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## FOUR-MONTH TREATMENT WITH NEW ANTIDIABETIC AGENTS (GLP-1/SGLT-2I) IMPROVES CARDIOVASCULAR FUNCTION IN PATIENTS WITH TYPE 2 DIABETES MELLITUS AND ISCHEMIC STROKE

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**Background and aims:** Patients with type 2 diabetes mellitus (T2DM) and ischemic stroke present impaired markers of vascular and endothelial function. Glucagon-like peptide-1 receptor agonists (GLP-1) and sodium-glucose cotransporter-2 inhibitors (SGLT-2i) are novel antidiabetic agents reducing the risk of cardiovascular complications. We investigate the effect of treatment with GLP-1 or SGLT-2is on cardiovascular and endothelial function in patients with T2DM and ischemic stroke.

**Methods:** We recruited in total 81 patients with T2DM and ischemic stroke who received dulaglutide (n=27), dapagliflozin (n=27) or insulin (n=27). We measured at baseline and at four months post-treatment the: a) Carotid-femoral pulse wave velocity (PWV) b) Augmentation index (Aix) c) Central systolic blood pressure (cSBP) d) Perfused boundary region (PBR) of the sublingual arterial microvessels and e) Left ventricular global longitudinal strain (GLS).

**Results:** At baseline, patients among the three groups had similar age, sex, HbA1c and markers of endothelial and cardiovascular function ( $p > 0.05$ ). After four months treatment, patients on dapagliflozin and on dulaglutide displayed a greater reduction of PWV ( $12.98 \pm 3.23$  vs.  $11.62 \pm 1.74$  m/s,  $p = 0.017$ ,  $14.77 \pm 1.97$  vs.  $13.59 \pm 2.20$  m/s,  $p = 0.042$  respectively), of cSBP ( $132.15 \pm 14.03$  vs.  $120.27 \pm 10.05$  mmHg,  $p = 0.035$ ,  $139 \pm 7.25$  vs.  $129 \pm 7.75$  mmHg,  $p = 0.045$  respectively), of Aix ( $17.10 \pm 17.83$  vs.  $5.97 \pm 28.99$ ,  $p = 0.028$ ,  $8.59 \pm 20$  vs.  $7.46 \pm 6.36$ ,  $p = 0.039$  respectively) and of GLS ( $-16.87 \pm 3.28$  vs.  $-18.76 \pm 3.35$ ,  $p = 0.001$ ,  $-16.31 \pm 3.42$  vs.  $-17.48 \pm 3.14$ ,  $p = 0.004$  respectively) compared to patients on insulin. PBR values were improved only in patients on dulaglutide ( $2.10 \pm 0.16$  vs.  $2.00 \pm 0.14$ ,  $p = 0.025$  vs. dapagliflozin:  $2.04 \pm 0.23$  vs.  $2.00 \pm 0.11$ ,  $p = 0.696$  vs. insulin:  $2.13 \pm 0.3$  vs.  $2.15 \pm 0.3$ ,  $p = 0.567$ ).

**Conclusions:** Dulaglutide and dapagliflozin improve cardiovascular function, but only dulaglutide improves endothelial glycocalyx in patients with T2DM and ischemic stroke after four months treatment.

**Disclosure:** No

1711

## THE EFFECTIVENESS OF ADDITIONAL CORE STABILITY EXERCISES IN IMPROVING DYNAMIC SITTING BALANCE, COORDINATION AND LOWER LIMB SPASTICITY FOR SUBACUTE STROKE-SURVIVORS (CORE-TRIAL). A RANDOMIZED CONTROLLED TRIAL

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**Background and aims:** Trunk impairment produces disorders of motor control, balance and gait in post-stroke survivors. Core stability exercises (CSE) are a good strategy to improve local strength of trunk but little information is available for acute phase of stroke individuals. Therefore the aim of this study is assess the effectiveness of CSE in subacute (< 1 month) stroke patients in addition to CP.

**Methods and analysis:** This is a two parallel group, single-blind, multi-center randomized controlled trial. All stroke survivors performed conventional physiotherapy (CP), active-assisted mobilizations, stretching and strength exercises of hemiparetic side, balance training and gait in parallel bars. Control group (CG) trained 1 hour of CP and EG performed 30 minutes of CSE and 30 minutes of CP during five days a week for five weeks in the first month post-stroke. Primary outcome measures were dynamic sitting balance, assessed by Spanish-Trunk Impairment Scale and Spanish-Function in Sitting Test and gait by Brunel Balance Assessment (stepping). Secondary outcomes were postural control (mobility and balance) assessed by Spanish-Postural Assessment Scale for Stroke, standing balance assessed by Berg Balance Scale and lower-limb spasticity by Modified Ashworth Scale, the degree of disability by modified Rankin Scale and activities of daily living by Barthel Index. The evaluators were blinded to intervention and individuals were measured at baseline and 5-week. Descriptive statistics have been used for the characterization of the sample. The mean value and standard deviation were calculated for continuous data in both groups and individuals characteristics were described using frequencies and percentages. Statistical analysis was performed with IBM SPSS Statistics software (Version 24). Paired T Test was used for comparison analysis with a significant level of 0.05.

**Results:** Eighty-seven individuals were evaluated, CG: 45 and EG: 42. The groups were comparable at baseline (Table 1). Both groups improved after five weeks of treatment (Table 2). The lower limb modified Ashworth Scale score (Figure 1), dynamic sitting balance, coordination (Figure 2) and standing balance scores were statistical significant in favor EG (Table 3).

**Conclusions:** Twenty-five sessions of CSE in addition to conventional physiotherapy improve dynamic sitting balance, sitting coordination, standing balance and prevents lower-limb spasticity in subacute (< 1 month) stroke survivors with moderately severe disability.

The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee Research of each hospital. It was funded by Fundació Marató TV3, grant number 201737-83. Protocol registration is in ClinicalTrials.gov number Identifier NCT03975985.

**Table 1.** Patients Characteristics at baseline (n=87).

Variable	Scoring Range	Experimental Group (n=42)	Control Group (n=45)	P value*
Age		71.38 (11.789)	69.33 (15.331)	0.758
Gender (women/men)		12/30	18/27	0.296
BMI		26.56 (5.556)	27.51 (4.773)	0.425
Time post-stroke, days		25.12 (17.3)	21.37 (16)	0.225
Paretic side, (left/right)		20/22	26/19	0.286
Type of stroke, ischemic/hemorrhagic		35/7	37/8	0.891
Thrombectomy/thrombolysis		2/2	6/1	0.317
NIHSS stroke severity	0-42	8.02 (4.297)	7.04 (4.226)	0.287
Physical activity (previously)		19 (50.0%)	21 (42.2%)	0.467
Falls (previously)		2 (4.8%)	4 (8.9%)	0.448
<b>Primary outcome measure</b>				
S-TIS dynamic sitting balance	0-10	3.38 (2.837)	3.69 (2.575)	0.597
S-TIS coordination	0-6	1.45 (1.131)	1.89 (1.434)	0.120
S-TIS total	0-16	4.83 (3.449)	5.58 (3.230)	0.301
BBA stepping section	0-6	1.175 (1.893)	1.56 (2.323)	0.416
<b>Secondary outcome measure</b>				
Barthel Index	0-100	42.44 (25.449)	44.33 (27.810)	0.743
Berg Balance Scale	0-56	21.20 (18.236)	23.89 (19.010)	0.505
S-Function in Sitting Test	0-56	44.38 (15.611)	43.29 (18.299)	0.767
Modified Ashworth Scale	0-4	0.56 (0.812)	0.58 (0.923)	0.929
Modified Rankin Scale	0-6	3.98 (1.000)	3.91 (1.151)	0.863
S-PASS mobility	0-21	14.15 (5.734)	14.82 (5.086)	0.564
S-PASS balance	0-15	6.71 (3.600)	7.27 (3.875)	0.491
S-PASS (total)	0-36	20.36 (9.466)	22.09 (8.612)	0.374

Values are presented as mean and standard deviation (SD) or absolute frequency, \*p value < 0.05, the method of pairwise comparison was used. Abbreviations: BBA: Brunel Balance Assessment, BMI: Body mass index, NIHSS: National Institutes of Health Stroke Scale, S-PASS: Spanish Postural Assessment Scale for Stroke, S-TIS: Spanish Trunk Impairment Scale 2.0.

**Table 2.** Post-treatment values.

Variable	Experimental Group (n=41)	P value*	Control Group (n=45)	P value*
<b>Primary outcome measure</b>				
S-TIS dynamic sitting balance	9.15 (2.338)	<b>0.000*</b>	6.35 (2.844)	<b>0.000*</b>
S-TIS coordination	4.22 (1.405)	<b>0.000*</b>	2.98 (2.773)	<b>0.005*</b>
S-TIS total	13.53 (3.220)	<b>0.000*</b>	9.95 (4.460)	<b>0.000*</b>
BBA stepping section	3.05 (2.207)	<b>0.000*</b>	2.84 (2.339)	<b>0.000*</b>
<b>Secondary outcome measure</b>				
Barthel Index	64.74 (26.609)	<b>0.000*</b>	66.98 (27.258)	<b>0.000*</b>
BBS	35.70 (20.081)	<b>0.000*</b>	35.49 (17.957)	<b>0.000*</b>
S-Function in Sitting Test	48.93 (14.083)	<b>0.004*</b>	50.05 (11.598)	<b>0.000*</b>
Modified Ashworth Scale	0.48 (0.640)	1.000	1.05 (1.154)	<b>0.003*</b>
Modified Rankin Scale	3.27 (1.062)	<b>0.000*</b>	3.28 (1.076)	<b>0.000*</b>
S-PASS mobility	18.30 (4.847)	<b>0.000*</b>	17.81 (4.398)	<b>0.000*</b>
S-PASS balance	9.93 (3.377)	<b>0.000*</b>	9.23 (3.689)	<b>0.000*</b>
S-PASS total	28.23 (7.830)	<b>0.000*</b>	27.05 (7.734)	<b>0.000*</b>

Abbreviations: BBA: Brunel Balance Assessment, S-PASS: Spanish Postural Assessment Scale for Stroke, S-TIS 2.0: Spanish Trunk Impairment Scale 2.0. Values are presented as mean and standard deviation (SD) \*p value < 0.05.

**Table 3.** Comparison between experimental and control groups post-treatment.










Variable	Mean difference standard error	P value*
<b>Primary outcome measure</b>		
S-TIS dynamic sitting balance	2.801 (0.574)	<b>0.000*</b>
S-TIS coordination	1.248 (0.488)	<b>0.012*</b>
S-TIS total	3.578 (0.901)	<b>0.000*</b>
BBA stepping section	0.213 (0.500)	0.672
<b>Secondary outcome measure</b>		
Barthel Index	2.240 (6.002)	0.710
Berg Balance Scale	0.212 (4.176)	0.445
S-Function in Sitting Test	1.122 (2.824)	0.692
Modified Ashworth Scale	0.572 (0.207)	<b>0.007*</b>
Modified Rankin Scale	0.004 (0.238)	0.769
S-PASS mobility	0.486 (1.015)	0.258
S-PASS balance	0.692 (0.778)	<b>0.039*</b>
S-PASS total	1.178 (1.709)	0.095

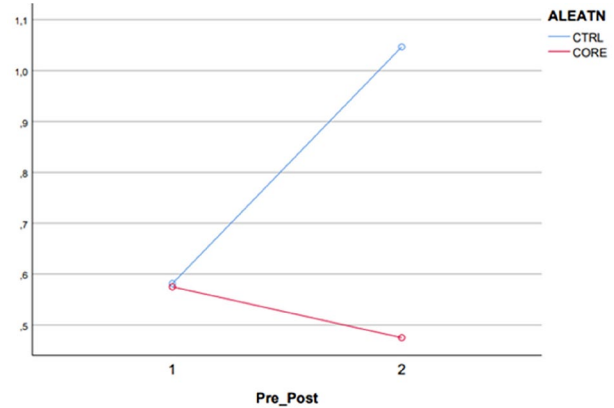
Abbreviations: BBA: Brunel Balance Assessment, S-PASS: Spanish Postural Assessment Scale for Stroke, S-TIS 2.0: Spanish Trunk Impairment Scale 2.0.

\*p value < 0.05.

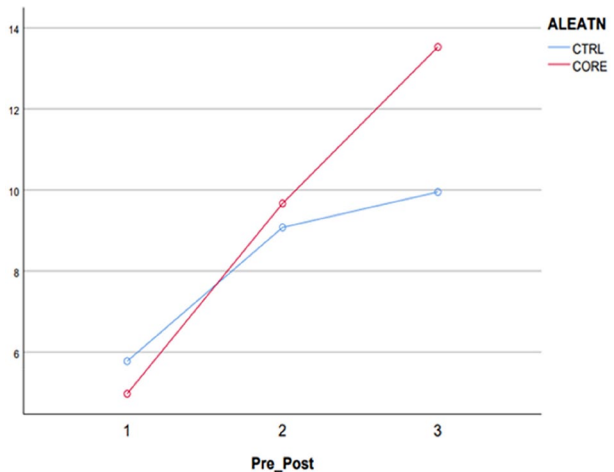
**Core Stability Exercises Program**

**Supine position** The exercises intensity increased by flexing the patient's elbows.

<p><b>1. Pelvis anteversion-retroversion:</b> The hips and knees at 90° flexion and the patient's feet and hands resting on the plinth. Selective pelvis anteversion-retroversion. The physiotherapist helping the patient may be placed in front of her/his or on the affected side and keep the patient's leg.</p>	
<p><b>2. Upper trunk rotation:</b> The patient resting his/her trunk on the plinth with knees flexed at 90° and the feet flat on the support surface. His/her arms are flexed on the ribcage. The physiotherapist steadied the patient's pelvis and patient rotates affected side to unaffected side and vice versa. When patient do correctly this exercise, the physiotherapy apply a slow resistance on patient's shoulder.</p>	
<p><b>3. Single bridging:</b> Starting position is the same that exercise 1. The patient lifts the pelvis of the plinth maintaining a neutral lumbar and pelvic alignment. When patient does this exercise easily an elastic band is put on your iliac crests to increase difficulty.</p>	
<p><b>4. Lateral movement:</b> Starting position is the same that exercise 1. Patient lift the pelvis of the plinth and moves to the right and left side. The physiotherapist steadied the patient's knees and feet if it is necessary and her/his hand is under patient's sacrum to help her/him.</p>	
<p><b>5. Pre-unilateral bridging (a):</b> Starting position is the same that exercise 1. Unaffected patient's leg is forward 20 centimetres of affected foot and she/he lifts the pelvis. (b): Unaffected patient's leg is resting on the physioball and patient lifts the pelvis with his/her affected leg at 90° knee and hip flexion.</p>	
<p><b>6. Unilateral bridging:</b> Starting position is the same that exercise 1. Lifting the unaffected leg off the plinth, with the patient maintaining the pelvic bridge position, the physiotherapist steadying the affected leg.</p>	
<p><b>7. Unilateral bridging physioball:</b> The patient's leg rest on a physioball and she/he lifts the pelvis and the unaffected leg. The physiotherapist steadying the affected leg if it is necessary.</p>	
<p><b>8. Lower trunk rotation:</b> The patient's leg rest on a physioball at 90° flexion knees and hips. The patient rotates lower trunk. The physiotherapist steadied the patient's chest and supported the affected leg.</p>	
<p><b>9. Lower trunk flexion:</b> The same position that exercise 8, but legs patient bend on her/his chest.</p>	



**Figure 1:** Modified Ashworth Scale. In the experimental group (CORE) decrease lower limb spasticity and in the control group (CTRL) increase it.



**Figure 2:** Spanish-Trunk Impairment Scale 2.0. Coordination subscale, experimental group (CORE) is better than control group (CTRL).

**Disclosure:** No