Applications, effectiveness and limitations of robotic physiotherapy in patients with spinal cord injury

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ABSTRACT

Spinal cord injury (SCI) is a particularly serious pathological condition which puts a great strain on the health and functional status of the affected patient, while at the same time is accompanied by a very high morbidity and mortality rate. Among the various rehabilitation methods that have been used for the treatment of SCIs, since the 1990's, robotic physiotherapy has been an innovative alternative option. Robotic physiotherapy involves the application of a series of robotic devices the use of which is intended to assist and enhance the level of a number of the patient's functions that have been severely affected form the SCI, including their motor and sensory performance. This paper will attempt a brief narrative review of the literature in relation to the most recent research data regarding the applications, the effectiveness and the limitations of the use of robotic physiotherapy in patients suffering from spinal cord injury.

A total of 73 published papers since 2010 were isolated and studied, including 49 original research studies and 24 reviews / systematic reviews / meta-analyses. The main conclusion of the review is that with the use of these devices, patients with SCI have the possibility of a satisfactory level of safe walking, combined with the improvement of their activities of daily living and their quality of living. Ongoing research in this field will most probably enable the further improvement of the applications of the method in the coming years.

Key words: Spinal cord injury, Robotic, Rehabilitationw

Introduction

Spinal cord injury (SCI) is a particularly serious pathological condition which puts a great strain on the health and functional status of the affected patient, while at the same time it is accompanied by a very high morbidity and mortality rate. According to the recent epidemiologic data, it is estimated that for the year 2019, an incidence of 900.000 new cases were recorded globally, while at the same time, the total number of patients suffering from this injury during this period of time (prevalence) was estimated at 20.6 million [1]. At the same time, the highly significant epidemiological indicator of years in which patients lived with severe functional impairment (years lived with disability - YLD) was estimated at 6.2 million years; during the same period of time, the incidence of the injury was increasing, while the age of the affected

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patients was decreasing. It has now become apparent that both the incidence and severity of injury have been steadily increasing over the last 30 years, with the most severe effect being recorded in men and patients in older age groups [2].

The most commonly accepted and currently used classification of SCIs is the I.S.N.C.S.C.I. system (International Standards for Neurological Classification of Spinal Cord Injury system), which is more commonly known as the ASIA system (American Spinal Injury Association classification system) [3]; ASIA system classifies SCIs into five separate categories (A, B, C, D, E), according to the sensory and the motor impairments that have resulted from the injury. Grade A designates complete injury, whereas grade E patients present with no impairment at all [4]. In addition, incomplete SCIs can be classified into six syndromes with different clinical features one from the others: those are the anterior cord, the posterior cord, the central cord, the Brown-Sequard, the connus medullaris and the cauda equine syndromes, with varying clinical features and prognosis [5].

The effects of a severe SCI are not only limited to the impaired mobility and independence of the patient, but also include a large number of complications of the injury, including bowel and bladder disturbances (including recurrent and severe urinary tract infections), cardiovascular and pulmonary pathologies (orthostatic hypotension, deep vein thromboses, respiratory system infections), autonomic system complications (spasticity, autonomic dysreflexia) and even musculoskeletal system complications (fractures and pressure ulcers) [6]. Taking all the above into account, it is obvious the great importance of a comprehensive and well-designed rehabilitation programme, which will seek to improve the patient's mobility, while minimising, as far as possible, the complications of the SCI; this involves, in the vast majority of the cases, a long, expensive and even exhausting for the patient – and the therapists – rehabilitation program [7].

Among the various rehabilitation methods and systems that have been used for the treatment of SCIs, since the 1990's, robotic physiotherapy has been an innovative alternative option. Robotic physiotherapy involves the application of a series of robotic devices the use of which is intended to assist and enhance the level of a number of the patient's functions that have been severely affected form the SCI, including their motor and sensory performance [8]. A number of studies have shown that compared to conventional rehabilitation techniques, robotic applications have the potential to offer a fully controlled and intensive rehabilitation regimen, providing accurate information on the patient's progress, while at the same time greatly reducing the physical burden on therapists [9,10]. The use of robotic devices for the gait training commenced in 1994 with "Lokomat" [11], and in the following years, a wide range of rehabilitation robotic devices were developed and applied, which were classified into four main categories: 1) Grounded exoskeletons, 2) End – effector devices, 3) Wearable exoskeletons and the most recently developed 4) Soft exoskeletons or "exosuits" [12].

Despite, however, the significant recent technological development and the scientific research in this field, it is still not clear which type of robotic devices and rehabilitation protocols are the optimum for each therapeutic indication [13].

This paper will attempt a brief narrative review of the literature in relation to the most recent research data regarding the applications, the effectiveness and the limitations of the use of robotic physiotherapy in patients suffering from spinal cord injury. An extensive literature review was carried out on the following scientific databases: PubMed/NCBI, Scopus, Science Direct, Nature and PEDro, starting from the year 2010. The key-words (mesh terms) used in the search engines of the above data bases were: *spinal cord injury* AND *robotics* AND (*physiotherapy* OR *rehabilitation*). The inclusion criteria were original research studies, reviews and systematic reviews / meta-analyses concerning human participants. The flow-diagram of the literature review, according to the principles of PRISMA [14] is presented in Diagram 1.

Discussion

A total of 73 published papers were isolated and studied, including 49 original research studies and 24 reviews / systematic reviews / meta-analyses. The main findings of the present literature review are going to be presented in the following sections.

Applications of robotic physiotherapy

Following serious traumatic injury to the central nervous system, whether it involves the brain (head injuries) or the spinal cord, patient's balanced is significantly disturbed, due to spasticity, muscle weakness and muscle imbalance [15]; the end result is that motor commands given by the patient do not produce the expected motion, causing gross disturbances in his movement patterns. It is therefore obvious that the rehabilitation process following severe spinal cord injury is a very complex and demanding process.

As early as the beginning of this century, hospitals and rehabilitation centers gradually began to incorporate the use of robotic physiotherapy as a key part of the multi-level rehabilitation program for patients with severe traumatic spinal cord injuries. The main advantages offered by robotic physiotherapy can be summarized as follows [16]: (a) the robotic devices that are available today allow the patient to practice a wide range of motor activities, at various levels of intensity and with the possibility of unlimited repeatability, (b) during training with robotic devices, the patient is offered continuous feedback on the results of his/her movements, either in the form of visual or local-sensory stimuli, (c) robotic devices provide the advantage of training diversity, both in generic movements and activities, but also in their variations, along with special tasks and skills of the patient's activities of his daily life, (d) finally, robotic physiotherapy provides a safe environment for exploring their motion skills.

The first robotic physiotherapy device used was the "Locomat" (Hocoma AG, Volketswil, Switzerland) [17], whose function was based on the use of two robotic arms adapted to the patient's legs and assisted the movements of his knee and hip joints during the patient's practice of walking on an electric treadmill; at the same time, one part of the patient's body is supported by an overhead unloading device, thus allowing the patients, even in cases of great muscular weakness, to start exercising in the early stages after the injury.

Nowadays, a fairly large number of robotic devices are used in the rehabilitation of patients with severe spinal cord injuries, including the ARGO, the Brain-controlled robotic exoskeleton (EXO), the EKSO Bionics, the HAL (Hybric assisted limb), the INTEGO, LokoHelp robotic device, the Lokomat FreeD Module Pelvic, the Lokomat-Pro (without FreeD Module), the LOPES exoskeleton robotic device, the Mindwalker exoskeleton, the ReWalk exoskeleton, the WPAL (wearable power-assist locomotor) and the Welwalk WW-1000 robotic device [18]. Their purpose is to assist rehabilitation of the musculoskeletal, cardio-respiratory, urinary, neuronal and somatosensory system at all stages, while at the same time reducing to the best possible extent the physical fatigue and strain of their therapists [19].

Recent literature data

Since it is not possible, in the context of a short literature review, to present all the encountered original clinical studies, the results of the systematic reviews and meta-analyses will be presented. Table 1 summarizes the main findings of those systematic literature reviews.

Swinnnen et al. in 2010 [20] published a systematic literature review regarding the effectiveness of robot – assisted training of the gait of patients who sustained a serious spinal cord injury. The authors included four pre-experimental cohort clinical trials and two randomized-controlled trials, with 43, in total, participants. Lokomat was the robotic device used in five of the clinical trials and the LokoHelp robotic device was used in the last one. The main research questions of the review were to assume whether robot-assisted gait training (a) improved SCI patients' motor ability, while at the same time reduced spasticity, (b) improved performance and participation in daily-life activities, (c) improved social participation and overall quality of life and, (d) improved components of the International Classification of Functioning, Disability and Health (ICF 19) scale [21] better than other rehabilitation methods. The final conclusion was that they is insufficient evidence to reach to solid scientific findings in relation to the efficacy of the method since the participants' sample was very small, the rehabilitation and training procedures were heterogenous, the follow-up periods were not sufficient and higher quality clinical trials are needed in order to answer the above mentioned research questions.

Two years later, Mehrholz et al., [22] published in Cochrane Database of Systematic Reviews a systematic review and meta-analysis of 5 randomized-controlled studies (309 participants in total), regarding the efficacy of the various locomotor training methods, including robotic devices, after SCI. Lokomat was the robotic device used for the patients' rehabilitation, and the primary outcome measures of the review was speed of walking and walking capacity. The main finding of the study were that there was no clear evidence in relation to the superiority of any of the rehabilitation methods compared to the others; particularly for the robotic (Lokomat) assisted training, the effects regarding the outcome criteria of the

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TABLE 1:

The main findings of the systematic literature reviews

Author / country	Type of study	Participants	Method of robotic rehabilitation	Research questions	Results
Swinnen et al, (2010), Belgium [20]	Systematic literature review	6 clinical trials, 43 patients with SCI	Lokomat, LokoHelp	Improvements in motor ability, spasticity, daily life activities, social participation, quality of life and ICF 19 score	Cannot reach to a definite conclusion – small sample, methodological flaws, heterogenous rehabilitation procedures, small follow-up.
Mehrholz et al., (2012), Germany [22]	Systematic literature review and meta-analysis	5 randomized-controlled clinical trials, 309 patients with SCI	Lokomat	Speed of walking, walking capacity	No clear evidence regarding the superiority of any rehabilitation method, including the robotic-assisted.
Saartje Duerinck and Swinnen (2012), Belgium [24]	Systematic literature review	15 clinical trials	4 different types of robotic-assisted ankle-foot actuation orthotic devices	Neuromotor control of walking, restoration of normal gait pattern	Difficult to draw solid conclusions – robotic-assisted orthotic devices are a promising prospective for restoring normal gait pattern after SCI
Morawietz and Moffat, (2013), U.K. [23]	Systematic literature review	8 randomized-controlled clinical trials, 411 patients with incomplete SCI	Lokomat	Ambulatory function and gait characteristics	Inconclusive findings – no obvious superiority of one method (including the robotic-assisted) over the others.
Mehrholz et al., (2017), Germany [13]	Systematic literature review	13 randomized-controlled clinical trials, 586 patients with incomplete SCI	Lokomat	Walking distance and walking speed	There is strong evidence that robotic-assisted training is not superior in comparison to the conventional rehabilitation methods
Cheung et al., (2017), Hong Kong [25]	Systematic literature review and meta-analysis	11 randomized-controlled clinical trials, 443 patients with SCI (both complete and incomplete)	Lokomat	Physical activity, mobility and functional ability	Walking impendence and endurance had better improvement in the robotic-assisted group; lower limb robotic-assisted training was as effective as the other forms of rehabilitation.
Nam et al., (2017), S. Korea [26]	Systematic literature review and meta-analysis	10 clinical trials, 502 patients with SCI	Lokomat	Gait distance, leg strength, functional level of mobility and independence	Lokomat-assisted gait training is superior to the conventional methods in improving mobility-related outcomes of patients with incomplete SCI.
Hollanda et al., (2017), Brazil [17]	Systematic literature review	39 clinical trials	12 different rehabilitation robotic devices	Multiple functional parameters	The rapid evolution of technology provides multiple opportunities to improve the results of SCIs patients' rehabilitation with the aid of various types of robotic devices.
Singh et al., 2018, Canada [27]	Systematic literature review	12 clinical trials, 72 patients with SCI	Upper extremity robotic rehabilitation devices: RiceWrist, Haptic Master, Armeo Spring, ReoGo, MAHI Exo-II and the InMotion 3.0 Wrist robot.	Body structure, function and activity level outcome measures	Substantial clinical improvement was observed in patients who had mild to moderate impairment of their neurological function (those who had mild spasticity while maintaining some level of motor function).

Hayes et al., (2018), UK [28]	Systematic literature review	12 clinical trials, 521 patients with SCI	ReWalk, Lokomat	Walking distance and walking speed	The use of robotic - assisted therapy did not improve the patients' outcome criteria more than conventional methods of rehabilitation; this method provides the best results in the context of a multimodality rehabilitation intervention.
Sackleton et al., (2019), S. Africa [29]	Systematic literature review and meta analysis	27 clinical trials, 308 patients with SCI	ReWalk, Ekso, Indego, Rex	Walking perforamce, cardiovascular demand, VAS, Quality of life	The most favorable findings were found in relation to walking parameters; limited evidence regarding its training effects.
Alashram et al., (2021) [30]	Systematic literature review	16 clinical trials, 658 patients with SCI	Lokomat	Various functional parameters	The Lokomat robotic device has the potential to improve walking speed and distance, range of motion, strength and mobility of the patients - the so-far evidence does not support its effectiveness on balance, cardiorespiratory fitness, quality of life and depression.
Zhang et al., (2022), China [30]	Systematic literature review	12 clinical trials, 353 patients with SCI	Lokomat versus wearable exoskeleton	Walking paramaters.	Both robotic device systems had positive clinical effects on the rehabilitation of this group of patients, especially on walking distance and speed; wearable exoskeleton robotic devices have an advantage over the Lokomat robotic device in walking speed rehabilitation.

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study were not clear. The following year, the systematic review of Morawietz and Moffat [23], which investigated the same research question, came to roughly the same conclusions: the current evidence regarding the effectiveness of the various methods of locomotor rehabilitation (including the robotic – assisted physiotherapy methods) in patients with incomplete SCI is inconclusive, without demonstrating the clear superiority of one method over the others.

In a different context, Saartje Duerinck and Swinnen (2013) [24] published a systematic literature review regarding the efficacy and the added value of the robotic-assisted, actuated ankle-foot orthotic devices in restoring gait function in patients with SCI. Fifteen relevant clinical studies were analyzed, in which four different ankle-foot actuation orthotic devices were used according to their actuator and control mechanism. Once more, the small sample of the participants along with the wide variety of the studies' designs, made it impossible to reach into solid conclusions; nevertheless, it seems that artificial pneumatic muscles along with myoelectric control are a promising perspective in the effort to restore the normal gait pattern of patients with severe SCI.

Mehrholz et al., (2017) [13] conducted a systematic literature review comparing the effectiveness of robotic-assisted gait training or body-weight-supported treadmill training (BWSTT) to other rehabilitation methods in patients with SCI. They included 13 randomized-controlled studies with 586 patients, with the primary outcome criteria being walking distance and walking speed. The main conclusion of the review was that both robotic-assisted training and BWSTT did not show superior results in gait training compared to conventional rehabilitation methods. In fact, these results were so strong, based on very good quality studies, that according to the authors, no further research is needed in this specific area.

Another systematic literature review and meta-analysis was published in the same year [25] regarding the efficacy of robot-assisted training in patients with SCI; 11 randomized-controlled studies with 443 participants were included in the statistical analysis. The results of the study showed that walking impendence and endurance had better improvement in the robotic-assisted group, whereas lower limb robotic-assisted training was as effective as the other forms of rehabilitation. According to the authors, robot-assisted training seems to be a useful adjunct rehabilitation method for patients suffering from severe SCI. Similar positive results in relation to the use of the robotic device Lokomat for the improvement of walking function and activity of patients with SCI concluded the systematic review and meta-analysis of Nam et al., (2017) [26], which analyzed 10 trials (both randomized-controlled trials and parallel group or cross-over design trial), with 502 participants. The main finding of this review was that robot-assisted gait training is superior to the conventional methods in improving mobility-related outcomes of patients with incomplete SCI, especially in the acute stages of the injury.

Holanda et al., (2017) [18], published a large systematic literature review (39 published papers) on the efficacy of robotic assisted gait rehabilitation for patient with SCI; they included a large number of different and novel robotic devices, which showed very promising results in many outcome criteria (pain perception, spasticity, proprioception, sensitivity to pressure, vibration and temperature, walking parameters, sitting posture and even psychological functions). The authors' final conclusion was that the rapid evolution of technology provides multiple opportunities to improve the results of SCIs patients' rehabilitation with the aid of various types of robotic devices.

Singh et al., [27], one year later, in a different context, published a systematic literature review regarding the efficacy of robot-assisted rehabilitation for the upper extremity in patients with SCI; they included 12 original papers, with 73 participants in total. The robotic devices used in the rehabilitation process were the RiceWrist, Haptic Master, Armeo Spring, ReoGo, MAHI Exo-II and the InMotion 3.0 Wrist robot. The results of the study showed that substantial clinical improvement was observed in patients who had mild to moderate impairment of their neurological function and more specifically in those who had mild spasticity while maintaining some level of motor function.

In another systematic literature review, Hayes et al., (2018) [28], studied the effect of robot assisted gait training on the temporo-spatial characteristic in patients with SCI; the study involved 12 clinical trials with 521 participants, whose neurological level of injury ranged from C1 – L3. The primary outcome measures of the study were the patients' walking distance and walking speed. The key finding of the study was that the use of robotic - assisted therapy did not improve the patients' outcome criteria more than conventional methods of rehabilitation. Some potential for improving patient's mobility was observed, but it is not clear exactly which robotic device and which group of patients offers the greatest benefit. It appears that this method provides the best results in the context of a multimodality rehabilitation intervention rather than monotherapy.

Sackleton et al., (2019) [29], in a systematic literature review and meta-analysis studied the effectiveness of robotic-assisted locomotor training on a number of parameters of patients with SCI, including gait performance, cardiovascular system functions, secondary complications of the injury and overall patient satisfaction with the rehabilitation method. The most favourable findings were found in relation to walking parameters (6 and 10 minutes walking test), whereas, no statistical significant changes were found in the cardiovascular indices. According to the authors, robotic-assisted physiotherapy is a useful tool in the rehabilitation process of patients with SCI, with limited evidence regarding its training effects.

Alashram et al., (2021) [30], investigated the effectiveness of the robotic device Lokomat for the gait training in patients suffering from SCI; after analyzing 16 clinical trials (658 patients), they concluded that 1) After an incomplete SCI, the Lokomat robotic device has the potential to improve walking speed and distance, range of motion, strength and mobility of the patients, but on the other hand, 2) The so-far evidence does not support its effectiveness on balance, cardiorespiratory fitness, quality of life and depression. The last study that will be discussed in the context of this literature review is the recently published systematic literature review of Zhang et al., (2022) [11], who compared the efficacy of Lokomat and wearable exoskeleton-assisted gait training in patients after SCI. The authors, after analyzing 12 clinical trials (353 patients in total), concluded that both robotic device systems had positive clinical effects on the rehabilitation of this group of patients, especially on walking distance and speed; it seems that wearable exoskeleton robotic devices have an advantage over the Lokomat robotic device in walking speed rehabilitation.

Over the last 20 years, the use of robotic devices in the rehabilitation process of patients with severe neurological impairments caused by either acute stroke or SCI has gained increasing acceptance in the scientific community. These are devices that have the ability to provide continuous, repetitive and systematic physiotherapy movements and interventions, greatly assisting the role of physiotherapists [31,32]. In addition, apart from the relief they offer to the difficult daily tasks of the physiotherapists, through the various sensors integrated in them, they give continuous feedback to the patients in relation to their performance of the exercises, while at the same time they evaluate the general progress of their rehabilitation process [16, 33]. In recent years, a large number of robotic devices have been manufactured and used in clinical practice, most of which are wearable and at the same time operate very close to the joints of patients, exerting a synergistic action with them [34]. Lokomat was the first robotic device used widely for this purpose, a fixed exoskeleton which was suspended over a treadmill [35]. Gradually, with the evolution of technology and the experience that was acquired, rehabilitation with the help of robotic devices gradually began to move away from this model and focus on the use of overground powered lower limb exoskeletons which allow the SCI patients with a significant degree of muscular weakness of the lower limbs to stand and walk with a type of gait that closely resembles the normal one [36, 37].

In the present literature review, recent scientific data regarding the applications, the effectiveness and the limitations of robotic physiotherapy were investigated, analysing the relevant systematic reviews and meta-analyses that have been published since 2010. The main findings of the review can be summarized in the following: (a) none of the earliest chronological reviews had reached a clear conclusion regarding the effectiveness of robotic physiotherapy [13,20,22-24]. For example Mehrhrolz et al., (2017) [13], reported that robotic-assisted physiotherapy had no advantage over conventional rehabilitation methods in improving patients' walking speed, (b) gradually, over time, as the experience of therapists in the use of these devices increased and their technical characteristics improved outcomes were more favorable. For example, Nam et al., (2017) [26], reported that Lokomat-assisted gait training is superior to the conventional methods in improving mobility-related outcomes of patients with incomplete SCI, whereas Singh et al., (2018) [28] observed the best results in those patients with SCI who had relatively mild degrees of spasticity, while retaining acceptable motor function and (c) nowadays research

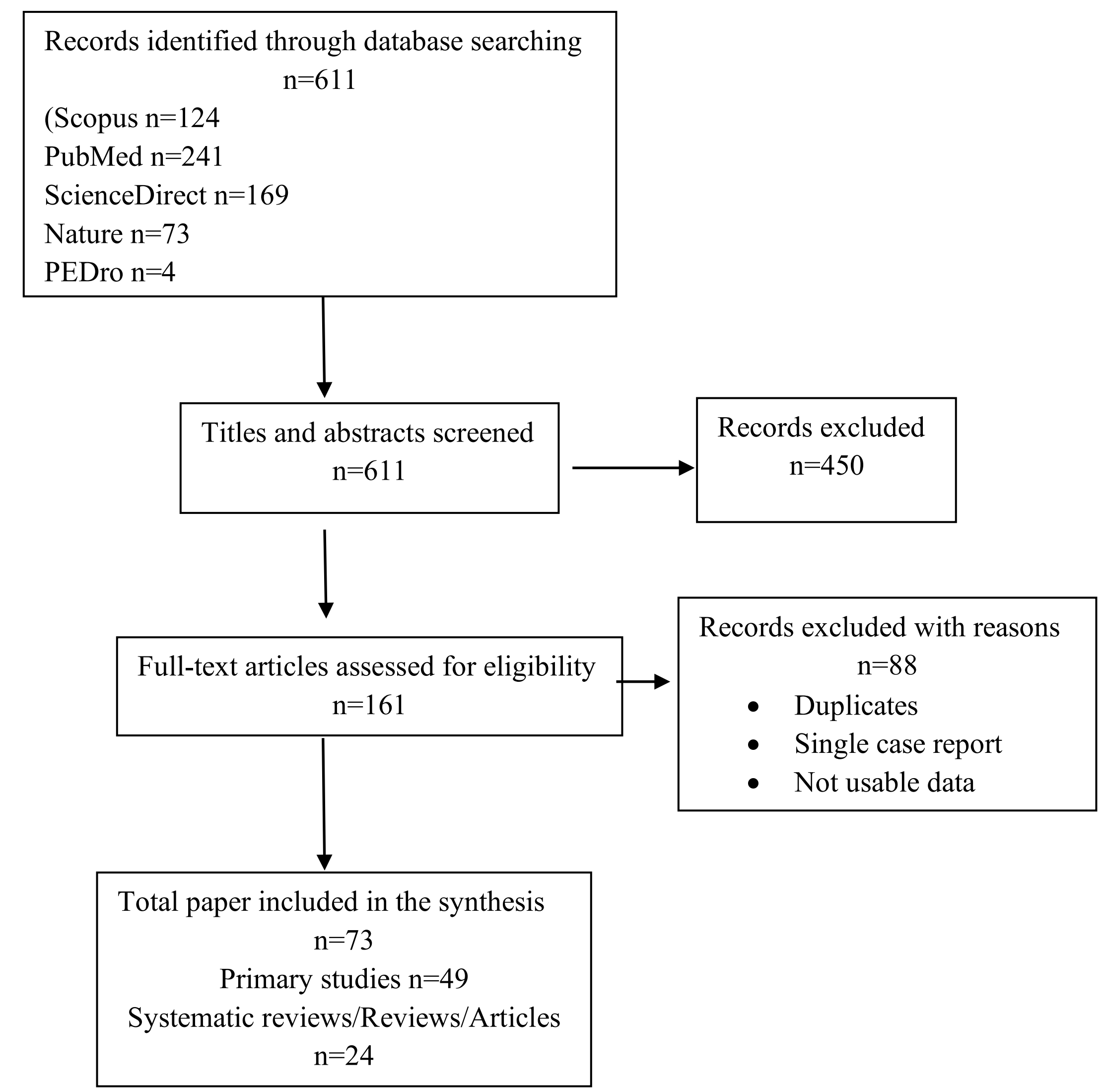

Diagram 1: The flow-diagram of the present literature review

data suggest that it is likely that the newest exoskeleton robotic devices, have some advantage over Lokomat – the first introduced one, for walking speed [30].

Conclusion

With the contribution of modern technology the applications of robotic-assisted physiotherapy are now an important tool in the multimodal rehabilitation effort of patients with severe SCIs. The recent research data show that with the use of these devices, patients with SCI have the possibility of a satisfactory level of safe walking, combined with the improvement of their activities of daily living and their quality of living. Ongoing research in this field will most probably enable the further improvement of the applications of the method in the coming years.

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