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ORIGINAL ARTICLE

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Is there a long-lasting effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke?

A 6-month follow-up study

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Abstract The aim of this study was to evaluate the long-lasting effect of pelvic floor muscle training (PFMT) in women with urinary incontinence after stroke measured by quality of life parameters. Twenty-four (24/24) women with urinary incontinence after stroke, who had completed a prospective, randomised controlled and single-blinded trial evaluating the effect of 12 weeks PFMT, were included in this follow-up study. The follow-up assessments were done by telephone interview 6 months after the intervention. The effect was evaluated by The Short Form 36 (SF-36) Health Survey Questionnaire and Incontinence Impact Questionnaire (IIQ). Twenty-four subjects completed the study. In the treatment group, the SF-36 showed a trend to a long-lasting effect in one of the eight domains and the IIQ showed a tendency to decreased impact of UI in two sub-scales compared to the control group. Our data indicated that PFMT may have a long-lasting effect measured by quality of life parameters.

Keywords Physiotherapy · Pelvic floor muscle training · Stroke · Quality of life · Women

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Introduction

Urinary incontinence (UI) is a highly prevalent symptom after stroke [1, 2]; however, research-based evidence for the long-term effect of treatment is very limited [3].

UI affects quality of life (QoL) [4] in social, psychological, occupational, domestic, physical and sexual aspects of 15–30% of women of all ages [5]. UI in stroke affects QoL even more because of the accompanying neurological deficits such as motor disability, visual field defects, cognitive problems and dysphasia [1, 6, 7]. In addition, UI in stroke has also a negative impact on QoL in caregivers of persons with stroke [1, 8].

Pelvic floor muscle training (PFMT) [9] has been found to be a fairly effective, non-invasive treatment, and side-effects are uncommon and reversible [10]. The cure rate varies from 23–94% in treatment of UI in neurological healthy women, depending on the evaluation method, the population and the type of incontinence [10–12]. In previous publications, PFMT was found to have a statistically significant effect in women with UI after stroke in frequency of voiding in daytime (P=0.018), 24 h pad test (P=0.013) and dynamic endurance of pelvic floor muscle (P=0.028) in the treatment group (TG) compared to the control group (CG) [13]. Whereas, the samples size were too small to detect any significant differences of PFMT measured by two QoL parameters [14].

The aim of the present study was to evaluate the long-lasting effect of PFMT in women with UI 6 months after ischemic stroke measured by QoL parameters.

Materials and methods

Method

Between July 1, 1999 and September 1, 2001, all 24 (24/24) subjects who completed the initial prospective, randomised and controlled, single-blinded intervention study evaluating the effect of 12 weeks PFMT in women with UI after stroke, were contacted by telephone for the follow-up study. The detailed description of randomisation and run-in procedure has been published previously [13, 14].

The follow-up assessment was done by telephone interview 6 months after the intervention. One trained physiotherapist (GL) performed all the telephone interviews. The rater was the same physiotherapist who had done all the interviews in the previous intervention study, and who was blinded for the randomisation codes.

The subjects had received written and verbal information and signed an informed consent. The ethical committee for The Copenhagen County had approved the study (KA 98117).

The subjects were outpatients at the time of the previous intervention study, and all subjects were still living and contacted at their private accommodations.

Subjects

The sample was recruited from the clinical departments at Copenhagen University Hospital, Glostrup (acute stroke unit, neurological, geriatric, rehabilitation) and general physical therapy clinics and the public rehabilitation centres in The Copenhagen County from January 1, 1999 to March 1, 2001.

The inclusion criteria were: (1) women, diagnosed with first ever ischemic stroke according to the definition of World Health Organisation and verified by CAT scan [15]; (2) stroke symptoms in at least one month; (3) normal cognitive function (mini-mental state examination a.m. Folstein > 25) [16]; (4) urinary incontinence according to the definition of ICS [9], and started in close relation to the stroke; (5) independent walking abilities indoors >100 m with/without aids; (6) independence in toilet visits; and (7) age between 40–85 years.

Exclusion criteria were: (1) urinary tract infection; (2) symptoms of descensus urogenitale; (3) chronic respiration diseases; (4) psychiatric diseases; (5) other neurological diseases; and (6) do not speak Danish.

Measurements

The subjective outcomes were measured by two QoL instruments:

1. A generic questionnaire: The Short Form 36 (SF-36) Health Survey Questionnaire (primary outcome) [17]. The SF-36 consists of 36 items grouped in eight health-related domains: physical functioning (10 items), role limitations due to physical problems (four items), body pain (two items), general health perceptions (five items), vitality (four items), social functioning (two items), role limitation because of emotional problems (three items) and general mental health [psychological distress and psychological well-being (five items)]. A single item is added to assess any change in health compared with 1 year before. Each scale was ranged from 0 (worst case) to 100 (best case). The reliability and validity of SF-36 had been studied in several populations [10, 18, 19].
2. A condition-specific QoL questionnaire: The Incontinence Impact Questionnaire (IIQ) (primary outcome) [20]. The IIQ questionnaire measured UI impact on different activities and feelings. The questionnaire consist of 30 items grouped (emerged) in four subclasses: physical activities (six items), travel (six items), social relationships (10 items) and emotional health (eight items). Each sub-scale ranges from 0 (best case) to 100 (worst case). IIQ had been tested for reliability and validity [20]. The questionnaires were in a Danish version, and the permission for using the Danish version of SF-36 had been acquired.

Intervention

The subjects in TG were treated in a systematic, controlled, intensive PFM program in 12 consecutive weeks by the same specialist physiotherapist. The procedure is presented in Table 1 and the detailed description of the treatment program has been published previously [13].

The subjects in CG followed the normal, standard program of rehabilitation without any specific treatment of urinary incontinence.

Statistics

Statistical calculations were done by means of SPSS (Statistical Package of Social Science), version 12.0.1.

For data on ordinal scale, we used non-parametric statistic tests because these tests did not assume normal distribution of the data.

Median and quartile ranges are presented. The null hypothesis was tested by Mann–Whitney *U* test between

Table 1 Treatment program of pelvic floor muscle treatment in women with urinary incontinence after stroke

Introduction (theory)	1 h
Group treatment	6–8 patients/group
Frequency	1 h/week
Duration	12 weeks
Attendance in group treatment sessions	Eight times (minimum)
Vaginal palpation	Two to three times
Home exercises	One to two times daily

groups and by Wilcoxon test within groups. The level for statistical significance was set to $p<0.05$.

Results

Twenty-four women with first ever ischemic stroke were included and completed the follow-up study, 12 in TG and 12 in CG. One subject ($n=1$) from CG did not complete the IIQ questionnaire property because of fatigue. The median age for the 24 subjects was 60 years and the inter-quartile range was 56–74 years. Baseline characteristics and neurological characteristics has been published previously [14]. There were no significant differences between the TG and the CG. The median interval between the post-test at the intervention study and the follow-up assessment was 182 days and the inter-quartile range was 176–183 days.

SF-36

The results of SF-36 are presented in Tables 2 and 3. In TG, a weak tendency to improvement was seen in the sub-scale regarding role limitation because of emotional problems from baseline to follow-up assessment ($p=0.098$). There were, however, no statistically significant differences within or between the TG and CG groups in any of the eight sub-scales of SF-36.

IIQ

In IIQ, the distribution of the results for each sub-scale is shown as box plots presented in Fig. 1. The median value decreased in TG regarding social relationships and emotional health. In CG none of the median values decreased. Also, the 75th percentiles (shown as the top of the box in the plot) were smaller in TG regarding sub-scales total scores, travel, social relationships and emotional health compared to the CG. Likewise, the decrease of the 75Th percentiles in CG regarding physical activity, travel and social relationships was smaller. Although there were changes in the distributions, no statistical significant differences between scores at baseline and follow-up assessment were detected within or between the groups (Table 3).

Discussion

Our data indicated that PFMT may have a long-lasting effect in women with UI 6 months after stroke measured by QoL parameters, although the results are based on a very limited number of subjects due to very strict inclusion and exclusion criteria [13, 14]. On the other hand, the strict inclusion and exclusion criteria resulted in a high level of completion as the 24 subjects, who completed the intervention study, also completed the follow-up SF-36 assessment and 23 completed the IIQ assessment. Only one subject in CG suffered from severe fatigue and was unable to complete the IIQ properly at follow-up, but as the procedure with the interview of SF-36 and IIQ questionnaires in one session was strictly maintained to

Table 2 Results of Short Form (SF-36) Health Survey Questionnaire in 24 women with urinary incontinence after stroke

		Baseline	Follow-up	*P* value
Physical functioning	TG	63 (43–88)	60 (45–89)	1.000
	CG	70 (43–89)	70 (35–89)	1.000
Role limitation due to physical problems	TG	88 (6–100)	75 (31–100)	1.000
	CG	50 (6–100)	87 (37–100)	0.229
Body pain	TG	62 (44–100)	68 (41–100)	0.726
	CG	84 (63–100)	81 (39–100)	0.674
General health perceptions	TG	70 (41–91)	57 (41–86)	0.476
	CG	82 (56–92)	54 (47–88)	0.182
Vitality	TG	65 (50–74)	52 (37–72)	0.238
	CG	70 (45–89)	70 (46–84)	0.607
Social functioning	TG	88 (53–100)	100 (66–100)	0.301
	CG	100 (100–100)	100 (90–100)	0.655
Role limitation because of emotional problems	TG	100 (8–100)	100 (66–100)	0.098
	CG	100 (75–100)	100 (100–100)	0.197
Mental health	TG	84 (57–96)	82 (64–92)	0.533
	CG	84 (83–92)	84 (76–92)	0.722

The scales ranges from 0 (worst case) to 100 (best case)
Data presented as median value and quartile range
TG Treatment group ($n=12$), *CG* control group ($n=12$)

Table 3 Results of Short Form (SF-36) Health Survey Questionnaire and Incontinence Impact Questionnaire (IIQ) in 24 women with urinary incontinence after stroke

		Treatment group (n=12)	Control group (n=12)[a]	P value
SF-36				
Physical functioning	Baseline	63 (43–88)	70 (43–89)	0.799
	Follow-up	60 (45–87)	65 (35–85)	0.695
Role limitation due to physical problems	Baseline	88 (6–100)	50 (6–100)	0.713
	Follow-up	75 (31–100)	75 (25–100)	0.695
Body pain	Baseline	62 (44–100)	84 (63–100)	0.514
	Follow-up	68 (41–100)	62 (32–100)	0.928
General health perceptions	Baseline	70 (41–91)	82 (56–92)	0.319
	Follow-up	57 (41–87)	52 (47–77)	1.000
Vitality	Baseline	65 (50–74)	70 (45–89)	0.514
	Follow-up	53 (38–73)	70 (45–80)	0.379
Social functioning	Baseline	88 (53–100)	100 (100–100)	0.101
	Follow-up	100 (67–100)	100 (88–100)	0.413
Role limitation because of emotional problems	Baseline	100 (8–100)	100 (75–100)	0.410
	Follow-up	100 (67–100)	100 (100–100)	0.316
Mental health	Baseline	68 (57–96)	84 (73–92)	0.443
	Follow-up	84 (64–92)	84 (76–92)	0.786
Total score	Baseline	598 (362–713)	655 (477–692)	0.443
	Follow-up	563 (430–682)	623 (494–676)	0.608
IIQ				
Physical activity	Baseline	0 (0–11)	0 (0–14)	0.843
	Follow-up	0 (0–18)	6 (0–11)	0.566
Travel	Baseline	6 (0–36)	3 (0–26)	0.590
	Follow-up	8 (0–11)	6 (0–22)	0.651
Social relationships	Baseline	2 (0–17)	0 (0–11)	0.630
	Follow-up	0 (0–2)	3 (0–9)	0.190
Emotional health	Baseline	8 (4–22)	8 (1–28)	1.000
	Follow-up	4 (1–17)	13 (0–29)	0.525
Total	Baseline	14 (8–99)	17 (5–80)	0.799
	Follow-up	20 (1–50)	27 (6–93)	0.449

[a]Only 11 patients in the IIQ follow-up, as one subjects dropped out
Median (quartile range) are presented
The SF-36 scales ranges from 0 (worst case) to 100 (best case)
The IIQ-scales ranges from 0 (best case) to 100 (worst case)

minimise bias, no other attempt to complete the IIQ was done. In comparison, Harari et al. [21] found a dropout rate of 24% at his 6-month follow-up assessment in a randomised, controlled trial with treatment of constipation and faecal incontinence in stroke patients.

Previous studies

To our knowledge, this is the first follow-up study of a randomised, controlled and single-blinded trial, evaluating the effect of PFMT measured by QoL parameters in women with UI after stroke. Recently, Thomas et al. [3] included seven trials with a total of 399 participants, in a review of randomised or quasi-randomised controlled trials, evaluating the effect of interventions designed to promote continence in people after stroke. None of the seven trials addressed the intervention in a compatible way ruling out any comparison between the trials and none had published follow-up results.

In the above mentioned study of Harari et al. [21], the result of bowel movements per week graded as "normal" was significantly higher in intervention vs control patients at 6 months follow-up. The same result was true for the mean number of bowel movement per week, although the subjects in intervention group did not show any benefit in specific or general QoL measures [22]. Similar to these findings, studies of secondary prevention through education in stroke patients show that although knowledge and adherence to lifestyle changes improves, perceived health status and QoL measures remain unaltered [23].

In our previous studies [13, 14], we found a significant effect in clinical variables measured by diaries, pad tests and vaginal palpation, but none evaluating by QoL

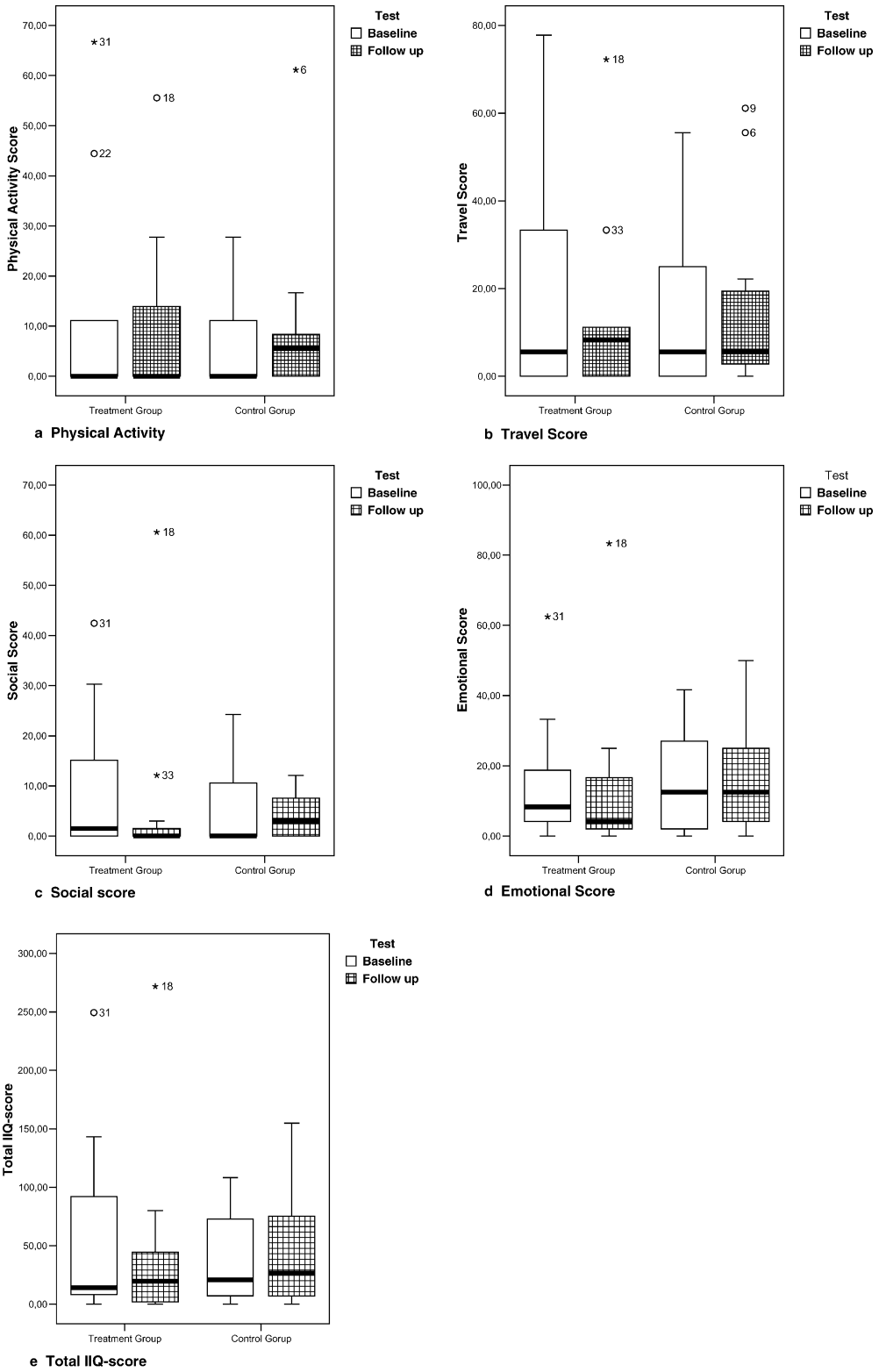

Fig. 1 Box plots of Incontinence Impact Questionnaire (IIQ) scores

parameters. Unfortunately, the clinical variables were not evaluated in the present follow-up study because we had only planned to do follow-up assessment of QoL variables by a telephone interview due to practicalities. Therefore, we recommend a future study with a follow-up of all outcome variables in a clinical setting.

Methodology

Our findings had to be considered from the perspective of three methodological issues, definition, evaluation methods and design.

The first issue was the definition of long-term effect. In our design, we defined 6 months follow-up time, as long-lasting effect. In previous follow-up studies, the interval between treatment and evaluation varied from 1 month to 10–15 years, depending on the patient group and their disorders.

The Standardisation Committee of International Continence Society (ICS) for outcome in UI recommended evaluation after 1, 6 and 12 months after treatment and at yearly interval thereafter, continued as long as possible and preferable for at least 5 years [24].

There are few studies of long-term effect of stroke rehabilitation and these studies had mostly examined the effects and costs of stroke rehabilitation focusing on acute stroke trials.

The second issue was the method of data collection, which may be result in bias. Studies in a non-neurological survey assessing QoL by SF-36 had proved that subjects rate lower scores by face to face interview than by self-administration [25]. How the difference is between scoring by face to face interview and telephone interview in follow-up studies in stroke patients remains to be clarified, although we assume that these different methods did not affect the data. We chose the telephone interview for follow-up instead of a face to face interview due to relatively restricted strain for the patients.

The third issue was the statistical power. It may be argued that the present study was under-powered and that important beneficial long-lasting effect of PFMT in stroke, assessed by SF-36 and IIQ had remained undetected. In our research protocol, the sample size was estimated to 60 subjects, but due to the restrictive inclusion criteria, as discussed before, the number of included patients was minimised.

Clinical implication

PFMT can be recommended as the first line of treatment for subgroups of women with stroke according to our prior study [13]. Although we were unable to demonstrate a significant longer-term effect measured by SF-36 and IIQ, a weak tendency to a long-lasting effect could be noted, and no sign of decoration was found, as expected. In addition, PFMT is a treatment with a marked health education factor.

Perspectives

With an annual incidence of 10,000 stroke patients in the population of 5 million in Denmark, there is an urgent need for screening, education and evidence-based treatment of UI in stroke.

This study may serve as a pilot study for a larger, future intervention study and may also be included as a part of a multidisciplinary intervention study.

Furthermore, we suggest the development of a short, specific disease QoL questionnaire for stroke patients, which can improve the focus of UI symptom in stroke rehabilitation.

In conclusion, further studies are needed to confirm our pilot study to determine the long-lasting effect of PFMT in stroke.

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