Improving balance in subacute stroke patients: a randomized controlled study

Nika Goljar, Helena Burger, Marko Rudolf and Irena Stanonik

The aim of the study was to compare the efficacy of balance training in a balance trainer, a newly developed mechanical device for training balance, with conventional balance training in subacute stroke patients. This was a randomized controlled study. Fifty participants met the inclusion criteria and 39 finished the study. The participants were randomly divided into control and balance trainer groups. The first had conventional balance training while the second trained balance in the balance trainer. All the participants trained balance 20 min per day, 5 days per week for 4 weeks and had additional 25 min of physiotherapy. Balance was assessed by the Berg Balance Scale, one-leg standing, Timed Up and Go (TUG) Test and 10 m walk. There was significant improvement in Berg Balance Scale ($P<0.001$), TUG ($P<0.001$) and 10 m walk ($P=0.001$) in both the groups, whereas no differences were found in any of these measures between the two groups either regarding overall average level or regarding average improvement. Both the groups improved significantly in standing on the healthy ($P=0.001$) as well as the impaired lower limb ($P=0.005$), whereby no significant differences were observed between the groups. Within both groups, significantly fewer subjects needed assistance of a physiotherapist for the 10 m walk and the TUG test at the end than at the beginning of the study ($P=0.016$). It can be concluded that both conventional balance training and training balance in the balance trainer equally improved balance in subacute stroke patients. The balance trainer cannot replace a physiotherapist but it is a safe and efficient supplementary method.


El objetivo de este estudio fue comparar la eficacia del entrenamiento del equilibrio utilizando un dispositivo para el entrenamiento del equilibrio (un dispositivo mecánico recién creado para el entrenamiento del equilibrio) en comparación con el método tradicional de entrenamiento del equilibrio en pacientes en la etapa subaguda de un accidente cerebrovascular. Se trata de un estudio aleatorizado de comparación. Cincuenta participantes cumplieron los criterios de inclusión y 39 cumplimentaron el estudio. Se dividió a los participantes, de forma aleatoria, en dos grupos: un grupo de comparación y un grupo de entrenamiento del equilibrio. El primer grupo realizó el entrenamiento del equilibrio mediante el método tradicional, mientras que el segundo grupo lo realizó utilizando el dispositivo para el entrenamiento del equilibrio. Todos los participantes realizaron el entrenamiento del equilibrio durante 20 min al día, 5 días de la semana, durante 4 semanas y recibieron, además, 25 min de fisioterapia. El equilibrio se valoró mediante la escala del equilibrio de Berg, la prueba del equilibrio estando de pie apoyado en una sola pierna, la prueba del tiempo que toma levantarse y empezar a andar (Timed Up To Go, TUG) y la prueba de andar durante 10 minutos ($P=0.001$). Se observó una mejoría importante del equilibrio en la escala del equilibrio de Berg ($P<0.001$), la prueba TUG ($P<0.001$) y la prueba de andar durante 10 min ($P=0.001$) en ambos grupos. Sin embargo, no se hallaron diferencias en ninguna de estas medidas entre ambos grupos con relación a los valores medios generales.
ni con relación a los valores medios de la mejoría. En ambos grupos se observó una mejoría importante del equilibrio tanto al estar de pie apoyado en la pierna sana (P=0.001) como al estar de pie apoyado en la pierna afectada (P=0.005), de modo que no se observaron diferencias importantes entre ambos grupos. En ambos grupos, la cantidad de participantes que necesitaron la ayuda del fisioterapeuta durante la realización de la prueba de andar durante 10 min y de la prueba TUG fue significativamente menor al final del estudio que al principio de éste (P=0.016). En resumen, podemos concluir que tanto el método tradicional de entrenamiento del equilibrio como el entrenamiento del equilibrio utilizando el dispositivo mecánico creado mejoraron, de forma similar, el equilibrio en pacientes en la etapa subaguda de un accidente cerebrovascular. El dispositivo para el entrenamiento del equilibrio no podría reemplazar al fisioterapeuta, pero es un método complementario eficaz e inocuo.

Cette étude avait pour objectif de comparer l’efficacité de la rééducation à l’équilibre avec un plateau gonflable «balance trainer», un dispositif mécanique nouvellement mis au point pour la rééducation à l’équilibre, par rapport à la rééducation classique chez des patients victimes d’accidents cardio-vasculaires en phase aiguë. Étude contrôlée et randomisée. Cinquante participants répondaient aux critères d’inclusion et 39 ont suivi l’étude dans son intégralité. Les participants ont été répartis aléatoirement en groupes de contrôle et en groupe de rééducation avec le balance trainer. Le premier groupe a suivi une rééducation à l’équilibre conventionnelle, tandis que le second a utilisé le balance trainer. Tous les participants ont suivi une rééducation de 20 min par jour, 5 jours par semaine pendant 4 semaines et ont reçu 25 min supplémentaire de physiothérapie. L’équilibre a été évalué par l’échelle d’équilibre de Berg, debout sur une jambe, un test TUG (Timed Up and Go) et 10 minutes de marche. Une amélioration significative a été constatée sur l’échelle d’équilibre de Berg (P<0.001), TUG (P<0.001) et au niveau de la marche de 10 min (P=0.001) dans les deux groupes, alors qu’aucune différence n’a été détectée dans ces mesures entre les deux groupes, soit concernant le niveau global moyen soit l’amélioration moyenne. Les groupes ont nettement progressé en termes d’équilibre debout sur le membre inférieur en bonne santé (P=0.001), ainsi que sur le membre inférieur affaibli (P=0.005), alors qu’aucune différence significative n’a été observée entre les deux groupes. Au sein des deux groupes, un nombre significativement moindre de patients a nécessité l’assistance d’un kinésithérapeute pour la marche de 10 min et le test TUG à la fin qu’au début de l’étude (P=0.016). En conclusion, on peut estimer que les deux types de rééducation à l’équilibre, conventionnelle et avec le balance trainer, ont amélioré à titre égal l’équilibre chez les victimes d’accidents cardio-vasculaires en phase aiguë. Le balance trainer ne peut pas remplacer un physiothérapeute, mais il constitue une méthode complémentaire sûre et efficace. International Journal of Rehabilitation Research 00:000–000 © 2010 Wolters Kluwer Health | Lippincott Williams & Wilkins.

Introduction
Stroke ranks as the third most common cause of death in industrialized countries. It is a leading cause of serious, long-term disability in Europe (European Stroke Organisation, 2008) and in the United States (Michaels et al., 2005). Two-thirds of the survivors have difficulty in walking immediately after suffering a stroke, and 6 months later over 30% (States et al., 2009). Stroke is the greatest risk factor for falls among the elderly (Mayo et al., 1990; Jorgensen et al., 2002). Teasell et al. (2002) reported that 37% of all inpatient stroke patients fell at least once during rehabilitation and even more fell after discharge (Mackintosh et al., 2005).

As balance problems are common after stroke and are of importance in mobility and activities of daily living (ADL) (Carod-Artal et al., 2005; Wee and Hopman, 2005; Tyson et al., 2006; Van de Port et al., 2006; Patterson et al., 2007), treatment of balance continues to be standard of care in stroke rehabilitation. ‘Practicing of balance’ is one of the most frequent physiotherapeutic interventions in inpatient rehabilitation facilities (Jette et al., 2005; Tyson and Selley, 2006). It is challenging for both the patient and the physiotherapist, as it has to be both safe and effective at the same time.

No general physiotherapy approach has been proven to be superior for promoting balance recovery from stroke (Pollock et al., 2007). In a Cochrane review, Barclay-Goddard et al. (2004) indicated that providing feedback from a force platform resulted in improved stance symmetry after stroke but did not improve balance during active functional activities, nor did it improve overall independence. Previous studies have also reported the ineffectiveness of sensory stimulation, electromyography feedback or body weight supported treadmill training on balance and related ADL in stroke patients (Geurts et al., 2005).
Matjačić et al. (2000, 2003, 2005) presented a novel approach to train balance during standing and stepping, where the participant had to perform several tasks during standing using the balance trainer. The appliance provides an impaired individual with a fall-safe balancing environment, where the balancing efforts of a standing individual are augmented by stabilizing forces acting at the level of pelvis in the sagittal and frontal planes of motion, assisting the balancing activity of ankle and hip muscles and at the level of shanks, assisting the knee extensor muscles. The level of stiffness support can be selected according to current balancing abilities of the impaired individual.

The aim of this study was to find out whether the efficacy of balance training in the balance trainer is comparable with conventional balance training. The hypothesis was that similar results would be achieved by both methods.

Methods

Patients

Out of all the patients admitted to the Institute for Rehabilitation in Ljubljana after stroke, the study included those patients who met the following inclusion criteria: first stroke, no other neurological or musculoskeletal impairments, able to walk for 10 m (walking aids, orthoses or assistance of one person allowed), and willing to participate. Ethics committee of the Institute for Rehabilitation approved the study. All the patients signed an informed consent.

Among the 262 admitted patients, 50 met the inclusion criteria. Six of them refused to participate. The remaining 44 were randomized into two groups, 22 in each.

Randomization

The patients were randomly divided into two groups: the control and the balance trainer group. Randomization was done by sealed envelopes prepared by a computer program. After a medical decision on a patient’s inclusion into the study and the patient’s signing of the consent, a physiotherapist opened the envelope.

Instrumentation

Balance trainer is a commercially available (Medica Medizintechnik GmbH, Hochdorf, Germany) mechanical device that provides a fall-safe balancing environment for patients with balance problems. It augments patients’ balance during standing by stabilizing forces acting at the level of pelvis in the sagittal and frontal planes of motion, assisting the balancing activity of ankle and hip muscles.

The supporting forces are generated entirely by passive, compliant materials. The level of supporting forces can be varied from zero up to the level where no balancing activity is needed from the standing patient. Further, an advanced balance training and evaluation program was developed to facilitate and test balancing in the whole range of anterior–posterior and medio-lateral postural space in a gradual and systematic way (Matjačić et al., 2005). Detailed and comprehensive information on the balance trainer and its predecessor device are given in Matjačić et al. (2000, 2003).

Therapeutic interventions

Both the groups received 45 min of physiotherapy per day, 5 days a week for 4 weeks. The control group received a conventional physiotherapy program, which included 20 min of balance training. Instead of the conventional balance training, the balance trainer group performed the balance trainer program for 20 min (Fig. 1). Both the groups trained under supervision of the same two senior neurophysiotherapists. In the control group, the physiotherapist was in charge of the patient’s safety and physical management (preventing falls), whereas in the balance trainer group patients practiced balance in a fall-safe environment under the supervision of the physiotherapist.

Outcome measurement

The severity of activities limitation was evaluated by Functional Independence Measure at the beginning and at the end of the study.
Balance was measured by Berg Balance Scale (BBS) (Berg et al., 1989), one-leg standing, Timed Up and Go Test (TUG) (Ng and Hui-Chan, 2005) and 10 m walk (Wade, 1992). All the tests were performed twice – at the beginning of the study and after 4 weeks of training, that is, at the end of the study.

The BBS is a 14-item test. It uses a 5-point scale (0–4) to rate each item; the maximum is 56 points, indicating good balance. The BBS was validated in acute stroke patients and has very high intrarater and interrater reliability (Berg et al., 1989, 1992, 1996).

One-leg standing measured the time patients were able to stand on one leg with hands crossed on their chest. Three measurements were done on the healthy and three on the impaired leg at each measurement and the mean was calculated for further analyses.

TUG is a test of physical agility. It measured the time the patients needed to stand up from a chair, walk around an obstacle placed 8 feet in front of the chair, and sit again. The patients who were not able to stand up without using hands were allowed to use hands for support. They were also allowed to use walking aids, orthoses or assistance of one person when needed. The test was repeated three times at each measurement and the mean was calculated for further analyses.

The 10 m walk measured the time the patients needed to walk 10 m. The patients were allowed to use walking aids, orthoses or assistance of one person when needed. The test was repeated three times at each measurement and the mean was calculated for further analyses.

**Sample size**
All the sample size and power calculations were done assuming the 5% α level. The sample size (Fig. 2) was considered sufficient for detecting a notable difference in efficiency between the two methods, because if change scores were compared between the two groups and a difference of 5 points were found on the BBS in favor of either group, given a change scores' standard deviation (SD) of 5 points in both groups, an independent-samples t-test on change scores would achieve almost 90% power with 22 participants in each group. At the same time, assuming that no difference in efficiency exists between the two methods, a paired t-test on the pooled sample could be used to prove that improvement had been achieved, and under the assumption of a mean change score of 7 and change scores’ SD of 15 in both groups, which is realistic for TUG as well as for the 10 m walk test, the pooled sample size of 44 yields over 85% power. Assuming about 10% attrition in both the samples (which actually occurred – see the Results section), 20 patients in each group would still yield over 80% power for both scenarios described above.

**Statistical analysis**
The data were analyzed using SPSS 14.0 (SPSS Inc., Chicago, Illinois, USA) for Windows (Microsoft Corporation, Ljubljana, Slovenia). Descriptive statistics were calculated for all variables. For all numerical outcomes, two-way mixed-model analysis of variance was used with group as between-subjects factor and time (either beginning or end of the study) as within-subjects factor. Exact McNemar test was used for assessing the change from study beginning to study end in proportion of patients needing assistance of a physiotherapist for walking.

**Results**
Five patients (three in the balance trainer and two in the control group) did not finish the study owing to medical complications not related to the study (Fig. 2). As a result, 20 women and 19 men finished the study.

On average patients were 61 years old (SD 8.9 years). Time from stroke to admission ranged from 1 to 10...
months, with a median of 3 months (mean 3.2, SD 2.0 months). Twenty-two patients had the right side of the body affected, 17 were affected on the left side; 25 suffered an ischemic stroke, 14 hemorrhage. The brain areas most commonly affected were hemispheres (17 patients), followed by thalamus (14), while cerebellum orpons were affected in the other patients. The number of concomitant diseases ranged from none (in two patients) to four (in three patients), one being the median.

There was improvement in BBS, TUG Test and 10 m walk in both the groups (Table 1). The study found no differences in any of these measures between the two groups either regarding overall average level (i.e. there was no significant group effect in the analysis of variance), or regarding average improvement (i.e. there was no significant interaction effect). Similarly, both groups improved significantly in standing on the healthy as well as the impaired lower limb, whereby no significant differences were observed between the two groups (Table 1).

For the 10 m walk and the TUG Test, 53% of patients in the control group and 80% of patients in the balance trainer group needed assistance of a physiotherapist at the beginning of the study. At the end of the study, 16% of the patients in the control group and 45% in the balance trainer group still needed assistance of the physiotherapist (Table 2). Within each group, the reduction in proportion of patients needing assistance was statistically significant (P=0.016 for both the groups).

Discussion
Good balance is of utmost importance for independence in ADL and walking (Bohannon and Leary, 1995; Juneja et al., 1998; Fong et al., 2001; Bonan et al., 2004; Cardo-Artal et al., 2005; Marigold et al., 2005; Van de Port et al., 2006). Balance can be practiced by conventional physiotherapy methods as well as by using different feedback systems (Yavuzer et al., 2006) and special devices (Matjaæt et al., 2003, 2005). Devices, especially those allowing practice in a fall-safe environment, decrease the demand on the physiotherapist. After preparing the patient and explaining the instructions, the physiotherapist can concentrate on specific tasks only or even work with others.

The results of our study showed that both methods, conventional balance training and training balance in the balance trainer, improved balance in subacute stroke patients. There were no significant differences between the two groups in any of the measured parameters. The results of the study are similar to others, who also showed that different therapeutic approaches improved balance in stroke patients (Vearrier et al., 2005; Bayouk et al., 2006; Katz-Leurer et al., 2006).

All the patients in the study liked training on the balance trainer. In the introductory sessions, the physiotherapist instructed and guided the patients, while later he or she just monitored their practice. Most of them knew exactly what to do after three to five sessions. The same balance exercises were performed in the balance trainer group and the control group, except that in the control group, the physiotherapist was in charge of the patient’s safety.

One-leg standing is important for many daily activities, such as walking (single leg support phase) and climbing stairs, stepping on an escalator or on the sidewalk as well as for reaching things, dressing the lower body, and similar. At the beginning of the study, in both the groups standing on the impaired lower limb was much shorter than it is required for the single support phase during normal walking at normal speed. At the end, achieved values were still very low and it could be questioned whether their improvement

Table 1 Patients’ characteristics and results of balance testing

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<tr>
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<th>Control group</th>
<th>Balance trainer group</th>
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<tbody>
<tr>
<td></td>
<td>Beginning</td>
<td>End</td>
</tr>
<tr>
<td>Sex (M/F)</td>
<td>10/9</td>
<td>9/11</td>
</tr>
<tr>
<td>Age (years)</td>
<td>62.3 (8.3)</td>
<td>60.0 (8.6)</td>
</tr>
<tr>
<td>Motor FIM</td>
<td>43.5 (12.5)</td>
<td>46.3 (10.9)</td>
</tr>
<tr>
<td>Cognitive FIM</td>
<td>26.0 (3.1)</td>
<td>24.6 (5.6)</td>
</tr>
<tr>
<td>Total FIM</td>
<td>69.5 (13.9)</td>
<td>71.0 (12.9)</td>
</tr>
<tr>
<td>Berg Balance Scale</td>
<td>26.0 (13.3)</td>
<td>24.1 (11.4)</td>
</tr>
<tr>
<td>Standing on healthy lower limb (s)</td>
<td>7.4 (14.8)</td>
<td>5.2 (9.6)</td>
</tr>
<tr>
<td>Standing on impaired lower limb (s)</td>
<td>0.20 (0.47)</td>
<td>0.08 (0.37)</td>
</tr>
<tr>
<td>Timed up and go test (s)</td>
<td>34.4 (18.3)</td>
<td>38.8 (14.3)</td>
</tr>
<tr>
<td>10 m walk (s)</td>
<td>28.6 (21.2)</td>
<td>30.1 (12.7)</td>
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<tr>
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<td>Control group</td>
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<tr>
<td>Timed up and go test (s)</td>
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<td>38.8 (14.3)</td>
</tr>
<tr>
<td>10 m walk (s)</td>
<td>30.1 (12.7)</td>
<td>30.1 (12.7)</td>
</tr>
</tbody>
</table>

Numerical variables are reported as mean (SD).
F, female; FIM, Functional Independence Measure; M, male; SD, standard deviation.
was really clinically important. However, in both the groups, their average theoretically allowed normal duration of the single support phase on the impaired lower limb.

At the end of the training, a significantly smaller number of patients in both the groups needed assistance of a physiotherapist or walking aids. Walking without assistance means greater independence as patients can walk when they are alone at home or can go to the toilet independently. Furthermore, walking without additional support means to have free hands to carry objects or perform other activities.

Despite the large improvement, there was still a high proportion of patients in the balance trainer group needing assistance at the end of the study. This is mainly because of the high percentage of patients initially needing assistance in that group. But it also seems that despite of considerable improvement in all the clinical tests, patients’ confidence during activities in a nonfall-safe environment was low. This shows that task-oriented exercises seem to be important, especially at the activity level. Further research is needed to determine the best type of task practice, and whether more sustained practice would lead to better results.

There are some limitations to this study, such as the rather heterogeneous group of stroke patients, short duration of treatment, and lack of long-term follow-up. Furthermore, our findings and conclusions are based on the population of stroke inpatients without severe cognitive deficits who cooperated well in the rehabilitation program. Generalizing the results must be considered cautiously. Further studies are needed to explore the long-term effects of this intervention on homogeneous subgroups of stroke survivors.

It can be concluded that both conventional balance training and training balance in the balance trainer equally improved balance in subacute stroke patients. The balance trainer cannot replace a physiotherapist but it is a safe and efficient supplementary method. Especially at the beginning of rehabilitation, the device can markedly reduce the extent of physical assistance required by the physiotherapist. Later in the rehabilitation program, the device can be used as a supplementary therapeutic method for balance training and also after discharge for training at home.

References