  | 15  | 3.86             |                    |     |     |
| ROM forearm supination  | Intervention | 15  | 7.66             | 6.66               | 4.50| <0.001|
|                         | Control  | 15  | 1.00             |                    |     |     |
| ROM wrist extension     | Intervention | 15  | 7.66             | 5.33               | 3.93| <0.001|
|                         | Control  | 15  | 2.33             |                    |     |     |

Table 3. Analytical statistics of variables with normal distribution

| Variables | Group    | No. | Mean Differences | Difference Changes | t    | P   |
|-----------|----------|-----|------------------|--------------------|------|-----|
| Chedoke   | Intervention | 15  | 6.73             | 4.2000             | 4.31 | <0.001|
|           | Control  | 15  | 2.53             |                    |      |     |
| Motricity | Intervention | 15  | 8.83             | 6.2000             | 3.56 | 0.001|
|           | Control  | 15  | 2.66             |                    |      |     |
sary changes in a short time. Fugl-Meyer (wrist and hand parts), Motricity Index (arm score part) and Chedoke Arm and Hand Activity Inventory were used to assess upper limb function status.

According to the increase in Fugl-Meyer, CAHAI and Motricity Index scores, the upper limb function skill was generally improved. Goniometer measures on a range of motion changes, compared to the baseline, revealed the efficacy of intervention in the VR E-Link group. This may be explained by the similarity of selected exercises of VR with the necessities of volitional forward movement. In addition, significant differences of Modified Ashworth Scale scores indicated the efficacy of our intervention on forearm supination/pronation and wrist flexion/extension muscle tone. Although there were no specific exercises for muscle tone reduction, the increased scores could be the results of improvements in the self-engagement of patients in motor control and their abilities in performing voluntary movements. These results are consistent with the previous studies; however, most of the previous studies used Wii system.

Carregosa et al. reported that after Nintendo Wii intervention, motor learning retention was observed in patients, which indicates obtaining a sustained benefit through the technique. Therefore, sub-item and total score values related to the upper limb motor function by the Fugl-Meyer scale and functional capacity by the SF-36 questionnaire were sustained. This finding indicated that the therapeutic consequences would possibly remain by the pass of time [26].

Brunner et al. indicated similar results in sub-acute phase of stroke patients [27]. Kong et al. presented the efficacy of Nintendo Wii in facilitating upper limb recovery in stroke patients, in companion with conventional methods. They compared the results of 12 sessions of upper limb exercises by Nintendo Wii gaming, and conventional therapy within 3 weeks. They indicated that none of the methods were effective in promoting upper limb motor recovery, in comparison to control group [28].

Park et al. has stated that game-based VR movement therapy may be helpful for upper extremity functional recovery. They used the Fugl-Meyer assessment tool and Box and Block Test as well as the quality of movement subscale of the motor activity log [29]. Studies examined stroke patients in the acute phase. However, due to the spontaneous capability for recovery of patients in this phase, their results are not reliable. Moreover, assessment tools used in previous studies were not subtle enough to be used in occupational therapy assessments. Stroke Impact Scale was used to examine patients ADL and IADL status. This scale revealed more significant changes in the control group.

Kwon et al. indicated no benefit for intensive VR programs combined with conventional techniques in the acute phase of stroke, compared to conventional techniques alone. No significant difference was observed in ADL performance and upper extremity function [16]. In our study, the comparison of pre-treatment and post-treatment values for both groups were significant, except for SIS. Our results highlight the effectiveness of implementing VR practices simultaneously with traditional occupational therapy techniques to improve upper limb function in stroke survivors.

The results of the current study could be explained by the compact and targeted VR practices, occupational therapy interventions, neuromuscular system flexibility and consequent movement improvements in both groups of participants. Percentage comparison of changes in tests suggested that VR along with occupational therapy improved Fugl-Meyer, Motricity Index and Chedoke test scores of upper limbs, except for SIS test in the intervention group. The improvement of the measures in the intervention group is because of the advantageous effects of traditional occupational therapy practices along with VR practices. Daily living activities did not significantly affect the groups [5, 30, 31]. Additionally, the high satisfaction rate of participants indicates the joyful and motivational nature of such activities accompanied by traditional treatments.

5. Conclusion

This study suggested that VR and common occupational therapy techniques could improve upper limb function in post-stroke patients who are in their chronic phase. Therefore, we suggest that this technology be successfully accompanied by traditional techniques to gain more efficient results in upper extremity functional activity among stroke patients.

Ethical Considerations

Compliance with ethical guidelines

This clinical trial was registered (IR.IUMS.REC1395.9411355008) and approved by the Ethics Committee of the Rehabilitation Center of Iran University of Medical Sciences. Written informed consent was
obtained from all participants before their enrollment to the study.

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**Authors contributions**

Conception, design and writing: Afsoon Hassani Mehraban; planning: Malek Amini; Implementation of intervention: Hossein Soufi Ahmadi; and helping in writing: Maryam sheikhi.

**Conflict of interest**

The authors declared no conflict of interest.

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