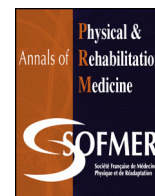




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Letter to the editor

Post-stroke rehabilitation devices offered via the Internet: Based on randomized controlled evidence?



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Dear Editor,

In 2013, there were 25.7 million stroke survivors and 6.5 million stroke-related deaths [1]. Previous studies have indicated that approximately 40% of stroke survivors remain with functional impairments and need physical rehabilitation [2]. However, many barriers could limit access to continuous physical rehabilitation for these patients, so devices that complement or assist in the rehabilitation process can be of great help [3].

The quality, safety and efficacy of medical devices should be evaluated in randomized controlled trials (RCTs) [4]. However, the efficacy of many medical devices entering the market in the United States and the European Union (EU) has not been evaluated [5]. Unproven post-stroke rehabilitation devices could be useless or even harmful to patients, thereby increasing healthcare costs [6]. Previous studies have found that post-stroke rehabilitation devices without a rigorous evidence base are being commercialized [5,6]. However, we lack information on the prevalence of these devices.

The objective of this cross-sectional study was to determine the prevalence of post-stroke rehabilitation devices offered via the Internet whose efficacy was proven in an RCT and factors associated with this prevalence.

We searched Google for post-stroke rehabilitation devices during July 2016 by using the terms (stroke devices), (stroke rehabilitation devices), and (acute stroke devices). Then, one of the authors revised the first 100 results of each search to build a list of all post-stroke rehabilitation devices found. We also collected the characteristics of the device by visiting the official Webpage for the device. Finally, we searched Medline via PubMed and Google Scholar for the mechanism of action of the devices for rehabilitation purposes and evaluated whether the mechanism had been found efficacious in an RCT.

Our main outcome was the prevalence of devices with an RCT that had proved efficacy for rehabilitation purposes. Factors associated with this prevalence were the limb exercised (only upper limbs, only lower limbs, or both), price (≥ 250 USD, < 250 USD, price not mentioned), the inclusion of a telerehabilitation service (yes or no), whether the device could be also used as a splint (yes or no), whether the device could also help with daily activities such as eating or walking (yes or no), and whether the device also provided electrical stimulation (yes or no).

Data are described with number (%). To evaluate factors associated with the main outcome, we used Poisson regression with robust variance to calculate prevalence ratios (PRs) and their 95% confidence intervals (95% CIs). All analyses involved using STATA 14.0. $P < 0.05$ was considered statistically significant.

We found 97 different commercial post-stroke rehabilitation devices offered via the Internet: 86 (88.7%) were designed for upper limbs, 24 (24.7%) with cost < 250 USD, 47 (48.5%) without a mention of price, 15 (15.5%) included telerehabilitation devices, 25 (25.8%) were electrical-stimulation devices, 18 (18.6%) could also help with daily activities such as eating or walking, and 32 (33.0%) could also be used as splints (Table 1). Overall, 34 devices (35.1%) had an RCT that had proved efficacy for rehabilitation purposes.

The RCTs evaluated included several diverse outcome measures defined by the International classification of functioning, disability and health [7], such as range of motion; ability to pick up, move and release objects; movement control; tone and muscle strength; reflex activity; balance and gait velocity; postural oscillation; upper-extremity function; performance speed in a fine motor task; neurologic deficit; unilateral gross manual dexterity; elbow extension; activities of daily living; and quality of life.

In the regression analysis, only electrical stimulation property was associated with prevalence of having an RCT proving efficacy for rehabilitation purposes (PR = 1.78, 95% CI: 1.06–3.01) (Table 1).

Most of the evaluated devices were designed for upper limbs possibly because upper limbs are usually more severely affected than lower limbs after a stroke, and the rehabilitation usually lasts longer [8]; however, the clinical use of these upper-limb devices is poor [9]. In addition, one third of the devices were also used as splints, which could prevent the development of contracture and support the paralyzed segments avoiding painful limitation of passive movements, although the usefulness of splints to improve rehabilitation is still inconclusive [8].

The low prevalence of devices with an RCT that proved efficacy is not surprising, given that current legislation is flexible in many countries. The US Food and Drug Administration is responsible for the surveillance and approval of medical devices and classifies them as low-, moderate-, or high-risk devices [5]. Although the last 2 categories are required to prove efficacy for commercial approval, moderate-risk devices could be exempt from this requirement if they prove to be “substantially equivalent” to a pre-existing legally marketed device in terms of safety and

Table 1

Factors associated with post-stroke rehabilitation devices offered on the Internet whose efficacy was proven in an RCT ($n=97$).

Characteristics	Device with an RCT ^a			P-value
	No $n=63$	Yes $n=34$	PR (95% CI)	
<i>Limb exercised</i>				
Only upper limbs	45 (68.2)	21 (31.8)	Ref.	
Only lower limbs	8 (72.7)	3 (27.3)	0.86 (0.31–2.41)	0.770
Upper and lower limbs	10 (50.0)	10 (50.0)	1.57 (0.89–2.77)	0.117
<i>Price</i>				
< 250 USD	16 (66.7)	8 (33.3)	Ref.	
≥ 250 USD	15 (57.7)	11 (42.3)	1.27 (0.61–2.62)	0.520
Did not mention price	32 (68.1)	15 (31.9)	0.96 (0.47–1.94)	0.904
<i>Telerehabilitation device</i>				
No	52 (63.4)	30 (36.6)	Ref.	
Yes	11 (73.3)	4 (26.7)	0.73 (0.30–1.78)	0.487
<i>Can be used as a splint</i>				
No	40 (61.5)	25 (38.5)	Ref.	
Yes	23 (71.9)	9 (28.1)	0.73 (0.39–1.38)	0.335
<i>Can also be used to help with daily activities</i>				
No	50 (63.3)	29 (36.7)	Ref.	
Yes	13 (72.2)	5 (27.8)	0.76 (0.34–1.69)	0.496
<i>Electrical stimulation devices</i>				
No	51 (70.8)	21 (29.2)	Ref.	
Yes	12 (48.0)	13 (52.0)	1.78 (1.06–3.01)	0.030

Data are n (%). PR: prevalence ratio; 95% CI: 95% confidence interval.

^a An RCT that proved efficacy for rehabilitation purposes.

effectiveness. This exception has been criticized for allowing the sale of new devices without a formal evaluation [6].

In the EU, commercial medical devices must be approved by Notified Bodies, which have been criticized for approving medical devices with insufficient scientific evidence for efficacy [5]. In fact, the EU pre-approval process does not require demonstration of a device's efficacy, and no RCT is required [10]. Moreover, studies are not required to be published and can be held by companies and therefore not accessible to the scientific community [10].

Having an RCT proving efficacy was more frequent with electrical-stimulation devices, probably because the mechanism of these devices is similar and has been well studied for physical rehabilitation of many muscular groups [11].

Governments should require medical devices to have published RCTs that demonstrate efficacy and should improve their regulation mechanisms. They should consider the possibility of delegating regulatory activities to highly qualified independent agencies. Moreover, because of the importance of this information to the public, a registry of medical devices approved for commercialization that includes evidence from clinical studies should be developed [5].

In addition to the importance of an RCT that proves the efficacy of any rehabilitation device, these RCTs must use outcomes relevant to the patient. In the reviewed studies, several RCTs used outcomes that improved some measures of range, movement or tone of the upper or lower extremity. However, these measurements cannot ensure achievement of recovery that improves functionality, quality of life or even morbidity and mortality of the study population.

The limitation of our study was that we used only 2 search engines to find RCTs, although Google Scholar could be extensive enough to give most of the relevant published RCTs [12].

In conclusion, just more than one third of evaluated post-stroke physical-rehabilitation devices offered via the Internet had a RCT

that proved efficacy, and this prevalence was greater for electrical stimulation devices. This finding could be a reflection of the flexible regulation mechanisms in several countries. The impact of these devices without a scientific evidence base on population health and healthcare costs should be studied and the consensus of device approval for commercialization defined.

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Disclosure of interest

The authors declare that they have no competing interest.

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