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CONTENTS

Wishes for the future of therapeutic exercise

R. GATTI

San Raffaele Scientific Institute, Milan, Italy

Over the years the therapeutic exercise has become rich of new proposals. To derive the exercises from physiology is still considered the best way to set a correct physiotherapy planning. This concept is rationale but its realization is not so easy. If that had been easy, the development of methods for analyzing the evidences to support therapeutic exercises would not have been necessary. On the contrary, it is even more common among physiotherapists to integrate clinical practice with the evidences arising from meta-analysis published in the scientific literature. Unfortunately, the results about the evidences supporting the therapeutic exercises are not often encouraging.

In this occasion, I do not want to discuss about the possibility that meta-analysis underrate the real efficacy of analyzed variable of physiotherapy discipline. The difficulties to develop randomized controlled trials in physiotherapy field are well described.[1]

Instead, I will try to underline some difficulties to connect correctly therapeutic exercise with its physiology rationale and I would like to express a wish for the future.

The first observation is that also a simple motor task is influenced by a lot of mechanical, neurophysiological, cognitive and psychological aspects. As a consequence, it is not always possible to derive therapeutic exercises from a single physiological variable but it is necessary to consider all the components involved in movement. Probably, the huge variability recorded in executing the same action results from the numerous components involved in motor task.

It is true that some neurophysiological discoveries allowed to propose therapeutic approaches in rehabilitation field. The studies by Knapp, Taubb *et al*.[2] about the theory of "learning nonuse" from experiments on monkeys which permitted to develop the constraint induced movement therapy are an example of this,[3] as the studies by Rizzolatti *et al*. about the mirror neuron system,[4] that allowed to propose the action observation treatment.[5] It is worth noting that: 1) same approaches do not produce same results in all patients; and 2) different approaches can produce same results.

Especially this last aspect has not been sufficiently considered. An overview of scientific literature in both musculoskeletal and neurologic physiotherapy allows to detect different approaches for the same clinical conditions and the comparison between these approaches do not affirm a clear superiority of one on the others. There are two ways for explaining this situation.

The first one is that the therapeutic exercise specificity does not exist. As a result, to derive the therapeutic exercise from physiological concepts is not necessary anymore. It is not important what movement to perform but the movement itself.

The second explanation is that specificity of therapeutic exercise and its connection with physiological concepts exists but this connection is not the one proposed by the authors. I mean that different approaches could share more similar physiological aspects than their authors believe. In this direction some techniques of manual therapy and osteopathy could be analyzed. Similarly, the effectiveness of different

approaches proposed for the back pain could be researched in their effects on the epidural circulation. Again, the effects of both the robotic approaches and the functional electrical stimulation in the motor relearning of subjects with central brain injuries could be connected with the repetitive task oriented exercises. Finally, the effectiveness of the somatosensory stimulation for the motor improvement of subjects after stroke could have physiological connection with the use of TENS for decreasing the spasticity of antagonist muscles.

These are only few examples but I want to underline a wish more than to create hypothesis.

My wish is that research in physiotherapy will begin to analyze the physiological common points among different physiotherapy approaches in order to understand if the specificity of therapeutic exercise exists and to give new elements for the development of novel therapeutic exercises.

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Efficacy of motor relearning approach on hand function in chronic stroke patients. A controlled randomized study

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ABSTRACT

Aim. Arm-hand performance problems are likely to occur after stroke. Major progress in neuroscience has resulted in novel concepts for rehabilitation interventions after stroke. Despite the growing number of studies showing evidence on task-oriented interventions its effect on hand function needs more investigation. The aim of the study was to investigate the effectiveness of motor relearning program on improving hand functions in chronic stroke patients.
Methods. This was a single blinded randomized controlled study design. Forty stroke patients were given 2 hours session three days per week for six weeks for the affected upper limb. Patients were randomly assigned into two equal groups. The Bobath treatment group (BT) was the control group that received treatment based on Bobath approach while the motor relearning group (MR) underwent the motor relearning program. In addition both groups received 30 minutes of electrical stimulation to wrist and finger extensors. Outcome measures used were Purdue Pegboard test score, hand grip strength, resting angle of ulnar deviation and wrist flexor spasticity.
Results. No pre-existing differences were found between groups on any demographic variables or outcome measures. A significant difference was found in favour of MR group only for hand grip strength and ulnar deviation after treatment.
Conclusion. Motor relearning program has substantial effect on improving hand grip strength and decreasing spasticity of ulnar deviation but not the fine hand functions or wrist flexor spasticity. *(It J Physiotherapy 2012;2:121-27)*

Key words: Stroke - Motor activity - Hand.

Stroke is the major cause of disability in adults.[1] If the upper limb is affected; only 5-20% of stroke patients will regain full arm and hand function,[2] leaving the majority with severe impairment or complete loss of function in the long term.[3-5]

Motor impairment is a frequent complication after stroke, and is an important contributory factor to a patient's ability to live independently.[6] It can be regarded as a loss or limitation of function in muscle control or movement.[7] Therefore, much of the focus of stroke rehabilitation is on the recovery of impaired movement and the associated function.[8] This emphasizes the need for valuable and effective treatment regimens focusing on hand function.

Different therapeutic approaches have been developed to enhance the functional recovery of patients after stroke. One approach is the motor relearning that was based on motor learning theory. Carr and Shepherd [9] proposed that training motor control requires anticipatory actions and ongoing practice. To further enhance relearning, the motor tasks involved are practised within a context that can be task or environment specific. Another common approach is the neurophysiological approach, which emphasizes facilitation and normalization of motor functions.[10] Pol-

lock *et al*.[11] carried out a systematic review on the effect of different physiotherapy approaches on disability in stroke patients. Four controlled studies used the motor relearning approach as the intervention.[12-15] The results of these studies showed improvement in the ability to balance during seated reaching activities;[12] a significant increase in gait velocity;[13, 14] patients tended to have a short hospital stay and high functional independence.[15] However, these studies did not provide detailed information on how task-oriented strategies were developed and used. The reviewers, however, indicated that this approach was found to be no more effective than other neurophysiological approaches. The authors stressed the need to further investigate the efficacy of this approach by conducting high-quality, randomized, controlled trials and refining the intervention techniques. This study is intended to address this need.

Both Bobath approach [14, 16, 17] and motor relearning program [12-13, 18, 19] have been studied separately or comparatively [14, 20] to evaluate their respective effectiveness. However, no study has been found comparing the two protocols exclusively for hand motor recovery. Hence the main objective of the study was to investigate the efficacy of motor relearning *versus* Bobath approach on motor recovery of hand function in a group of post-stroke patients.

Materials and methods

Fifty-three consecutive patients were recruited from the Neurology outpatient clinic, Kasr El-Aini hospital and assessed for eligibility. Forty patients met the inclusion criteria and approved to join the study. The inclusion criteria for participation in the study were as follows: 1) patients had to be between 40 and 60 years of age; 2) diagnosed as having suffered a first stroke; 3) time since stroke more than six months; 4) patients had to be able to follow simple instructions; 5) in stage 3 of Brunnstrom recovery stage of the hand;[21] and 6) Mini-Mental State Examination score ≥26. Patients with visual deficits, cerebellar lesions, painful shoulder, any contracture or deformity of the upper extremity or other neurological disorders other than stroke were excluded from the study. Figure 1 shows a flow diagram of patient participation.

Written informed consent was obtained from each patient before participation in the study. Patients were then randomly assigned by means of drawing lots (computer generated random numbers) into either control, *i.e.*, Bobath treatment group (BT) or the study, *i.e.*, motor relearning group (MR). The randomization process was carried out by a physiotherapist who was not involved in any part of the study (allocation concealment). All clinical assessments were conducted by a physiotherapist who was blind to the study.

Clinical protocols

In both groups, the patients received training for a total of six weeks in the form of three one hour and fifteen minutes sessions each week (18 sessions total). The researchers conducted the motor relearning program while another qualified physiotherapist with three years of experience with neurological patients conducted the conventional physiotherapy programme. The therapist responsible for the conventional therapy program was trained in the standardized procedure for conducting the control program. Both programs were conducted in the same treatment area.

Neuromuscular electrical stimulation program: The Phy-Action apparatus (787 - made in Netherlands) was used to apply electrical stimulation in both groups. The stimulation parameters were square-wave electrical pulses of 0.1 ms duration with a stimulus intensity ranges from 10-30 mA. To stimulate the extensor carpi radialis longus and brevis, extensor digitorum and extensors pollicis muscle two surface electrodes were used. One electrode was placed proximally over the forearm below the elbow, and the other was placed distally on the forearm (positioned for optimally balanced joint movement). The position of the electrodes was marked with a permanent marker for the duration of the treatment to guarantee the electrodes were placed consistently across stimulation sessions. Patients in both groups received the stimulation for 30 minutes. Electrical stimulation at the wrist in combination with other rehabilitation strategies can result in increased grip strength and improved motor function.[22]

Bobath Program

Retraining normal movement pattern was based on Bobath treatment principles. These patterns were facilitated through appropriate sensory and proprioceptive input; direct manual facilitation; key point control and visual and verbal feedback. Recruitment of arm activity in functional situations with various positions (*i.e.*, lying, sitting, standing and walking).[10, 23] Each patient received 45 minutes of Bobath program each session.

Motor relearning program

Patients were seated on an adjustable chair with back support and feet positioned flat on the floor. They were secured to the chair with two Velcro straps attached across their trunk. Participants then performed drinking task through grasping a cup, moving the cup toward the mouth, reaching down toward the table then releasing the cup on the table.

The intervention technique followed four sequential steps: identification of the missing performance components (step 1); training using remedial exercises (step 2); training using functional task components (step 3), and transfer of skills to functional task performance (step 4). Throughout the training session, the therapist stressed the importance of relating the training processes taking place in steps 2 and 3 to practices in step 4. The session lasted for 45 minutes.

Outcome measures

The following measures were assessed before the beginning of the program (within one week) and after the end of the six weeks program (within one week).

Primary outcome measurements

Grip strength of the affected hand was measured by Jamar Hand Dynamometer (Model No. 1528, USA) as the best of three measurements with a handheld dynamometer. Results were recorded as pounds. It was reported that Jamar dynamometer was reliable for measurement of hand grip strength.[24]

Fine manual dexterity was measured with the Purdue Pegboard test.[25] In this test, the subject has to pick up and place small metal pegs in small holes in a standardized board within a 30-s period. Results are calculated as number of pegs per 30 second. The Purdue Pegboard test proved to be a valid and a reliable tool to assess fine motor function.[26]

Secondary outcome measures

The resting angle of the wrist ulnar deviation was measured by electro-geniometer (if the posture of the wrist was in flexion, the wrist was passively extended to an angle of 0° and then allowed to return to the resting position before the resting posture was measured. the rational for using it is explained by: ulnar deviation of the wrist (due to dominance of flexor spasticity of the upper limb) interferes with the optimum position of the hand for functional activities. Variability and reliability of joint measurements have been reported.[27]

Muscle tone during passive extension of the wrist was assessed using the modified Ashworth scale. Reliability of the scale has been reported.[28]

Statistical analysis

Statistical analyses were completed using SPSS version 17.0 (SPSS, Inc., Chicago, IL, USA). Differences were determined by a χ^2 test for categorical variables and an independent samples t-test for continuous variables. All values are expressed as a mean ± standard deviation (SD). Student's *t*-test was used for evaluation of group differences regarding resting angle of wrist ulnar deviation, grip strength and fine manual dexterity. Non parametric testing (Mann-Whitney test) was used for the modified Ashworth scale. Level of significance was set at $P \leq 0.05$.

Results

Both groups were similar in terms of their baseline characteristics as presented in Table I.

As shown in Figures 2-5 both groups were similar as at base line ($P \geq 0.05$). A statistically significant difference was found for BT before

Table I.—*Demographic and clinical characteristics of study participants.*

	BT (N.=20)	MR (N.=20)	P
Sex			
Male n. (%)	13 (65)	11 (55)	0.7469[a]
Female n. (%)	7 (35)	9 (45)	
Age	49.45±2.892	50.7±2.618	0.1600 [b]
Side of lesion			
Lt. n. (%)	9 (45)	8 (40)	0.7491[a]
Rt. n. (%)	11 (55)	12 (60)	
Duration of illness (months)	7.95±1.146	8.6±1.536	0.1376 b
Type of stroke			
Ischemic n. (%)	18 (90)	17 (85)	0.6326[a]
Haemorrhagic n. (%)	2 (10)	3 (15)	0.7411 [a]
Dominant arm affected n. (%)	12 (60)	14 (70)	

[a]Significance determined by Chi-square test; [b]Significance determined by an independent sample t-test. BT: Bobath treatment group; MR: motor learning group. Values mean ±standard deviation.

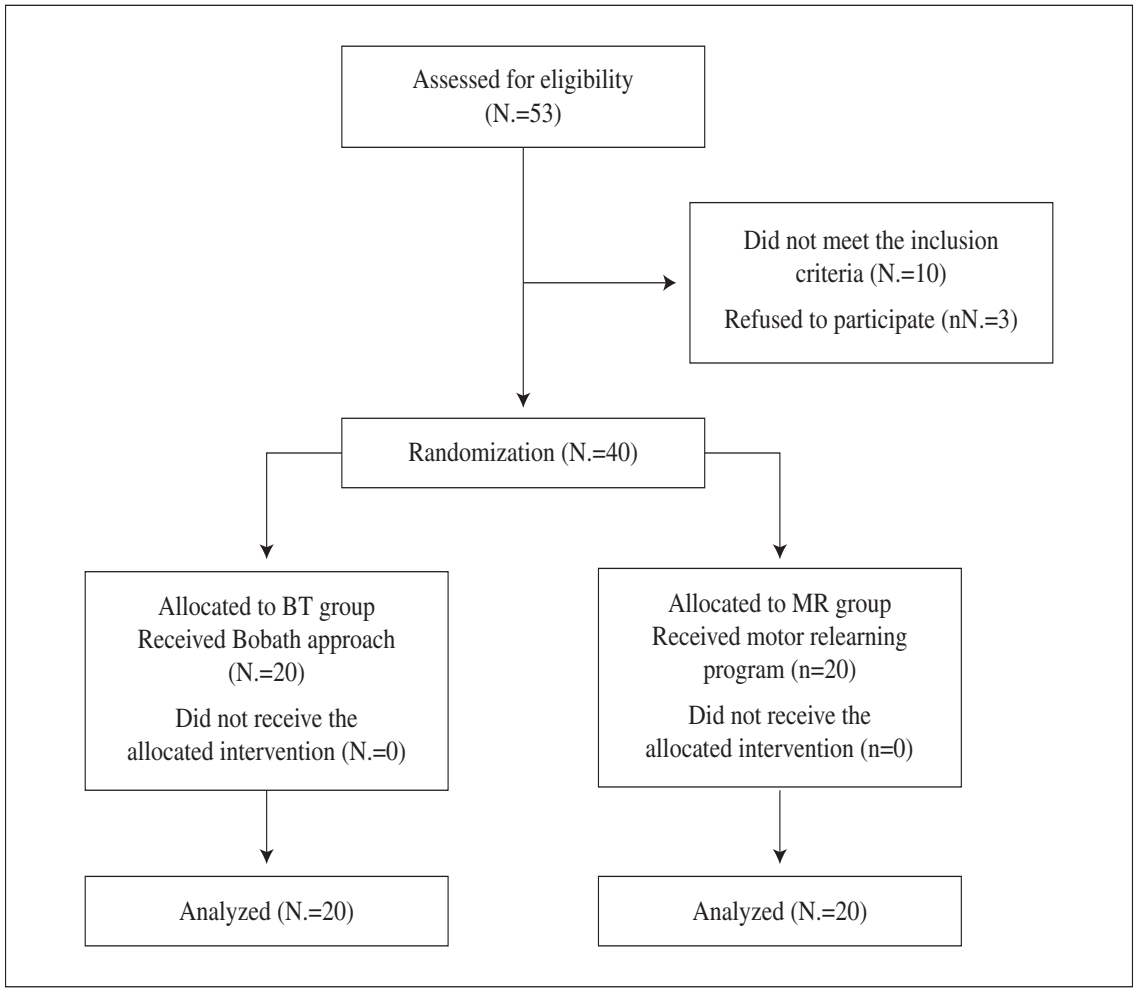

Figure 1.—Flow chart of the study.

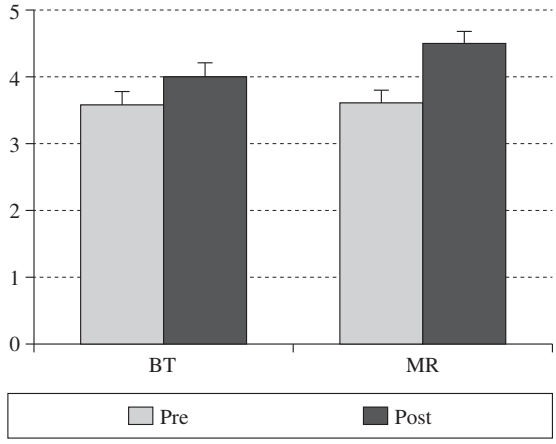

Figure 2.—Mean values of hand grip strength (pounds) pre- and post-treatment in Bobath treatment group (BT) and motor relearning group (MR).

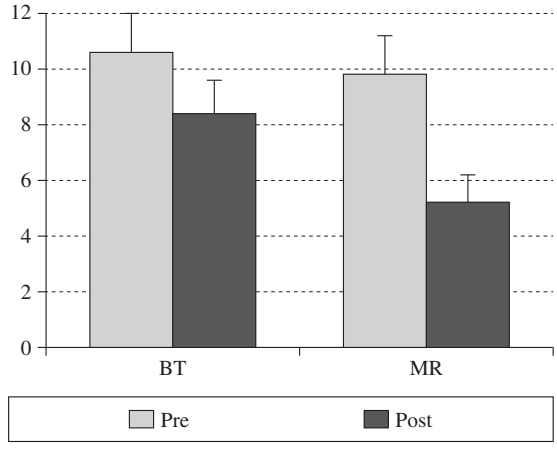

Figure 4.—Mean values of the resting angle of ulnar deviation (degrees) pre- and post-treatment in Bobath treatment group (BT) and motor relearning group (MR).

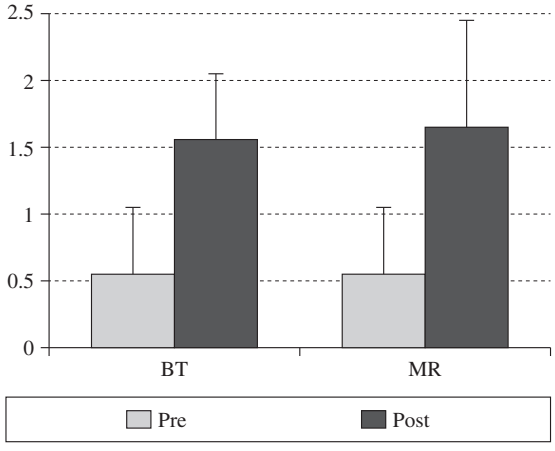

Figure 3.—Mean values of Purdue Pegboard test scores pre and post treatment in Bobath treatment group (BT) and motor relearning group (MR).

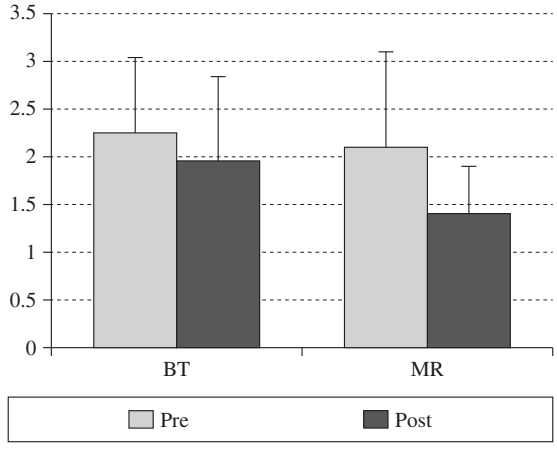

Figure 5.—Mean values of modified Ashworth scale sores pre- and post-treatment in Bobath treatment group (BT) and motor relearning group (MR).

and after treatment for hand grip strength, Purdue pegboard test score and the resting angle of ulnar deviation ($P<0.05$). On the other hand, no significant difference was found for the sores of modified Ashworth scale.

The mean values of hand grip strength, Purdue pegboard test, the resting angle of ulnar deviation and the modified Ashworth scale significantly differed after treatment for MR.

When comparing the mean values of hand grip strength and the resting angle of ulnar deviation after treatment between BT and MR a significant difference was found in favour of MR (P was 0.0001). No significant difference was found for Purdue pegboard test and modified Ashworth scale ($P>0.05$).

Discussion

The results of this study revealed that MR group in chronic stroke patients (more than six months) had more beneficial effect over BT group in terms of improvements in hand grip power and correction of the wrist posture that allowed better position for hand function (decreased resting angle of ulnar deviation). Alter-

natively fine dexterity of the hand improved in both groups with no significant differences between both treatment groups after treatment. As for modified Ashworth scale, a statistically significant difference was found for MR with no difference between the two groups after treatment.

The MR program used in this study did not have an effect on fine hand function when compared to BT group. This could be explained by that the functional movement trained, drinking task, did not involve training of sophisticated fine hand movements other than catch and release.

In an attempt to explain the valuable effects of MR several authors [29-31] claim that repetition of task specific training plays a major role in inducing and maintaining brain changes. However, repetition of a task in the absence of new meaningful skill learning is unlikely to induce cortical changes of significance. It was concluded that less intense (*e.g.*, 30-45 min), task-specific training regimens with the affected limb can produce cortical reorganization and associated meaningful functional improvements.

Likewise, Bayona *et al.*[32] stressed the importance of task-oriented therapy. The authors stated that the best way to relearn a given task is to train specifically for that task. Repetition alone, without usefulness or meaning in terms of function, is not enough to produce increased motor cortical representations.

In compliance with the result of this study, regarding the significant effect of MR program over BT approach in stroke patients; several studies supported the findings of this work. In a randomized clinical trial by Dean and Shepherd,[33] improvements in reaching; increased loading through the affected foot and increased leg muscular activity were recorded. Hesse *et al.*[34] noted that "task-specific therapy can enable hemiplegic patients to practice walking repetitively.

The MR did not appear to have a significant additional effect over BT on fine dexterity of the hand. A Cochrane review (Pollock *et al.*, 2007) [11] of four clinical trials of the MR suggested that the clinical effects of the MR did not vary significantly from other neurophysiological approaches. The findings of the review positively support the present study. However, the review considered the studies related to the lower extremities and posture only.

Likewise Van Vliet *et al.*[20] did not show that one approach was more effective than the other. The reason for these results could be that treatment was less intense. Also treatment began at a variable time within the first two weeks. Moreover, the motor relearning program was not stated in details; the intensity of treatment was too low; the duration of treatment was not standardized and the insufficient experience of the physiotherapist delivering the movement science based physiotherapy interventions as stated by authors.

Brock *et al.*[35] investigated the efficacy of interventions based on the Bobath concept in conjunction with task practice, compared to task practice alone. The study did not show a significant difference between groups for walking ability or balance.

The study done by Higgins *et al.*[18] agreed with the current study in that task-oriented intervention did not improve manual dexterity of the affected hand. On the other hand, voluntary movement did not improve. This contradiction between the results of this study and the current study could be explained by the following. First, the authors did not select patients based on their arm function at baseline and thus subjects with a wide range of arm dysfunction were included and second, it was difficult to challenge and motivate patients for whom no active movement of the affected arm was present.

One limitation of this study was that the outcome measures were recorded within one week. This was because of national holidays.

Conclusions

The MR intervention can be used to increase the power of hand grip strength and correction of the ulnar deviation of the wrist (due to flexor synergy of the upper limb) that interferers with the normal functional position of the hand.

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ORIGINAL ARTICLE

On the readiness of physical therapists to blow the whistle to protect the patient's interests

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ABSTRACT

Aim. This article presents a study of physical therapists' readiness to take action to stop misconduct in the workplace in order to protect a patient's interest.

Methods. The study distinguishes between an individual's reporting of the misconduct to authorities within an organization and/or to those outside of it. It also distinguishes between a colleague's wrongdoing and that of management.

Results. The findings of the study indicate that the participating physical therapists considered acts that are detrimental to the patient to be very serious. In problematic situations such as these, they reported a readiness to act, both internally and externally, in order to stop the misconduct.

Conclusion. The physical therapists also said they were more willing to take action when the offending individual was a colleague. *(It J Physiotherapy 2012;2:128-34)*

Key words: Whistleblowing - Ethics - Patient advocacy.

To "blow the whistle" on harmful actions performed by individuals in the workplace is a difficult dilemma, since the potential whistleblower must choose between the public good and loyalty to a colleague or a manager. Whistleblowing is also complex given the question of power involved in the act, which can affect the whistleblower. Although there are some cases where employers have rewarded whistleblowers for their efforts, the typical response is harassment and mistreatment.[1, 2]

In the healthcare professions the dilemma becomes even more complex because the damaged party is a patient. If a physician, a nurse, or other healthcare worker decides to do nothing to stop a colleague's or management's harmful conduct, he or she may be violating his or her basic professional commitment to promote and protect patients' health and welfare.

Whistleblowing has been identified as being especially important to the profession of physical therapy. Both the Guccione study of 1980, which surveyed 450 members of the American Association of Physical Therapists (APTA) in New England, and Triezenber's of 1996, which relied on the Delphi technique of a panel of experts, pointed to the duty of physiotherapists to report colleagues' misconduct. Both researches regard such duty as one of the key ethical and professional issues facing the profession for many years to come.[3, 4] But despite the topic's importance, there has only been one study since John D. Banja examined situations where whistleblowing was needed in the profession as well as the benefits and liabilities of taking such action.[5] This more recent study examined the willingness of physical therapy students to blow the whistle.[6]

The lack of research into this issue does not stem from the absence of abuses that might war-

rant reporting. Physiotherapists, like employees in any other field, must, at times, face ethical-professional dilemmas in which they are required to choose between the public's best interest and their loyalty to their professional colleagues or to their employer. It is thus important to know what physiotherapists actually-or are prepared to-do when confronted by the harm a patient is suffering due to the misconduct or negligence of a colleague or healthcare institution.

The goal of this study was to begin answering these questions. To that end, we designed it according to three main parameters. Firstly, we wanted to know if physical therapists were willing to take action to stop misconduct in the workplace in order to protect a patient's interest and how strong their willingness was. Secondly, we wondered to whom physical therapists would be willing to report the misconduct, to authorities within the organization and/or to an external authority with the power to intervene and stop the wrongdoing. Finally, it was important to examine whether there were differences in a physical therapist's readiness to disclose wrongdoing if the misconduct and harm stemmed from a colleague or from management.

Materials and methods

Study design and participants

A total of 101 certified physiotherapists working in hospitals and rehabilitation centers in the south and central regions of Israel were recruited for this study. Inclusion criteria were: being a certified physical therapist, having at least one year of professional experience, and being able to read and understand a questionnaire in the Hebrew language.

The questionnaires were administered at the workplace by an experienced research assistant. The distribution and presentation of the questionnaire were identical for all respondents. All prospective participants were informed that the questionnaire was a part of a survey on ethics, that the gathered data would be used for research purposes only, and that participation was voluntary and anonymous. The administration of the questionnaire lasted for about 15 minutes. The study was approved by the local ethics committee.

Instrument

The questionnaire was comprised of multiple choice questions regarding socio-demographic details and two vignettes (case stories) describing ethical dilemmas that were likely to arise in the workplace. The socio-demographic section collected information about age, gender, place of birth, marital status, level of religiosity, and years of professional experience (Table I).

The case stories were first presented to five physiotherapists to receive their preliminary input. Their responses were then used to finalize the questionnaire. The questionnaire presented two vignettes describing situations in

Table I.—*Participants' sociodemographic characteristics and professional experience (N.=101).*

Variable	N. (%) Mean	SD
Age (in years) (range 26-61)	39.12	8.73
Gender		
Women	67 (66.3)	
Men	34 (33.7)	
Place of Birth		
Israel	73 (77.3)	
Other	28 (27.7)	
Marital status		
Married	75 (74.3)	
Other (single, divorced)	26 (25.7)	
Religiosity		
Secular	78 (77.2)	
Conservative and orthodox	23 (22.8)	
Professional experience (in years) (range 1-35)	11.39	8.70

which physiotherapists were required to make a decision that involved whistleblowing. One vignette described an ethical dilemma in which the physical therapist had to choose between responsibility to a patient and loyalty to a colleague. The other vignette presented a dilemma in which the physiotherapists had to choose between responsibility to a patient and loyalty to management.

The case stories were designed to replicate specific characteristics seen in acts of whistleblowing, as well as to mark the internal/external divide. Each case story contained six questions: Question 1 asked the respondent to rate the severity of the misconduct, Question 2 referred to the physical therapist's readiness to take action to change the situation, Questions 3 and 4 dealt with internal whistleblowing, and Questions 5 and 6 with external whistleblowing. In order to examine the differences between the two types of whistleblowing, Questions 3 and 4 were summed into one index, which represented internal whistleblowing, and Questions 5 and 6 into another index representing external whistleblowing. All the questions were rated on a five-point Likert type scale. This scale is the most widely used rating scale, and the most adequate to our study since it uses fixed choice response formats are designed to measure attitudes or opinions.[7] The responses to the first question in our questionnaire were "not serious at all," "not serious," "undecided," "serious," and "very serious" while the answers to the other questions were "not likely at all," "not likely," "undecided," "likely," and "very likely."

Case stories

Dilemma 1

Protecting the patient's interests vs. being loyal to a colleague. You are a physical therapist in a rehabilitation center. Hana, a colleague of yours, is teaching an elderly patient after hip surgery how to climb stairs on crutches. While you watch them, Hana leaves the patient for a moment to answer the telephone and unfortunately the patient falls. Hana quickly goes to the patient, helps him to stand up, and leads him to his bed. Contrary to regulations, Hana does not report this incident, but makes sure that the patient is fully conscious and feels good. You know that Hana's behavior violates the regulations and could harm the patient.

1. How serious do you consider your colleague's behavior?

2. How likely is it that you will take actions to change the situation?

3. How likely is that you will talk to your colleague and try to persuade her to report the incident to her superiors?

4. If you decide not to talk to your colleague, or if you have talked to her about the matter and not succeeded in getting her to report the incident, how likely is it that you will go to someone at the center who has the power to intervene, such as the head of the physical therapy ward or the ethics committee, if there is one at the rehabilitation center?

5. If you decide not to approach anyone at the center, or if you do talk to someone and he or she does nothing to intervene, how likely is it that you will turn to the Physical Therapists' Association, an external body?

6. If you decide not to talk to the Physical Therapists' Association, or if you do talk to them and they do nothing, how likely is it that you will report the matter to the media?

Dilemma 2

Protecting the patient's interests vs. being loyal to management. You are a physical therapist in a municipally run center for victims of violence. It has recently come to your attention that the director of the physical therapy section intends to use money budgeted for buying modern physical therapy equipment to buy luxury fittings for her own office. You have sufficient knowledge that the director's decision was not approved by the appropriate authority and that the lack of the equipment will significantly delay the recovery of those who are cared for by the center.

1. How serious do you rate the director's behavior?

2. How likely is it that you will take action to change the situation?

3. How likely is it that you will try to persuade

the director not to use the money for her own office, but to purchase the needed equipment?

4. If you decide not to talk to the director, or if you have talked to her and not been able to change her mind, how likely is it that you will report the director's intentions to someone at the center who has the power to intervene, such as the center's general director or the ethics committee, if there is one at the center?

5. If you do not refer the matter to an authority at the center, or if you do and he or she does not intervene in the section's director decision, how likely is it that you will turn to the Physical Therapists' Association, an external authority?

6. If you decide not to report the matter to the Physical Therapists' Association, or if you do talk to them and they do nothing, how likely is it that you will report the matter to the media?

Statistical analysis

Descriptive data are presented. Group differences were assessed using t-test, associations between variables were examined by Pearson's correlation coefficient, and internal reliability was assessed using Chronbach's alpha. Significant level for all statistical analyses was set at $P<0.05$. All analyses were performed using SPSS version 17.

Results

The internal reliability of the questionnaire on dilemma 1 was high ($\alpha=0.80$). The correlations for the two questions measuring internal whistleblowing and for the two questions measuring external whistleblowing were ($r=0.57$, $r=0.61$), respectively. The internal reliability of the questionnaire on dilemma 2 was also high ($\alpha=0.83$). The correlations for the two questions measuring internal whistleblowing and for the two questions measuring external whistleblowing were ($r=0.62$, $r=0.68$), respectively. These high correlations in the questionnaires on both dilemmas suggest that each of the two questions representing the internal and external whistleblowing indices in each of them are conceptually the same.

The respondents' mean age was thirty-nine years. Sixty-seven (66.3%) were women and 75 (74.3%) were married. Seventy-three (72.2%) were born in Israel and seventy-eight (77.3%) identified themselves as secular Jews. The mean years of professional experience was 11.4 (Table I).

A comparison between the mean scores of the severity of the misconduct, readiness to take action to change the situation and the indices of internal and external whistleblowing for the two vignettes is presented in Table II.

The respondents rated the professional misconduct in both vignettes as "very high" on the scale's possible range.[1-5] No statistically significant difference was found between the two scores. The participants' also gave relatively high scores to their own willingness/readiness to take action to change the situation for both vignettes, with that for the colleague's misconduct being significantly higher than that for the director's misconduct. Concerning the whistleblowing indices, no statistically significant difference was found between the two vignettes for the internal index. However, the score for the director's misconduct was significantly higher than that for the colleague's misconduct on the external index.

Table II.—*A comparison between the respondents' scores for the two vignettes regarding the study variables*

	Possible range	Vignette 1 Colleague misconduct N.=101		Vignette 2 Director misconduct N.=101		t	P
		Mean	SD	Mean	SD		
Severity of the misconduct	1-5	4.76	0.57	4.84	0.42	1.13	0.26
Readiness to act to change the situation	1-5	4.36	0.79	4.09	1.03	-2.21	0.03
Internal whistleblowing	2-10	7.85	1.81	7.55	1.98	-1.19	0.24
External whistleblowing	2-10	3.52	1.66	5.23	2.24	7.65	0.001

Table III.—*A comparison between the indices of internal and external whistleblowing for the two vignettes.*

	Possible range	Internal whistleblowing (N.=101)		External whistleblowing (N.=101)		t	P
		Mean	SD	Mean	SD		
Vignette 1 colleague misconduct	2-10	7.85	1.81	3.52	1.66	23.24	0.001
Vignette 2 director misconduct	2-10	7.55	1.98	5.23	2.24	10.76	0.001

A comparison between the mean scores of the internal and external whistleblowing indices in the two vignettes are presented in Table III. For both, the mean score of the internal index was found to be significantly higher than the mean score of the external index. In other words, the respondents reported that they were much more likely to approach parties within the organization than those external to it in both scenarios.

No significant differences were found between the two whistleblowing indices and the respondents' gender, place of birth, marital status, and level of religiosity for both vignettes. Positive and significant correlations were found between the internal and external whistleblowing indices and years of professional experience for the ethical dilemma posed by the colleague ($r=0.31$, $P<0.01$; $r=0.22$, $P<0.05$, respectively). No significant correlations were found between the internal and external whistleblowing indices and professional experience ($r=0.18$, NS; $r=0.15$, NS, respectively) for the ethical dilemma posed by the director.

Discussion and conclusions

The findings of the study indicate that the participating physiotherapists considered acts that are detrimental to the patient to be very serious. In problematic situations such as these, they reported a readiness to act, both internally and externally in order to stop the misconduct. The physiotherapists also reported a greater readiness to act when the offending individual was a colleague.

The findings also reveal that, in both scenarios, the physiotherapists were more willing to blow the whistle internally rather than externally. They reported a greater readiness to blow the whistle externally for the director's misconduct, however, than for the colleague's.

Among the many cases of whistleblowing discussed in the literature, we can see that whistleblowers seem to follow a distinct pattern. Usually, they first report the case to their superiors, and it is only after the internal disclosure has failed to put a stop to the wrongdoing that they sometimes decide to disclose the behavior to an external authority.[8] In fact, most scholars agree that this procedure is the most prudent for would-be whistleblowers, for both strategic and ethical reasons.[9] Firstly, it allows employees to remain loyal to the organization even as they try to put a stop to its harmful activities. Secondly, it proves that they are free of ulterior motives and provides them with the moral justification for taking their case to an external authority, if necessary.

The answers of the physiotherapists in our study followed this same pattern. The participants' desire to correct a colleague's or superior's misconduct was coupled with a progressive retraction as the circle of disclosure widened. There may be several reasons for this retraction. It may reflect the respondents' concerns that external exposure could have negative consequences, not only for the wrong-doer, but also for the healthcare organization and for the individuals who receive its services. It may also reflect the respondents' awareness of the increasingly serious nature of each level of protest, with their believing external disclosure to hold more risks than internal disclosure. Case studies in the literature, including those in other health and care professions, clearly indicate that the price paid by the whistleblower gets higher when the misconduct is reported externally.[10]

The main limitation of this study is that the findings reflect the study participants' self-expec-

tations of how likely they would be to report the depicted misconduct, rather than their actual reporting patterns. Their self-assessment does not necessarily indicate what the respondents would actually do if they encountered the unethical behavior described in the vignettes. The relevant literature presents two opposing views on this question. Some studies have found that what people say they might do actually reflects what they have done in the past when encountering similar cases,[11] while other studies repeatedly point to the large discrepancies that exist between an individual's attitudes and his or her actual behavior.[12] There is no reason why the respondents who said they were unlikely to report misconduct, either internally or externally, will not be sufficiently disgusted with it to do so, or that those who said they were ready to report it will not do so.

This pioneer study was designed as an initial step in examining physiotherapists' readiness to report workplace wrongdoing. Its findings represent a starting point as well an opportunity for future studies. One of the objectives of such studies would be to corroborate whether the principle of the patient's best interest is not pursued to the utmost when it is a senior manager or colleague who is involved in the improper and harmful conduct. If that is indeed the case, then the reasons for this need to be analyzed. As the present study showed, there is a progressive retraction in an individual's willingness to blow the whistle as the circle of disclosure widens. Is fear of the possible consequences one of the reasons? The study also indicated that the retraction is greater in the case of the colleague than of the manager. Further studies could examine if this contention is true and, if yes, how an individual's socialization within the profession relates to and influences it.

Purtilo, Guccione, and others have noted that the increase in physiotherapists' clinical autonomy has also brought more complex ethical dilemmas with it.[3, 13-15] Whistleblowing is certainly one of these. One of the objectives of future studies would be to develop pedagogical and practical tools that might help physiotherapists to handle similar situations in their practice. At the pedagogical level it would be important to find out how to best integrate the subject of whistleblowing into the physical therapy curriculum. We recommend that, in addition to studying the ethical aspects of reporting wrongdoing, researchers and practitioners also consider whistleblowing as a tool for advocacy and social intervention, as is done in other health professions.[16] At the practical level we recommend that physiotherapists should receive information through such channels as their professional association, both with regards to the existing legislation protecting whistleblowers in their country and on the governmental and/or non-governmental organizations established to advise and support potential whistleblowers, thereby making it safer to take action to stop workplace wrongdoing.

Finally, the question of how to blow the whistle is no less important than that of whether to blow it or not. Many organizations have created internal channels for reporting misconduct, and our recommendation is to use them when necessary. Such avenues have the great advantage of avoiding the damage that public exposure might bring, to the institution and to the whistleblower him/herself. At the same the time, they help strengthen an individual's professional ethics and values.

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The reliability of neck positioning during the premanipulative hold

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ABSTRACT

Aim. Cervical spinal manipulation is frequently used in the treatment of people with neck problems. To study the effectiveness of certain techniques as well as the validity of specific neck positions, it is necessary for these positions or techniques to be reproducible. The repeatability of high velocity thrust techniques and premanipulative neck positioning has not yet been studied. The aim of this work was to determine the intra- and inter-examiner reliability of the premanipulative hold at the cervical spine.

Methods. Sixteen healthy adults without neck complaints, ages 18 to 41 years, were included. Two experienced manual therapists performed the premanipulative hold at levels C1-C2, C3-C4, and C5-C6 without performing the high velocity thrust. This position was registered by an electromagnetic tracking device, and the kinematics were analyzed afterwards using the method of Cardan angles. The reliability was investigated in a test-retest situation using intraclass correlation coefficients (ICCs).

Results. The ICCs for intraexaminer reliability ranged from 0.728 to 0.998 with small confidence intervals. The ICCs for interexaminer reliability varied from 0.660 to 0.978 and showed generally larger confidence intervals.

Conclusion. The findings indicate that experienced manual therapists can reposition a patient in the exact manipulative position after a pause. *(It J Physiotherapy 2012;2:135-41)*

Key words: Manipulation, osteopathic - Manipulation, spinal - Cervical vertebrae.

Because of the importance of evidence-based practice, spinal manipulative therapy has to be assessed in terms of effectiveness as well as possible adverse events. Efficacy studies require that the specific techniques used are reproducible. A search of the Cochrane, PubMed, and Web of Science databases identified no studies on the reliability of spinal manipulation or high velocity thrust technique.

The reliability of positioning and repositioning the neck in a specific well-defined position has not been studied either. The reliability of repositioning is important when screening patients for adverse events because the premanipulative hold is one of the tests in the screening protocol recommended to manual therapists.[1]

The purpose of this pilot study was to investigate the intra- and inter-examiner reliability of the pre-manipulative position (PMP) hold in a quantitative way and at three different cervical motion segments. Because of medico-ethical issues, the premanipulative hold was studied without analyzing the kinematics of the high velocity thrust itself.

Materials and methods

Choice of the registration device

Electromagnetic trackers were chosen for the three-dimensional (3D) registration of positions and orientations during global, also called regional, cervical movements. At present, dynamic 3D registration of segmental spinal kinematics *in vivo* remains unfeasible.[2]

The electromagnetic tracking device used in this study is the Polhemus Liberty (Polhemus, Colchester, VT, USA), an alternating current device with an optional diode warning for interference of the registration from ferromagnetic objects. According to the technical description by the manufacturer, the Polhemus Liberty has a static position accuracy of 0.8 mm and a static orientation accuracy of 0.15°.

Participants

Based on an acceptable pretesting power analysis of 0.80, and an estimated difference between registrations of 3° on each axis the minimal sample size was estimated at 10 people. Accounting for dropouts, measurement errors, practical issues, and the knowledge that power increases with sample size, we decided to include 16 participants.[3]

Participants were randomly chosen among healthy students and employees from the medical faculty at the Free University of Brussels; the final group consisted of 8 women (ages 18 to 41 years) and 8 men (ages 23 to 41 years). A preliminary training took place with four participants not included in the study. All volunteers were orally informed about the study and the possible risks of participating, and all signed an informed consent after the explanation. At the same time, each person completed a questionnaire regarding contraindications for cervical manipulative therapy. When no contraindications were reported, the participant was included. Ethics committee approval was obtained from the Academic Hospital of the Free University of Brussels.

Test-retest order

Participants were tested in the order of arrival. Test and retest were performed by both examiners consecutively in a preset order.

For the test, examiner 1 positioned the neck of each participant in the PMP at C1-C2, then C2-C3, and then C5-C6. This process was followed directly by examiner 2 doing the same positioning in the same order. For the retest, examiner 1 started at C5-C6 and ended at C1-C2, followed by examiner 2 performing the same process. The next participant was then positioned by examiner 2, followed by examiner 1 so that examiner order was reversed with alternating participants. This design was intended to minimize reminder and systematic influences from repeated testing.

Procedure

Electromagnetic interference was checked based on the device controls. Examiners 1 and 2 selected their individual desired table heights at 77 cm and 69 cm, respectively, measured from ground to surface of the treatment table. Both examiners are trained at the master of science level and highly experienced in manual therapy (respectively 20 and 15 years of clinical experience). As noted, they performed a preliminary training with four participants not included in the study.

Each participant was positioned supine on the table. One sensor was placed on the forehead at the midline of the junction between the os nasale and os frontale and fixed with Velcro strips. The second sensor was fixed at the angulus sterni with double-sided tape (Figure 1). The transmitter was placed next to the headpiece of the treatment table.

As described in the previous section, each examiner successively positioned the three motion segments C1-C2, C3-C4, and C5-C6 in the PMP. At each level, the premanipulative positioning was performed as for a supine high velocity thrust traction manipulation with the head in contralateral right rotation. Thus, the participant was supine with the head rotated to the right and with lateral flexion to the left side, as described by Van der El *et al*.[4] Each premanipulative positioning procedure was registered using the electromagnetic tracking system (Figure 1).

Statistical analysis

In this study, the 3D changes in the positions and orientations of the two sensors were recalculated as rotations around the three axes of the transmitters' reference frames. The calculation was done using a mathematical routine written in Mathcad using the ZXY Cardan convention.

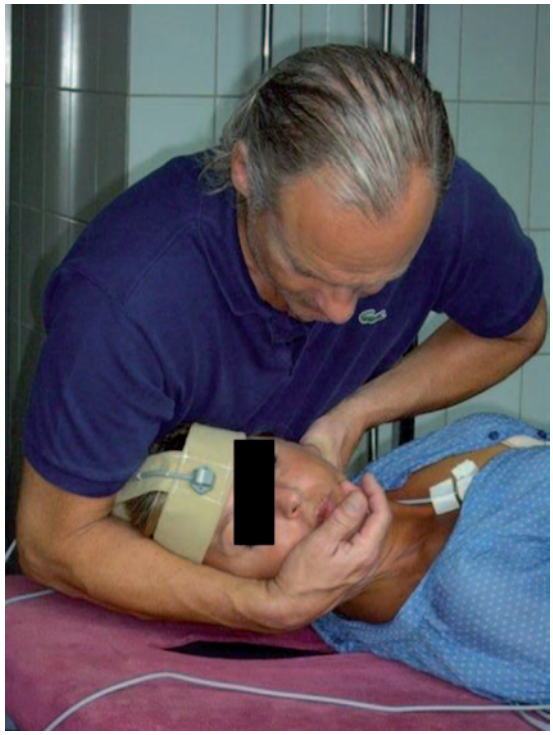

Figure 1.—Experimental situation: premanipulative hold at C1-C2.

The axes were positioned according to the ISB convention (Z: right, Y: up, X: front).[5] Positions and orientations were registered at 240 Hz. The data from the complete procedure were introduced into a Mathcad routine and graphically represented (Figure 2). The premanipulative hold was defined as the stable position around the three axes. With the use of the mathcad tracer function, the exact position of the premanipulative hold on the curves could be selected, and the rotations around each of the three axes were read. These rotations around the three axes were analyzed for reliability.

Statistical analyses were performed using SPSS 17 software (SPSS Inc., Chicago, IL, USA). The intra- and inter-examiner reliability was investigated using intra-class correlation coefficients (ICCs). The ICC is the most appropriate method to investigate reliability in repeated measures of one variable and can be used to asses either intra- or inter-examiner reliability. The ICC may vary between 0 and 1, with 1 indicating perfect reliability.[3, 6, 7]

A two-way random model, type absolute

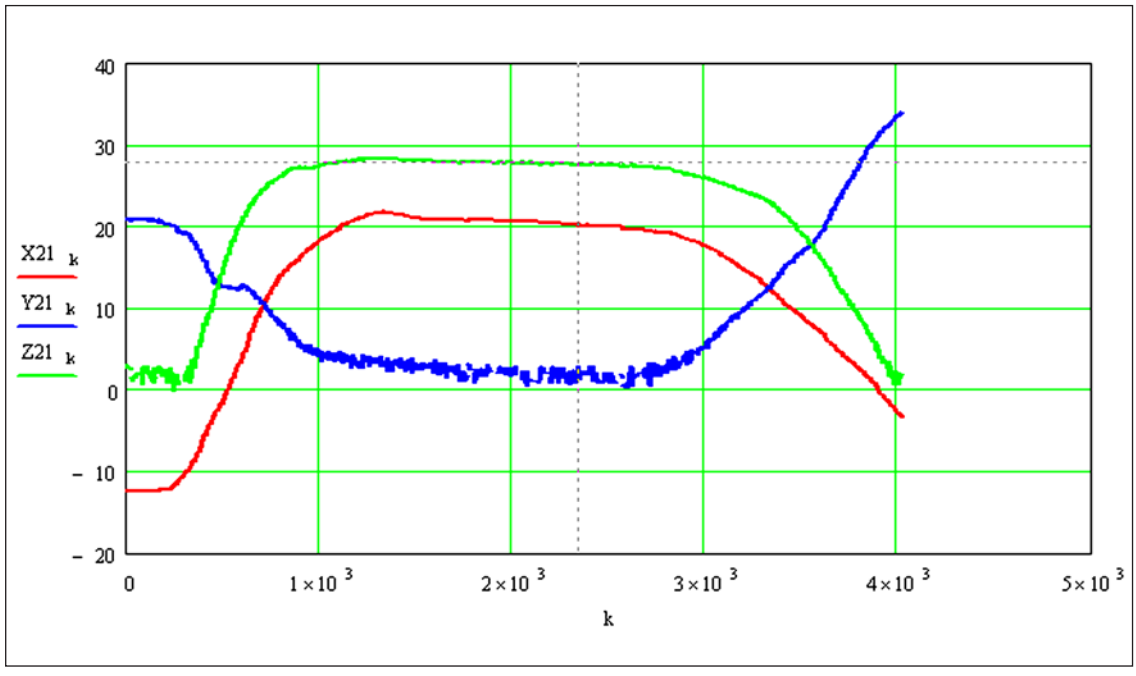

Figure 2.—Curves of rotations around 3 axes of 1 complete movement (each curve is 1 rotation around 1 axis). Rotations around X, Y, Z-axis respectively, horizontal: timeline, vertical: degrees of rotation.

Table I.—*Intraexaminer reliability for premanipulative testing (ICC-values).*

ICC (CI)	C1-2 R1	R2	C3-4 R1	R2	C5-6 R1	R2
X	0.872**	0.879**	0.925**	0.910**	0.768**	0.952**
	0.677-0.95	0.673-0.958	0.802-0.971	0.783-0.964	0.498-0.902	0.885-0.981
Y	0.608**	0.895**	0.895**	0.934**	0.728**	0.950**
	0.200-0.840	0.716-0.963	0.757-0.957	0.801-0.976	0.427-0.883	0.872-0.980
Z	0.195 ns	0.370 ns	0.841**	0.998**	0.880**	0.996**
	-0.307-0.616	0.157-0.733	0.646-0.934	0.994-0.999	0.723-0.951	0.991-0.999

Test-retest results (ICCx) and confidence intervals (CI) R1:examiner1/ R2:examiner2/ CI: 95% confidence interval/ *:significant at 0.05 level/**:significant at 0.01 level/ns: not significant.

Table II.—*Inter-examiner reliability for pre-manipulative testing (ICC-values).*

	C1-2	95%CI	C3-4	95%CI	C5-6	95%CI
TX	0.576**	-0.071-0.889	0.692**	-0.225-0.913	0.660**	0.162-0.864
TY	0.581**	-0.215-0.860	0.731**	-0.213-0.927	0.710**	-0.172-0.911
TZ	0.751**	-0.017-0.925	0.865**	0.561-0.952	0.910**	0.652-0.969
RX	0.429**	-0.151-0.810	0.761**	-0.196-0.940	0.839**	-0.022-0.956
RY	0.478**	-0.194-0.835	0.735**	-0.213-0.929	0.719**	-0.115-0.911
RZ	0.391**	-0.112-0.790	0.978**	0.046-0.996	0.966**	0.235-0.993

TX.Y.Z: test movement around X.Y.Z-axis/RX.Y.Z: retest X.Y.Z-axis/95%CI: 95% confidence interval/*: significant at 0.05/**: significant at 0.01/ ns: not significant.

agreement, was selected to compare the data. Single measures were used for intraexaminer reliability and average measures for interexaminer reliability.[8] The values of the ICC for the intraexaminer reliability were interpreted as >0.85 indicating "good", 0.65< to <0.85 indicating "fair", and <0.65 indicating "poor". The interexaminer reliability was scored at 5% less severe, as done in earlier research by De Jong *et al*.[9]

Each examiner positioned the cervical spine in the PMP at three different spinal levels in each of the 16 participants and performed each technique two times (test and retest). This resulted in 96 registrations.

Results

The 3D data were analyzed according to each axis separately for a total of 18 ICCs for intra-examiner reliability and 18 ICCs for interexaminer reliability for comparison. Tables I, II show the ICC values and their 95% confidence intervals.

ICCs for intraexaminer comparisons ranged from 0.728 to 0.998 depending on the motion component and spinal level and could be rated as "fair" to "good" for both examiners. One exception (ICC=0.608) was observed for examiner 1, involving the Y-axis motion component during the positioning at level C1-C2 (Table I). The ICCs of the Z-axis motion component at the level C1-C2 were not significant. The SEM showed high estimates of error for motion components around the Z-axis, especially for examiner 1 (Table III).

ICCs for interexaminer comparison ranged from 0.660 to 0.978 and could be rated as "fair" to "good" for each motion component at spinal levels C3-C4 and C5-C6. The analysis showed lower reproducibility rated "poor" to "good" at the level of C1-C2 with ICC values ranging from 0.391 to 0.751 (Table II). The SEM showed higher estimates of error for nearly all movements than at the intraexaminer comparison (Table IV).

Discussion

Because the reliability of the cervical pre-manipulative hold had not previously been investigated, a pilot study was set-up. The fact that an

Table III.—*SEM for intraexaminer reliability for premanipulative testing.*

SEM	C1-2 R1	R2	C3-4 R1	R2	C5-6 R1	R2
X	16.63	12.43	15.48	16.83	33.11	11.97
Y	29.34	13.84	19.66	13.54	33.15	12.75
Z	127.48	67.7	124.58	13.09	106.47	25.85

Test-retest standard error of measurement results (SEM). R1: examiner1/R2: examiner2.

Table IV.—*SEM for interexaminer reliability of premanipulative testing.*

	C1-2	C3-4	C5-6
TX	32.93	26.36	30.88
TY	80.97	133.1	105.43
TZ	21.35	21.88	20.81
RX	21.09	23.98	31.02
RY	20.88	18.5	40.55
RZ	32.93	26.36	30.88

TX,Y,Z: test movement around X,Y,Z-axis/RX,Y,Z: retest X,Y,Z-axis.

experienced manual therapist can reposition the cervical spine and that this position to a great extent approaches that taken by a fellow manual therapist could be useful in future effect studies. The present results allow for a cautious positive judgment about the reliability and some important conclusions.

Although the risk of serious adverse events is low, manual therapists are advised to use pre-manipulative tests to preventatively screen for complications at the cervical spine.[1, 10-13] To date, these tests have not been investigated for their validity, although a single qualitative reliability study of pre-manipulative tests showed good interexaminer reliability.[14] However, the correlation between a positive premanipulative test and a stroke after cervical manipulation is estimated to be low because of the low sensitivity and specificity of the premanipulative tests.[15] A recent study by Herzog *et al.*[16] suggested that moments applied during HVT may be too small to cause damage to the structures of the neck amongst which the arteria vertebralis is considered the most vulnerable.

Arnold *et al.*[17] demonstrated that among all pre-manipulative screening tests, the rotation and pre-manipulative hold may be the only useful screening procedures to identify individuals at risk for vertebrobasilar insufficiency (VBI) resulting from inadequate collateral blood flow. Kerry *et al.*[18] noted the lack of construct validity when testing on blood flow. One could conclude that of all pre-manipulative tests to screen for VBI, the pre-manipulative hold should be the first investigated for validity and should be reproducible at the start. This is the reason for selecting a rotational premanipulative hold in the present study.

In this light, this study of reliability can be seen as a first step in the validation process of PMP testing. Extrapolation of the results to a population of experienced manual therapists is reasonable. Both examiners are manual therapists with similar educational backgrounds: physical therapists with a professional master's in manual therapy from the Stichting Opleiding Manuele Therapie – the Netherlands (S.O.M.T.) and a master of science degree in manual therapy from the Vrije Universiteit Brussel - Belgium. They are also highly experienced in spinal manipulation, with respectively 20 and 15 years of clinical experience. Both practiced the manual and registration procedures in a training session on four participants.

Confidence intervals can have important additional value when interpreting ICCs. 95% confidence intervals were generally smaller for the intra-examiner compared to interexaminer comparison, meaning that the observed ICC should approximate the true ICC. The 95% confidence intervals for the ICCs of the interexaminer reliability were large, meaning that these ICC values must be interpreted with caution. The SEM showed also higher estimates of error for the inter-examiner reliability. The results support the generally tendency towards higher levels of intra-examiner reliability in manual therapy techniques. Acceptable levels of reliability are determinant for further validity studies.

Higher levels of intraobserver reliability indicate that therapist should be careful to rely on the indications of fellow therapist before deciding to apply specific procedures, as differences between therapist in performance may be present.

This study investigated the reliability of end-positions around the axes of a 3D anatomical reference frame and therefore indirectly offers a reasonable basis for extrapolating the results to other supine PMPs. These findings, however, cannot be extrapolated to premanipulative positioning in the sitting position, which is less standardized. Future studies should compare the reliability of the presently investigated techniques with other techniques, specifically in the sitting position.

The current work involved techniques performed in healthy participants. Patients with neck problems or headache were excluded, so care is required in extrapolating the results to patient groups. Future studies should additionally investigate reliability in patients with neck problems.

Limitations of the study

A limitation of the present study is the fact that the order of spinal levels was not randomized, which might lead to the risk of an order effect. Moreover, the premanipulative hold was investigated for reliability with the head of the patient in right rotation. Because both examiners are right handed, this factor could limit the findings. Further, the disadvantages of electromagnetic trackers are their susceptibility to interference from nearby ferromagnetic objects [19, 20] and the inability to perform in vivo registrations per motion segment.[21] Nevertheless, they were useful in this study because regional movements were analyzed and interference of ferromagnetic objects was demonstrated by the device in this setting.The relative small sample size is also a limitation but was based on a preliminary estimation of power and sample size. The present study should be considered a pilot study.

Conclusions

The purpose of this study was to determine the intra- and interexaminer reliability of the pre-manipulative hold at different cervical spine motion segments. The results indicate that the intraexaminer reliability of neck positioning during the premanipulative hold can be considered "fair" to "good" especially for the axial rotation and lateral bending components. For clinical practice, this finding means that an experienced manual therapist can position and reposition the patient after the necessary pause in the pre-manipulative position before initiating a high velocity thrust. The interexaminer reliability, however, should be interpreted with more caution because of larger variability of ICC's especially for the C1-C2 technique, and because of large confidence intervals. The positioning technique analyzed here is often used as a pre-manipulative test. Ideally in the clinical situation, both test and manipulation should be executed by the same therapist.

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ORIGINAL ARTICLE

Reliability and minimal important difference of the Treadmill Six-Minute Walking Test in people following cardiac surgery

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ABSTRACT

Aim. Treadmill Six Minute Walking Test (Tr6MWT) is often used as a convenient alternative to the corridor Six Minute Walking Test. The objective of this study is to investigate the test-retest reliability and to detect the Minimal Important Difference (MID) of the Tr6MWT in people who recently underwent cardiac surgery.

Methods. Inpatients from a Cardiac Rehabilitation Department performed an evaluation session consisting of three trials of the Tr6MWT before and after a two-week cardiac rehabilitation program. At discharge, patients were also asked to provide a rating of perceived change in walking ability. The test-retest reliability of the Tr6MWT was estimated using Intraclass Correlation Coefficient (ICC) for relative reliability and Standard Error of Measurement (SEM) for absolute reliability. The MID was determined with distribution and anchor-based methods.

Results. Forty-two inpatients were enrolled. After one practice test the Tr6MWT showed a high test-retest reliability: ICC value of .927 (95% CI .869-.960) and SEM of 27.87 m. It was not possible to investigate the MID using the anchor-based method due to lack of correlation between change in meters walked and participants' perception of change. Using the distribution-based methods the estimated MID is 53.65 m.

Conclusions. The findings support the use of the Tr6MWT in the population studied. It possesses high test-retest reliability after one practice test. The MID value of 53.65 m will help clinicians interpret change in the test performance and estimate sample size for research studies.

(It J Physiotherapy 2012;2:142-50)

Key words: Cardiac surgical procedures - Rehabilitation - Exercise test - Evaluation studies.

The Six-Minute Walking Test (6MWT) is commonly used in the rehabilitation field in order to evaluate functional capacity in people who have recently undergone cardiac surgery.[1, 2] Several authors suggest the use of a treadmill for the execution of the test because of its advantages: easy to administer, allows for easier monitoring of vital parameters, facilitates oxygen therapy and does not require a long corridor.[3-7] These characteristics make the treadmill-6MWT (Tr6MWT) particularly suitable in a cardiac rehabilitation setting involving people who have just recently undergone heart surgery.

The validity of the Tr6MWT has been investigated by Olper *et al.*, who conclude that this test is tolerable, possesses an adequate concurrent validity and is reliable and responsive for exercise capacity evaluation in people who have undergone cardiac surgery.[3] In order to

compare the distance covered during the classic corridor 6MWT with those walked during Tr6MWT, the study had a cross-over design. As a consequence, about half of the sample, performed three corridor 6MWT the day before taking the treadmill tests. This could have improved the reliability of the Tr6MWT in participants who performed the 6MWT first due to a training effect.

Up to now, the Minimal Important Difference (MID) of the Tr6MWT has not been studied. The important difference is defined by Copay *et al*. as a change that would be considered meaningful and worthwhile by the subjects.[8] The MID is a threshold value, any amount of change greater than the MID is considered to be meaningful or important. So the MID determination adds significance and relevance to the variation which has occurred. Further, when studying a group of people, it allows to identify the number of patients who truly benefited from the intervention.[9]

Several studies have described different methods to determine the MID and can generally be divided into two categories: anchor-based and distribution-based.[9] The first method is based on the relationship between the improvement in the test score and an external criterion as the person's perception of change in his/her status. This method identifies a sensitive and specific threshold above which the people who perceived a clinical improvement lie. On the other hand, the distribution-based method approximates the MID value from statistical properties of the measure in a population such as standard error of measurement (SEM) and effect size (ES). MID estimates are associated to a degree of uncertainty and variation, thus recent literature encourages the concurrent use of both anchor-based and distribution-based methods because aggregating evidence from multiple perspective further specifies clinical relevance.[9, 10]

The aim of this study was to confirm the reliability and to investigate the MID of the Tr6MWT in people who have recently undergone cardiac surgery.

Materials and methods

Sample

Subjects hospitalized to start a rehabilitation program at the Rehabilitation Department, San Raffaele Hospital, Milan, Italy, between January and October 2011 were screened for enrollment; only people over 18 years of age who have undergone cardiac surgery within the previous 15 days were included. People excluded were those for whom the protocol could represent a cardiac risk, those with hypertension (systolic blood pressure>160 mmHg; diastolic blood pressure >100 mmHg) or hypotension (symptomatic systolic blood pressure <90 mmHg), people with basal tachycardia (heart rate >120 bpm) and those with orthopedic, neurologic or cognitive deficits which would affect the execution of the test. All participants gave written consent to the protocol, which had been previously approved by the internal Ethical Committee of the San Raffaele Hospital.

Experimental Design

On the first day of rehabilitation participants underwent a 30 minute training session on a treadmill (JAS Trackmaster, JAS Manufacturing Company Inc, 3228 Skylane Dr, Carrollton, TX, USA) with 0% inclination, set at a comfortable speed in order to familiarize with the use of the treadmill. The following day the subjects underwent the test composed of three 6MWT trials on the treadmill with a 30 minute rest between each trial. This test was repeated after about two weeks, at participants' discharge. Each week of cardiac rehabilitation included five sessions of 30 minutes endurance training on a treadmill. The intensity of the training was set so as to reach a rate of perceived exertion of 3-4 on the Borg CR10 scale.

The test was performed on a treadmill inclined at 0%. The speed displayed on the monitor was hidden so as not to influence the participants. Distances covered were measured using an odometer placed on the treadmill. The accuracy of the odometer was verified by comparing the results obtained by the odometer with those obtained by multiplying the number of complete

treadmill belt revolutions in 6 minutes by the length of the belt. Instruction and encouragements provided were an adaptation of the ATS guidelines [11] and the same ones adopted by Olper *et al.* in their validation study.[3]

Before taking the first effective trial, the participants took a preliminary one minute trial. During this trial the investigator increased the speed of the treadmill until the participant felt the speed was the highest he/she could handle for six minutes. The speed reached during the preliminary trial was used as the starting speed for all the three Tr6MWT trials. Participants were instructed to hold onto the handrails and to walk the longest distance possible. They were allowed to increase or decrease the speed of the treadmill, which was changed by an investigator but always at the subjects' direction. When the participant asked to increase the speed, the latter was increased by 3 units, while when asked to decrease the speed it was decreased by 1 unit (1 unit=0.1 miles/hour; =1.61 km/h).

At the end of the rehabilitation period, before the final test, an investigator blinded to the participants' performances during assessment and rehabilitation asked them to report the subjective quantification of improvement with the following descriptors (anchors): "Since the beginning of your rehabilitation program, have you noticed a change in your ability to walk?".[12, 13] Participants could choose one of the following descriptions (anchors):

— It is: a little better; somewhat better; much better.

— It is the same.

— It is: a little worse; somewhat worse; much worse.

The postrehabilitation test was performed with the same modalities of the pre-rehabilitation ones. Two expert physiotherapists were in charge of all of the tests and of the rehabilitation program. Routinary measures such as blood pressure, heart rate, electrocardiogram and rate of perceived exertion were recorded before and after the completion of each trial.[14]

Statistical analysis

Data distribution was analyzed by the Kolmogorov-Smirnov test. Results are reported as means (standard deviations). To describe the change in walking distance, we calculated the difference between, pre and post rehabilitation, using the mean between the second and third trial. The statistical analysis was conducted by SPSS software for Windows (SPSS Inc version 13, 233 s Wacker Dr, Chicago, IL, USA). Statistival significance was set at $P<0.05$.

Reliability

In order to investigate the reliability, the pre-rehabilitation trials were analyzed and the following aspects were considered: presence of systematic error, relative and absolute reliability.

The presence of systematic error between the three trials was determined by the analysis of variance (ANOVA) for repeated measurements with post hoc comparisons. The type 2.1 Intraclass Correlation Coefficient (ICC) between the second and third trials was calculated in order to establish the relative reliability (which reveals consistent positioning or ranking of participants' scores within a group during repeated measurements).[15] It must be noted that in the literature there is no consensus as to what constitutes a good ICC value.[15] In general, it can be said that ICC values close to 1 indicate an excellent reliability [16] and values greater than 0.9 are considered as high reliability values.[17]

The SEM, estimated as the square root of the mean-square error term obtained from the ANOVA, was used to determine the absolute reliability (which reveals the variability of participants' scores during repeated measurements) between the second and third.[15]

Minimal important difference (MID)

The MID was assessed using both the anchor-based approach and the distribution-based methods. In order to apply the anchor-based approach, the correlation between change in walking distance and the anchors expressed by the participants was investigated using Pearson's correlation coefficient.

Concerning the distribution-based method, both the SEM and ES were used to estimate the MID as recommended by Beaton *et al.*[10] A per-

Table 1.—*Characteristics of participants who completed the protocol. Values are expressed as means (standard deviations) unless otherwise indicated.*

Characteristic	Value
No. of participants	42 (32 men, 10 women)
Age, y	60 (12)
Range	41-80
Weight, kg	72.9 (11.7)
Height, cm	171 (7.8)
Body mass index, Kg/m²	24.9 (3.4)
Ejection fraction, %	53.5 (6.8)
Type of cardiac surgery (no. of participants)	
Coronary Artery Bypass Graft	8
Valve Replacement	12
Both surgery procedures	1
Valvuloplasty	13
Other surgery	8
Time from surgery (days)	9.6 (3.9)

ception of at least a moderate improvement has been considered clinically relevant. According to Turner *et al*. for the SEM method the following formula was used to detect a change the subjects perceive as moderate: MID=1.96 SEM. When using the ES the following formula was used: MID=0.5 $SD_{baseline}$.[18]

Results

Forty-two participants were recruited and all of them completed the entire protocol. Their characteristics are summarized in Table I. The mean age of the participants was 60 years (SD=12, range=41-80), and the mean ejection fraction was 53.5% (SD=6.8%). The mean elapsed time between surgery and recruitment was 9.6 days (SD=3.9). The subjects underwent a mean of 9 rehabilitation sessions.

The means (standard deviations) of the distances covered by the 42 participants during the prerehabilitation and postrehabilitation Tr6MWT are reported in Table II.

Reliability

Systematic error

The ANOVA for repeated measures revealed a significant difference among the three subsequent trials (P=0.000). The *post hoc* comparison showed significant increments between the first and second trial and between the second and third trial.

Table II.—*Meters covered in the three 6MWT before and after the rehabilitation period.*

	Prerehabilitation meters	Postrehabilitation meters
Test 1	351.05 (109.49)	468.64 (103.70)
Test 2	381.76 (102.04)	497.36 (98.00)
Test 3	400.38 (104.37)	506.27 (100.77)
Mean test 2-3	391.07 (101.31)	500.09 (97.72)

Values are expressed as means (standard deviations).

Relative and absolute reliability

Regarding relative reliability the ICC of the second and third trial was 0.927 (95% Confidence Interval 0.869-0.960), while concerning absolute reliability the SEM value was 27.87 meters.

Minimal important difference

Figure 1 shows the distribution of the anchors chosen by the 42 participants. Two subjects reported "no improvement" in their ability to walk after rehabilitation, four participants reported their walking ability to be "a little better", 23 participants reported "somewhat better" and 13 subjects reported "much better".

The mean improvement of the participants who identified their improvement as "a little better" was 100.12±17.22 meters, those who felt they were "somewhat better" had a mean improvement of 104.91±37.22 meters and the mean improvement of participants who thought they were "much better" was 115.78±74.34 meters. The participants who felt they "did not improve" had a mean improvement of 124.75±49.14 meters. No difference in meters of improvement among the groups of different anchors has been found (P=0.881). Moreover, no correlation was found between improvement in meters walked and anchors referred by participants as inves-

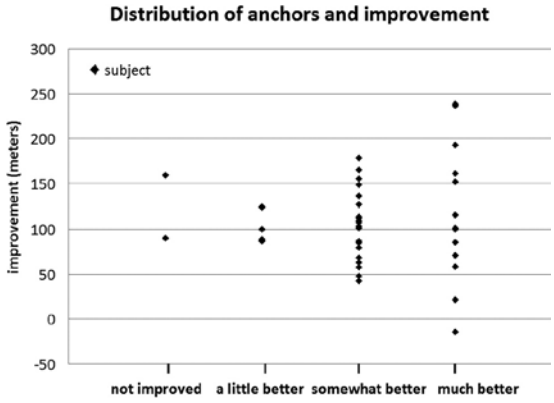

Figure 1.—Distribution of the anchors. The graph represents the subjects' improvement in meters (y-axis) and the anchor they chose (x-axis).

tigated with Pearson's correlation coefficient (r=0.097, P=0.543). As a consequence, it has not been possible to estimate the MID using the anchor-based method.

The MID value calculated with the ES was of 50.65 m, while when estimated with the SEM a value of 53.65 m was found. In order to be more specific in screening people who really improved, the value obtained with the SEM method which is higher has been considered. This value represents 13.7% of the mean initial distance covered. Of the 42 subjects included, nearly all the participants (38/42) reached the MID value.

Discussion

The aim of this study was to assess the reliability and the MID of the Tr6MWT in people who recently underwent cardiac surgery. It has been confirmed that the use of the treadmill for the test is suitable in this type of rehabilitation. In fact, as previously demonstrated, it is simple to perform, well tolerated by the subjects and allows to monitor vital signs easily.[3]

Reliability

Systematic error, relative reliability and absolute reliability were studied in order to evaluate the test-retest reliability.

Regarding systematic error, we found a significant increase of the mean distance walked from the first to the second trial and between the second and third trial (30.71 m and 18.62 m, respectively). The difference between the first and the second trial is greater than the difference between the second and third one. Although significant, the difference between the second and third trial is low, representing only 4.9% of the entire distance walked. This difference is less than 10% which Puhan et al. considers to be the minimal relevant change for the classic 6MWT.[19] Therefore, it can be suggested that one practice trial is enough.

For several reasons the training session was not sufficient to overcome the learning effect. Not all participants were familiar with the use of a treadmill and, despite the training session held the first day, they acquired more confidence during the trials. Furthermore, in some cases the subjects did not reach their maximum exertion to avoid feeling exhausted before the completion of the three trials. Similar results regarding the learning effect were reported by Olper *et al*.[3] but are in contrast with other studies. In fact, Laskin *et al*.[20] finds that the plateau of the distance walked is reached after the first test, while for other authors the plateau is reached after the second trial.[4, 5] The population in the latter studies was younger, had more stable clinical conditions, or had already been involved in a rehabilitation program using a treadmill. Furthermore, in these studies the encouragements to change treadmill speed were more frequent. All these aspects could have accelerated the learning effect presented in these studies.

Regarding relative reliability, we calculated the ICC between the second and third trial and found a value of 0.927. The value of ICC found in this study is in line with the ICC obtained by Olper *et al*. (>0.9) when studying the Tr6MWT in people after cardiac surgery.[3] To the best of our knowledge, good ICC values of the Tr6MWT are reported in the literature: Puthoff and Laskin report ICC values of 0.88 and 0.98, respectively.[20, 21] Therefore, it can be concluded that the Tr6MWT demonstrates a good relative reliability.

Concerning absolute reliability, the SEM value obtained was 27.87 m, which represents only 7.1% of the baseline mean distance values.

It can be suggested that a good absolute reliability value was obtained for the treadmill test. This result is similar to the one found in the previous Olper *et al*. crossover study (23 m).[3] To our knowledge, no other studies in the current literature investigate absolute reliability for the Tr6MWT.

Minimal important difference

To detect the MID we intended to use both anchor-based and distribution-based methods. Concerning the anchor-based method, no correlation between the difference in the test score (post-and pre-rehabilitation) and the subjects' perception of change was found. Thus, this method was not used to detect the MID. Several reasons may have affected the subjects' judgement on their ability to walk.

The question we asked the subjects "Has there been any change in your walking ability since you started the rehabilitation program?" was the same used in previous studies [12, 13] but has unknown reliability and validity. We found that for some people the meaning of the term "walking ability" was difficult to understand and often they needed additional explanations. Probably the use of more measurable and categorized parameters such as breathlessness during walking, or the elapsed time before feeling tired, would ensure more precise answers. Furthermore, this study enrolled people early after surgery (mean of 9.6 days), a period during which there is a simultaneous improvement of functional capacity but also of general wellness. For this reason when the people are asked a question regarding their walking ability, it could be difficult for them to discriminate between the two distinct clinical aspects. Moreover, in an inpatient setting the subjects do not have many opportunities to walk long distances and to experience their change. Another aspect to consider is the recall bias inherent to the anchor-based method due to its retrospective rating approach. Other similar studies successfully used the anchor-based method but the participants were in a chronic condition.[12, 13, 19, 22] Therefore, it could be easier for these subjects to identify a change in walking ability because their clinical condition was stable and they were able to test their walking ability during their daily activities. It is important to note that the people enrolled in this study were not able to successfully identify the change in their walking ability. As a consequence, the clinician cannot rely on the patients' global rating to assess the change in their performance and the intervention's efficacy, but in this population it may be better to consider the objective measures. The anchor-based method was not successful, thus the MID was investigated using a distribution-based approach using two formulas based on ES and SEM. In line with the literature we used .5 ES to approximate a moderate MID.[13, 18, 19, 23] Regarding the SEM, according to Turner *et al*., different coefficients should be used to multiply the SEM value in order to best describe the MID: in case of a small improvement the SEM should be multiplied by 1, for a moderate change by 1.96 and to describe a large improvement 2.77 should be used.[18] Despite 1 SEM is commonly used,[12, 13, 24] we considered 1.96 as the multiplication factor because a moderate change was expected in the participants' walking ability. In fact, they were in a very poor physical condition at the beginning of the rehabilitation period and underwent an important recovery of their physical wellness.

We decided to consider the value obtained with the SEM to approximate the MID because it provides a slightly higher result which allows us to be more specific in discriminating people who really improved. The MID found in this study is 13.7% of the mean initial distance covered by the participants. Considering that 38 of the 42 participants reached the threshold value, we determined the MID proportion [9] to include 90.5% of the cases. We expected this result in that at baseline the participants were very debilitated due to their poor clinical condition and they underwent a specific cardiac and physical training using a treadmill. In line with our finding, when studying a similar group of subjects after cardiac surgery, Fiorina *et al*. notes that the distance covered during the hallway 6MWT consistently increases after an in-hospital intense rehabilitation program of average duration of 15 days.[1]

To the best of our knowledge, this is the first study which investigates the MID for the treadmill 6MWT during a rehabilitation program in an acute phase after cardiac surgery. The MID value

is important in order to establish a useful cut-off to identify subjects who truly benefited from the physical training and to evaluate the suitability of the intervention. Further, in the research field this value can determine the clinical relevance of the improvement of a group of people.

Study limitations

One of the limitations of the present study was the small sample size when compared to other papers investigating the MID of other exercise capacity tests.[13, 22-24] A second limitation was that the method of sampling at a single site implicitly suggests some degree of weakness in the external validity of the study.

Conclusions

The present study confirms the high relative and absolute reliability of the Tr6MWT after one practice test. The first estimates of the MID, 53.65 m, were determined for the test in people who recently underwent cardiac surgery. This finding adds a parameter to use in clinical practice to make sense and interpret the objective change from a patient's point of view and may also be useful for planning future research and to inform on sample size choices.

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APPENDIX 1

Instructions and encouragements for the treadmill Six-Minute Walking Test

Instruct the patient as follows

"The object of this test is to walk as far as possible for 6 minutes walking on a treadmill. During the test you will sustain yourself on the treadmill hand rails. You will check the speed or, if you do not feel safe, I will check it for you on your prompt.

In any moment you can ask me to increase or decrease the speed of the treadmill. Six minutes is a long time to walk, so you will be exerting yourself. You will probably get out of breath or become exhausted.

You are permitted to slow down, to stop, and to rest as necessary. You may lean against the treadmill hand rails while resting, but resume walking as soon as you are able. To set the speed of the treadmill for the test, you will now take a preliminary one minute trial".

Instructions during the preliminary trial

"Before starting the test you will walk for one minute so that you can decide which is the highest speed you think you can handle for six minutes. We will start the test using this speed. Remember that the object is to walk as far as possible for six minutes".

At the end of the preliminary trial

"Now you can rest for one minute and then we will start the test" (the patient sits on a chair positioned on the treadmill)".

At the end of the break

"Now you will start the test at the speed you decided before. I remind you that during the six minutes I will check the speed of the treadmill on your prompt. In any moment you are permitted to increase or reduce the treadmill speed. Remember that the object is to walk as far as possible for six minutes but do not run or jog".

Are you ready to do that?

"I am going to use this counter to keep track of the distance walked. (show the odometer fixed on the treadmill). Once the test is finished I will read the distance walked.

Remember that the object is to walk AS FAR AS POSSIBLE for 6 minutes, but do not run or jog.

Start now or whenever you are ready".

Encouragement phrases

The subject starts walking at the speed he/she decided during the preliminary one minute trial.

After the first minute, tell the patient the following (in even tones): "You are doing well. You have 5 minutes to go. I remind you that in any moment you can ask me to increase or reduce the treadmill speed".

When the timer shows 4 minutes remaining, tell the patient the following: "Keep up the good work. You have 4 minutes to go. I remind you that in any moment you can ask me to increase or reduce the treadmill speed".

When the timer shows 3 minutes remaining, tell the patient the following: "You are doing well. You are halfway done. I remind you that in any moment you can ask me to increase or reduce the treadmill speed".

When the timer shows 2 minutes remaining, tell the patient the following: "Keep up the good work. You have only 2 minutes left. I remind you that in any moment you can ask me to increase or reduce the treadmill speed".

When the timer shows only 1 minute remaining, tell the patient: "You are doing well. You have only 1 minute to go. I remind you that in any moment you can ask me to increase or reduce the treadmill speed".

Do not use other words of encouragement (or body language to speed up).

If the patient stops walking during the test

and needs a rest, say this: "You can lean against the treadmill hand rails if you would like; then tell me that you want to continue walking whenever you feel able". Do not stop the timer. If the patient stops before the 6 minutes are up and refuses to continue (or you decide that they should not continue), wheel the chair over for the patient to sit on, discontinue the walk, and note on the worksheet the distance, the time stopped, and the reason for stopping prematurely.

When the time is over take off the odometer from the treadmill-belt and tell the patient that the treadmill is beginning the cool down.

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