Ashley Bender, Bridget Daly, Hannah Lukin

Critically Appraised Topic

Title: The Effects of a robotic arm on upper extremity function for individuals post-stroke in the acute phase (>8 weeks).

There is strong evidence to support the effectiveness for the use of a robotic arm to improve upper extremity motor function in the acute setting following stroke.

Prepared by: Ashley Bender, Bridget Daly, and Hannah Lukin

CLINICAL SCENARIO:
Conditions/problems:
- A stroke occurs when blood supply to a portion of the brain is blocked for a period of time which leads to damage of brain tissue. Depending on the location of the infarction, an individual may have impairments in vision, motor control, cognition, awareness, language, and sensation. The damage may lead to permanent or acute damage (less than 8 weeks). Impairments are usually found on the opposite side of the body in relation to the affected side of the brain.

Residual effects that are looked at through our intervention:
- Physical: neurological delays/impairments, brain damage, poor motor control, lack of motor skills (National Stroke Association, 2016).

Incidence/prevalence:
- Nearly 800,000 in United States have a stroke every year.
- Number 5 cause of death in the United States.
- Stroke kills around 130,000 people every year (1 in every 20 dies).
- Someone has a stroke every 40 seconds in the United States.
- Nearly three-quarters of all strokes occur in people over the age of 65. The risk of having a stroke more than doubles each decade after the age of 55.
- Strokes can and do occur at ANY age. Nearly one fourth of strokes occur in people under the age of 65 (CDC, 2016)
- More women have strokes than men (American Stroke Association, 2016)
- According to the National Stroke Association:
- 10% of stroke survivors recover almost completely
- 25% recover with minor impairments
- 40% experience moderate to severe impairments that require special care
- 10% require care in a nursing home or other long-term facility
- 15% die shortly after the stroke
- Approximately 14% of stroke survivors experience a second stroke in the first year following a stroke (NINDS, 2016)

Impact of the Problem on Occupational Performance:
- Stroke can lead to a variety of different impairments, which therefore has different effects on the ability to perform occupations. For example, motor impairments of the UE and LE can lead to difficulty in performing ADLs (dressing, feeding, bathing). Although unilateral occupations may be adapted to the use of the nonaffected side, occupations with bilateral movement may require greater assistance. To allow for as much independence as possible, preparatory methods may be used. With patients in the acute post-stroke phase (8 weeks or less post-stroke), all occupations will be impacted due to the residual effects of the patient. Some of

the most common occupations that will be impaired include feeding, bathing, dressing, and overall personal hygiene.

Intervention:

- The idea behind the robotic arm is that it can guide and support the individual's affected limb during ROM exercises. By supporting the affected limb, the client is able to perform a higher number of repetitions without completely fatiguing the muscles. Individuals have also found the robotic arm more interesting, which can improve their motivation during therapy compared to the conventional tactics.
- Intervention Schedule: Each study included therapy with a robotic arm in addition to conservative occupational therapy, one therapist conducted the robotic arm therapy and another OT conducted conservative therapy. Average robotic arm therapy was 40 minutes 5 days a week and conservative therapy was around 1 hour 30 minutes 5 days a week for 4-5 weeks. The robotic arm therapy was conducted separate from the conservative therapy and it was not stated if therapy was conducted in the client's room or a therapy room.
- Types of Robotic arm: The type of robotic arms were similar with one providing audio feedback to alert the client when to begin and end the motion and all three robotic arms provided visual feedback from a monitor. The robotic arms ranged in their degrees of freedom from 5 degrees of freedom in the fingers providing PROM with the wrist restrained, one provided assist-as-needed during 8 different reaching movements of the elbow and shoulder with 2 degrees of freedom, and another provided 3 degrees of freedom of the elbow and shoulder.
- Inclusion criteria: medically stable, sufficient cognition and language abilities, first CVA, unilateral paresis,
- Exclusion criteria: severe sensory deficit in affected limb, severe cognitive impairment, severe visual deficits, severe apraxia, younger than 18 or older than 85+

OT theoretical basis

- The motor learning and motor control frame of reference is an appropriate theory supporting the use of a robotic arm in therapy. The motor learning and motor control frame of reference sees learning as a process in which the body is constantly taking in sensory information, and with enough repetition of a sensory stimuli, changing the neuroplasticity of the brain. The process of learning is called motor learning and through this process an individual may improve/learn new motor skills and gain greater motor control of these movements.
- Hypothesis: With the use of a robotic arm, for preparatory exercises, client will display an increase in repetitions of movement and a decrease in assistance of the robotic arm due to the increased neuroplasticity of the affected upper extremity.

Science behind the intervention:

- The mechanism of change thought to be used with robotic arms is related to the concept of neuroplasticity in improving functional outcomes after a stroke. A robotic arm has the ability to offer a high intensity and high dosage training, which would assist in re-creating those neural connections that may have been impaired due to the

stroke (damage to the brain may impair ability to take in information, process information, and send out neural signals to allow for movement). By increasing the repetitions of movements with the UE, the brain will be able to reorganize itself to recognize the movement and recreate the motor movement pathway needed in order to allow function of the limb. The robotic arm also assists in preventing fatigue of muscle overuse during preparatory exercises which allows individuals to complete an increased number of repetitions, which is beneficial in impacting the neuroplasticity of the brain.

Why is this intervention appropriate for OT?

- This intervention takes a preparatory method approach. The robotic arm focuses on increasing the number of repetitions of UE tasks tolerated by the individual in hopes to relearn the motion of the UE by regaining neurological signaling. By doing this, the individual may regain motor control of a variety of different movements and therefore also be able to regain motor skills that are essential for function. Functional use of the UE is necessary for a variety of occupations (dressing, feeding, cleaning), especially those that require bilateral use of UEs in order for the individual to become independent. Therefore, as an occupational therapist we may use this intervention to assist in preparing the UE by regaining necessary motor control to help an individual be able to perform necessary occupations in the future.

FOCUSED CLINICAL QUESTION: What is the effectiveness of using a robotic arm with patients post-stroke in an acute setting (less than 8 weeks) on upper extremity function compared to conventional therapy?

SEARCH SUMMARY: robotic arm, acute phase, sub-acute phase, upper extremity function, hand function using the University of Wisconsin-La Crosse Murphy Library combined databases. We also searched for articles using OT Seeker, OT CATS, National Rehabilitation Information Center, and National Institute on Disability and Rehabilitation Research (NIDRR).

CLINICAL BOTTOM LINE: Studies have shown statistically significant improvements for robotic therapy, however, no statistically significant differences were found for conventional therapy and robotic therapy.

Limitation of this CAT: This critically appraised paper (or topic) has been reviewed by occupational therapy graduate students and the course instructor.

Search Terms	Inclusion and Exclusion Criteria
Robotic arm, acute phase, sub-acute phase, upper extremity function, hand function	Inclusion: acute (less than 8 weeks), upper extremity function, robotic arm Exclusion: chronic, sub-acute, lower extremity

TABLE 1: SEARCH STRATEGY

TABLE 2: SUMMARY OF STUDY DESIGNS OF ARTICLES RETRIEVED

Level	Study Design/ Methodology of Articles Retrieved	Total Number Located	Citation (Name, Year)
1a	Systematic Reviews or Metanalysis of Randomized Control Trials		
1b	Individualized Randomized Control Trials	4	(Sale, Mazzoleni, Lombardi, Galafate, Massimani, Posteraro, Damiani, & Franceschini, 2014) (Masiero, Armani, & Rosati, 2011) (Abdullah, Tarry, Lambert, Barreca, & Allen, 2011) (Masiero, Celia, Rosati, & Armani, 2007)
2a	Systematic reviews of cohort studies		
2b	Individualized cohort studies and low quality RCT's (PEDro ≤4)	1	(Duret, Hutin, Lehenaff, & Gracies, 2015)
3a	Systematic review of case-control studies		
3b	Case-control studies and non-randomized controlled trials (quasi experimental or clinical trials)		

4	Case-series and poor quality cohort and case-control studies		
5	Expert Opinion		

STUDIES INCLUDED : Although we were able to find 4 randomized control studies, we chose not to use two of the studies due to the fact that one newer study included one of the randomized control studies within the study and because one did not fit the necessary criteria to be considered acute treatment verses subacute.

	Study 1-Sale et al.	Study 2 - Duret et al.	Study 3-Masiero et al.
Design	RCT	Cohort study	RCT
Level of Evidence	1b (moderate)	2b (limited)	1b (moderate)
Rigor Score	PEDro Scale: 10/11	CASP Cohort Study Checklist: 6/10	PEDro Scale: 11/11
Population	20 Patients 30 + or – 7 days after ischemic/hemorrhagic lesions Inclusion: first acute event (stroke, unilateral paresis) , ability to under and follow simple directions, able to stay in sitting posture, MMSE= 20 or more, muscle strength for finger flexion and extension more than 2, and absence of sensory impairment Exclusion: bilateral impairment, severe sensory deficits, posterior circulation, cognitive impairment, behavioural dysfunction, other current severe medical problems, endogeneous depression history, severe psychiatric disorders, severe visual deficits, younger than 18 and older than 80, previous stroke,	17 patients 49 + or – 26 days post stroke, 13 ischemic, 4 hemorrhagic, with 13 left paretic side, and 4 right paretic side. Age range: 19-88. Inclusion: sufficient cognition and medically stable.	21 Patients after a first single ischemic or hemorrhagic CVA (within 20 days) with upper-limb impairment (hemiparesis or hemiplegia). Inclusion: diagnosis of recent single-sided stroke demonstrated by brain imaging, sufficient cognitive and language capacities to understand operator's instructions, paralysis or paresis with no ability for active movement against gravity or weak resistance. Exclusion: cardiovascular instability or orthopaedic or neurological conditions, multiple CVA lesions, early appearance of marked spasticity, upper limb joint pain or limitations to ROM that would have limited the subject's ability to

	cognitive disorders like neglect or UE apraxia.		complete the protocols, severe neuropsychological impairment, age >85years or <18 years.
Intervention Investigated	Robotic Arm (end-effector-based Armadeo Robotic System with five DOF)	30 minutes of individual, 30 minutes of group (4-5 times a week for 4 weeks) conventional therapy: passive stretching, active assisted movement, target reaching movements with or without elbow support and grasping tasks 45 minutes of roboted assisted therapy: adjustable chair in front of monitor displaying exercises and tracking movements of paretic hand, along with repeating assist-as-needed reaching movements (adaptive mode) towards 8 targets displayed in 8 different directions. Patient was instructed to perform as many movements as possible during time. Three minute breaks were taken every 80 movements.	A total daily treatment time of 120 minutes for 5 days/week for 5 weeks. -Conventional treatment of the proximal paretic arm was substituted with NeReBot training for 40 mins/day (2 20 min sessions). -Robot training by physiotherapist who defined the exercises according to the protocol, adapted cable velocities to the specific exercise and the patient's progress and in agreement with rehab team-defined treatment schedule weekly.
Comparison Intervention	Standard OT treatment based on client: different purposeful kinetic activities (unimanual or bimanual tasks) with or without ADLs activities	NA	A total daily treatment time of 120 minutes for 5 days/week for 5 weeks -Performed conventional functional rehab for 80 mins/day (proprioceptive exercises, functional re-education, gait training, OT, and passive/active-assisted mobilization of hand/wrist) but w/o specifically exercising the proximal paretic arm. This part of arm was exercised during a separate 40 min

			session.
Dependent Variables	Hand function	Upper limb motor function	Upper limb motor function
Outcome Measures	FM MRC MAS MI Box and block Barthel Index	Motricity index Number of movements Robotic assistance	MRC FM m-FIM MAS FAT Box and block Tolerability of treatment
Results	A Statistically significant improvement in EG and CG for the FM, the BB, MI, and MRC was found. A statistically significant increase in the MAS score in EG was found.	More severe initial motor impairment and abilities in patients benefited more from robot-assisted training.	Before-after improvements in MRC wrist flexor and wrist extensor (assesses muscle strength) were statistically significant for both. Yet, the CG found statistically significant improvements in MRC deltoid, MRC Biceps (muscle strength), FM-SEC MAS (reduced hypertonia and motor impairment), and the FA-T (basic ADLs and dexterity. No differences were found for either groups at the end of robot therapy. There were no between-group comparison differences revealed. All patients who used the robotic arm were in favor of using it for poststroke rehabilitation program.
Effect Size	No effect sizes (no between measures)	No Effect sizes (not RCT)	FM-tot=-.18 M-FIM= -.53 FA-T= .71 Box and Block = .47
Conclusion	Both standard treatment and the robotic arm showed significant improvements for hand function over time for the MRC, FM, BB, and MI. Yet, only the robotic arm showed significant improvements with hand	An upper limb robot-assisted rehabilitation provides a highly repetitive and challenging exercises-based practice at the early phase of stroke recovery with an increased amount of	Both treatments showed significant improvements at the end of robot therapy. A 3-month follow up showed that there were improvement in muscle strength for the wrist flexor and extensor for both

	function when assessed by the MAS over time	number of repetitions associated and a decreased assistance within the training. Note: The more severely impaired patients benefited the most from this therapeutic option.	treatments. Yet, the CG group also found improvements in increased muscle strength in the biceps and deltoid according to the MRC, dexterity and basic ADLs according to the FA-T, and reduced hypertonia and dexterity according to the FM-SEC and MAS. No differences for found between treatments at any time.

SYNTHESIS SECTION:

PICO Question: What is the effectiveness of using a robotic arm with patients post-stroke in an acute setting (less than 8 weeks) on upper extremity function compared to conventional therapy?

Definitions:
Motor function=strength, coordination, grip, and pinch in the joints of the UE

Overall Conclusions:
Results: Similar Findings:
All three of these studies measured upper extremity function (motor function) of post-stroke patients receiving the robotic arm therapy. All three of the studies demonstrated that robotic arm therapy interventions did show statistically significant improvements in upper extremity motor function at the end of treatment. Conventional therapy was also shown to have statistically significant improvements in upper extremity motor function at the end of treatment. Yet it is important to note that one study found no significant differences between conventional therapy and robotic therapy for upper extremity motor function at the end of treatment. All studies took place in a rehab facility and had the same intensity of treatment with robotic intervention 4-5 days a week for 4-5 weeks for 45 minutes (treatment time ranged from a total of 12 to 18.75 hours over 4 to 5 week timeframe). The studies also had pre and post testing. However, some studies also had testing during the therapy schedule and one had testing 3 months following the end of treatment.

Results: Differences:
Demographics:
One study had a wide range for the age of participants from 19-88 with a mean age of 52.8 whereas the other two studies had mean ages between 67 to 75.5 for the various control and experimental groups.
Robotic Devices:
Each study utilized a different robotic device targeting either the hand/fingers or the arm (e.g. NeReBot, Armadeo Robotic System, and InMotion 2.0) One of the devices went through five degrees of freedom, another device went through three degrees of freedom, and one device went through two degree of freedom. Also, two devices focused on shoulder and elbow movement where the other device focused on hand movements. In addition, three devices had feedback, one had visual and auditory feedback, and two had visual feedback. Level of assistance provided by the robotic arm varied depending on patient severity of motor impairment and progression over the course of

treatment.

Blinding:

Two studies had a blinded clinician who was not involved in the research, but performed the assessments. One study had two therapists administer the interventions, one therapist for the robotic experimental group intervention and one therapist for the control group intervention.

Treatment Dosage:

The robotic therapy included rest breaks ranging from thirty seconds to three minutes at various times throughout the sessions. Each of the studies varied in regard to the amount of time the experimental groups received conventional therapy in addition to robotic therapy. Within the experimental group, one study only had robotic therapy (Sale et al., 2014). Another study split the total treatment time (120 minutes) for the experimental group between conventional (80 minutes) and robotic therapy (40 minutes) although they had the same daily treatment time (120 minutes) as the control group (Masiero et al., 2011). The final study's experimental group had 60 minutes of conventional therapy and 45 minutes of robotic therapy, 4-5 days per week (Duret et al., 2015).

Bottom-line Conclusion:

There is strong evidence to support the effectiveness for the use of a robotic arm to improve upper extremity motor function in the acute setting following stroke.

Boundaries:

There were a total of 58 patients with post stroke between the ages of 19 to 88 years of age participating in these three studies. Inclusion criteria included acute stroke patients (less than 8 weeks) with sufficient cognition to be able to follow instructions. Exclusion criteria for two studies included severe cognitive impairment, other severe medical problems, severe neuropsychological impairments and no prior history of CVA.

Implications for Practice:

All three of these studies utilized a robotic arm intervention program targeting the upper extremity and included conventional therapy. Interventions lasted an average of 45 minutes, 4-5 days a week, for 4-5 weeks with the shortest treatment time lasting 40 minutes. All sessions took place in a rehab facility. Despite the fact that the robotic devices used in each study differed they still had statistically significant changes. All three studies showed statistically significant improvements for robotic therapy, however, no statistically significant differences were found between conventional therapy and robotic therapy. Therefore, there is strong evidence to indicate that the robotic arm with conventional therapy improved upper extremity motor function in acute (less than 8 weeks) post-stroke patients.

Things we do not know

One of the biggest limitations to all of these studies were that they lacked detail in changes over time. For example, only one study completed outcome measures during the actual course of treatment (whereas other studies just did outcome measures at baseline, end of treatment, and 3 month follow-up post-treatment). Thus, we do not know whether the use of robotic arm or conventional therapy improves UE motor function faster within the 5 weeks of treatment. The studies also lacked a good definition of what conventional therapy involved. This was most likely due to the need to individualize treatment to meet the varying needs of patients. One study suggested that more severe motor impaired patients benefited the most from the robotic arm therapy compared to patients with less severe motor impairments, but did not provide how they came to this conclusion. Another limitation was with the outcome measures chosen in these studies. Due to the chosen outcome measures functional UE use cannot be generalized to functional occupational performance, which is essential for performing daily activities. Therefore, better outcome measures should be assessed.

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