CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In children aged 6-months to 5-years with neurodevelopmental delays is the Segmental Assessment of Trunk Control (SATCo) or the Early Clinical Assessment of Balance (ECAB) better at detecting progress in postural control and balance in sitting for children receiving physical therapy services?

AUTHOR

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CLINICAL SCENARIO

The clinical scenario that inspired this PICO question is a 2-year 9-month-old child with Microcephaly, Global Developmental Delays, Encephalopathy, Cortical Visual Impairment, and Absent Corpus Callosum who receives physical therapy services in the home. This young patient presented to physical therapy at the age of 6-months and has been receiving weekly physical therapy for just over 2-years. The patient was born at 36-weeks, complicated by delayed prenatal care. The patient spent significant time in the NICU with tachypnea, anemia, and newborn sepsis. Clinical presentation and primary impairments include increased muscle tone and spasticity throughout upper and lower extremities and neck musculature, inability to sit independently, diminished head and trunk righting reactions, extreme proximal muscle weakness, and severe visual impairment. These impairments are nearly identical to patients who eventually receive a diagnosis of Cerebral Palsy.[1] The patient has been routinely tested using standardized assessment tools, the AIMS, and the Bayley Scales of Infant Development III. Test scores reveal continuously scoring at the lowest level, more than two standard deviations below the mean with minor changes in raw scores, and little to no change in scaled scores. This clinical situation inspired me to want to find a way to more accurately assess this child's impairment, lack of intact postural control, and find a way to guide my intervention choices and justify ongoing treatment to payers. By using an outcome measurement tool specific to trunk control and sitting balance, could progress be detected over time that is not being captured with standardized assessment tools? Additionally, can this tool be used quickly and efficiently in the home, and can one of these outcome measures help guide physical therapy intervention choices?

SUMMARY OF SEARCH

[Best evidence appraised and key findings]

Eight studies met the inclusion and exclusion criteria of the PICO question, including one systematic review, five methodological non-experimental research studies, one single longitudinal cohort non-experimental study, and one prospective methodological (RCT enrolled) study.

- No one study compared the SATco and the ECAB measurement tools to each other, limiting direct comparison.
- The ECAB and SATco were created as tools to assess balance in young children with CP.
- Both have high construct validity and excellent inter and intra-rater reliability, demonstrating acceptable use in this population.[2,3] However, the SATco demonstrates some discrepancy (only 55% agreement) between live testing and video recorded testing for the reactive part of the test presenting questionable reliability.[3]
- The ECAB has a moderate to excellent correlation with the GMFM -66 (gold standard tool) and the Pediatric Reach Test (PRT) with high Spearman r.[2,4,5]
- The ECAB has lower measurement error (SEM=3.6-points) and smaller minimal detectable change (MDC=10-points) than the PRT, indicating it is a more precise measure to use in comparison to the Pediatric Reach Test.[2]
- The SATco has only an assumed MICD of at least 1 SATco level, based on the relationship of the GMFM. A formal MCID has not been established for the SATco.[3]
- The ECAB and the SATco have medium to large effect size noted with PT interventions (in separate research studies) suggesting the tools can be used to measure change over time.[4,6] However, the

GMFM-66 demonstrates 2 x larger effect size than the ECAB after 6-month of intervention, but the ECAB is significantly shorter to administer.[4]

- One study has published ECAB mean scores at ages 2 to 12 at different GMFCS levels (I-V). These mean scores can be used to detect the difference between developmental improvements versus treatment improvements, making detection of progress or decline more accurate for this tool.[7] Completion of all of the SATco levels, demonstrating complete postural control, is generally reached by typically developing children at age 9-months.[8]
- ECAB has a ceiling effect noted for children at GMFCS levels I and II seen at 3-5 years of age.[7]

CLINICAL BOTTOM LINE

There is no direct comparison of the SATCo and the ECAB limiting conclusions about which outcome measure is best at detecting progress for a child with neurologic impairment and developmental delay undergoing physical therapy treatment. Decisions regarding which tool to use must be made individually based on ease of use, ability to use the same tester, and with the possibility of a ceiling and floor effects for the individual child's mobility characteristics. Additionally, the ECAB may be easier to perform in the home setting, as the SATCo requires some equipment that may not be readily available to therapists working in the home.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

The above information should fit onto the first page of your CAT

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Infants Toddler Baby Pediatric "Young children" "Developmental delays" "Neurodevelopmental delays"	"Physical therapy" "Early intervention" "Neurodevelopmental treatment" "balance training"	SATco ECAB	sitting "independent sitting" "functional sitting" "Improved sitting balance" "postural control" balance equilibrium "trunk control" "head control"

Final search strategy (history):

Show your final search strategy (full history) from PubMed. Indicate which "line" you chose as the final search strategy.

1. infants OR toddlers OR pediatric OR baby OR children
2. "developmental delay" OR "neurodevelopmental delay" OR "global developmental delay"
3. "physical therapy" OR "early intervention" OR "neurodevelopmental treatment" OR "balance training"
4. "Segmental Assessment of Trunk Control"[Title/Abstract]
5. "Early Clinical Assessment of Balance"[Title/Abstract]
6. "Segmental Assessment of Trunk Control" AND "Early Clinical Assessment of Balance"
7. "Segmental Assessment of Trunk Control" OR "Early Clinical Assessment of Balance"
8. ((#1 AND #2 AND #3) AND (#4 OR #5 OR #6 OR #7))
9. ((#1 AND #3) AND (#4 OR #5 OR #6 OR #7))
10. "sitting balance" OR "head control" OR "trunk control" OR "independent sitting" OR "functional sitting" OR "functional balance"
11. "postural control"
12. equilibrium
13. **((#6 OR #7) AND #10) – modified to (((#7)) AND (#10)**
14. (#1) AND (#6)
15. (#1) AND (#7)
16. (((#1) AND (#2)) AND ((#3) AND (#7)))
17. ((#4 OR #5) AND (#10))
18. #11 AND (#7)

In the table below, show how many results you got from your search from each database you searched.

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
Pubmed	**34**	**21 – applied filter - limited by 5 years – back to 34 -expanded by 10 years to include a systematic review**
CINAHL	**20**	**No filters**

PEDro	**2**	**Expanded search by simplifying search inquiry to "segmental assessment of trunk control": zero results for "Early Clinical Assessment of Balance"**
PTnow	**36**	**20 - applied filter of limited by 5 years**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Children • Diagnoses of: developmental delay, global developmental delays, cerebral palsy, neurologic impairment • Peer-reviewed studies • Outcome measure used either or both: SATco and ECAB
Exclusion Criteria
• Studies that include only typically developing children • Not in English • Studies older than 10-years

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

For each article being considered for inclusion in the CAT, score for methodological quality on an appropriate scale, categorize the level of evidence, indicate whether the relevance of the study PICO to your PICO is high/mod/low, and note the study design (e.g., RCT, systematic review, case study).

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
McCoy SW, Bartlett DJ, Yocum A, et al. (2014)[5]	**8/11 – Outcomes Checklist** – (Chirstina Jeorsch-Herold, 2005)	**2b – Portney & Watkins**	**Moderate**	**Methodological** ***Creation of ECAB outcome measure** **non-experimental**
Pierce SR, Skorup J, Miller A, Paremski AC, Prosser LA. (2019)[4]	**8.5/11 – Outcomes check List**	**2b – Portney & Watkins** ***downgraded from 1b due to participants enrolled in a simultaneous RCT but for this study no comparison between the groups. Primary**	**High**	**Methodological** **RCT enrolled but no comparison between groups with different interventions for this study** **Prospective**

		purpose of study was to establish effect size for different tools over time.		
Randall KE, Bartlett DJ, McCoy SW (2014)[2]	**11/11 – Outcomes Checklist**	**2b – Portney & Watkins**	**Moderate-High**	**Methodological** **Non-experimental** **Single cohort**
LaForme Fiss A, McCoy SW, Bartlett D, Avery L, Hanna SE (2019)[7]	**11/11 – Outcomes Checklist**	**2b – Portney & Watkins**	**Moderate**	**Longitudinal** **Single Cohort** **Non-experimental**
Saether R, Helbostad JL, Riphagen II, Vik T (2013)[1]	**8/11 -Amstar**	**2a – Portney & Watkins**	**Low**	**Systematic Review**
Hansen L, Erhardsen K, Bencke J, Curtis DJ (2013)[9]	**8/11 – Outcomes Checklist**	**2b – Portney & Watkins**	**Moderate**	**Methodological** **Single cohort** **Non-Experimental**
Argetsinger LC, Trimble SA, Roberts MT, Thompson JE, Ugiliweneza B, Behrman AL. (2019)[6]	**8/11 – Outcomes Checklist**	**2b – Portney & Watkins**	**Moderate**	**Methodological** **Prospective** **Single Cohort**
Pin TW, Butler PB, Cheung H-M, Shum SL-F (2018)[10]	**9/11 – Outcomes Checklist**	**2b – Portney & Watkins**	**Low**	**Methodological** **Non-Experimental** **Comparison** **Prospective**

*Indicate tool name and score

**Use Portney & Watkins Table 16.1 (2009); if downgraded, indicate reason why

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

- Pierce SR, Skorup J, Miller A, Paremski AC, Prosser LA. The responsiveness and validity of the Early Clinical Assessment of Balance in toddlers with cerebral palsy: Brief report. *Dev. Neurorehabil.* 2019;22(7):496-498. doi:10.1080/17518423.2018.1523244.

This study was chosen for its low risk of bias; the subjects are the same age and have the same diagnoses as those in the PICO question. Additionally, the purpose of the study was to explore the responsiveness of the ECAB while comparing it to a gold standard tool, the GMFM-66. This study was a part of a larger randomized control trial (CinicalTrials.gov Identifier: NCT02340026) with data collected at two distinct points: 3-months and 6-months. This is the same kind of progress reporting interval that typically takes place during pediatric physical therapy in the home or clinical setting, and therefore the standard response mean measurements at this time interval are relevant to the PICO question.

- Argetsinger LC, Trimble SA, Roberts MT, Thompson JE, Ugiliweneza B, Behrman AL. Sensitivity to change and responsiveness of the Segmental Assessment of Trunk Control (SATCo) in children with spinal cord injury. *Dev. Neurorehabil.* 2019;22(4):260-271. doi:10.1080/17518423.2018.1475429.

This study was chosen for its direct assessment of sensitivity and responsiveness to change using the SATco in a population of children undergoing physical therapy treatment. The length of time in treatment is 3-months, also highly relevant to the PICO question. The sample size is relatively small but similar to the sample size in the above study, which reduces the chance that the results are not comparable due to change in power via sample size. The population is less relevant to this PICO question as these children have undergone an injury with presumed normal development before the SCI; however, the age range is similar to those in the PICO question.

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of: "The responsiveness and validity of the Early Clinical Assessment of Balance in toddlers with cerebral palsy: Brief report" by Pierce et al. 2019

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to investigate the ECAB's validity and responsiveness. The authors compared the ECAB to a gold standard tool, GMFM-66 to determine if this new tool correlates to a highly researched and responsive measure to change over time in children with CP, under the age of 3, receiving PT treatment.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

Design: This prospective methodological study was performed in conjunction with a randomized controlled clinical trial where the participants were enrolled in a physical therapy intervention of either conventional PT or dynamic weight assistance technology program three times per week. For this study, the two groups were not compared to one another, but instead, data was collected on 27 children at baseline (before intervention), at 3-months (n=27), and 6-months (n=23). Four families chose to discontinue the intervention after 3-months, and therefore only 23 participates included in the 6-month data collection. The age of the children ranged between 12-months and 36-months of age.

Inclusion/Exclusion Criteria for Participants:

Inclusion

1. Between the ages of 12 and 36-months
2. Diagnoses of CP or suspected CP by using the Bayley Scales of Infant Development III percentile raking less than 10% and one neurologic sign associated with CP
3. Ability to initiate pull to stand at a surface
4. Cognitive ability to follow one-step command

Exclusion

1. Orthopedic, neuromuscular, or cardiovascular condition unrelated to CP
2. Hypotonia without a neurologic sign associated with CP
3. Independent walking already achieved
4. History of surgery or injury to lower extremities in the last 6-months

Data collected:

- ECAB part A (head and trunk postural control) and B (sitting and standing postural control), total score out of 100
- GMFM- 66 total score and sub-scores dimensions B (sitting), C (crawling), D (standing), E (walking)
- Data collected by one physical therapist, the lead author of the study

Data Analyses:

- Correlation between ECAB and GMFM-66 total score and GMFM Dimensions B,C,D, and E calculated with *Spearman's rho* to determine strength of the relationship between these two measures.
- *Standardized response mean* (SRM) calculated to determine responsiveness of the ECAB total score, GMFM-66 total score, and Dimension B,C,D, and E at 3-months intervention and 6-months intervention.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

The setting for data collection was not indicated in the article. However, the clinical trial ClinicalTrials.gov Identifier: NCT02340026 from which the participants were used for this study appear to be participating in interventions in a clinic setting at Children's Hospital of Philadelphia.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

N=27 at baseline assessment/data collection with decrease to N=23 when data was collected at 6-months

Mean age of participates = 25-months-old

13-female and 14-male

Gross Motor Function Classification System (GMFCS)	Level I	Level II	Level III	Level IV
Number of Children	2	8	9	8

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

Conventional physical therapy planned for 3 x per week. Group assignment not provided.

The two groups were not compared to one another.

Mean attendance was 28/36 sessions completed at the 3-month mark. Mean attendance was 55/72 sessions completed at the 6-month mark.

Experimental

Dynamic weight assistance technology program 3 x per week. Group assignment not provided

The two groups were not compared to each other.

Mean attendance was 28/36 sessions completed at the 3-month mark. Mean attendance was 55/72 sessions completed at the 6-month mark.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

- Early Clinical Assessment of Balance (ECAB) is a relatively new outcome measurement tool that is meant to measure postural stability in children with Cerebral Palsy. The test is broken down into 2 parts: [Head and Trunk Postural Control] and [Sitting and Standing Postural Control]. The maximum score is 100 with 36 maximum points in part 1 and 64 points in part 2.
- The Gross Motor Function Measure-66 (GMFM-66) is a gold standard assessment tool used to assess overall gross-motor ability and is criterion-referenced and proven to detect change over time in children with a diagnosis of Cerebral Palsy. Total score for the entire test and sub-scores on individual sub-sections can be calculated. For this study the sections measured included sitting (out of 60-points), crawling (out of 42-points), standing (out of 39-points), and walking/running (out of 72-points). The total score was also reported.
- The lead author and physical therapist administered the two tests. The tester was trained on how to administer and score the GMFM by training on video recorded assessments and scoring the child using the GMFM. The scores were compared to another rater confirming reliability for scores found during this study.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. You may summarize results in a table but you must explain the results with some narrative.]

- Correlation between the ECAB (total score) and the GMFM-66 (total score) is excellent with a Spearman's Rho r =.87 with p =.001 at baseline.
- Correlation between ECAB and Dimensions B, C, D, and E range between moderate to excellent with r = .63 to .88 with a p = .001 at baseline (see **Table 1** for breakdown of Spearman rho scores).
- Responsiveness was calculated with a Standard Response Mean calculation, providing an effect size at 3-months and 6-months for the ECAB, the GMFM-66 total score, and GMFM dimensions B, C, D, and E (see **Table 2** for breakdown of raw scores, standard deviations, and SRM calculations).
- Medium effect size for the ECAB at 3-months SRM = .62 and large effect size at 6-months SRM = .92
- Large effect size for GMFM-66 (total score) at 3-months SRM = .84 and very large effect size at 6-months SRM = 2.02.

Table 1: Correlation between GMFM-66 and ECAB at baseline

	ECAB
GMFM-66 total score	r = .87
GMFM B (sitting)	r = .88
GMFM C (crawling)	r = .84
GMFM D (standing)	r = .63
GMFM E (walking, running, jumping)	r = .68

Table 2: Raw Scores, Standard Deviation, Standard Response Mean (SRM) at 3-months and 6-months of intervention for the ECAB and the GMFM-66 total and sub dimensions

Tool	Mean Raw Score (standard deviation) Baseline	Mean Raw Score (standard deviation) at 3-months of PT intervention	SRM at 3-months	Mean Raw Score (standard deviation) at 6-months of PT intervention	SRM at 6-months
ECAB	26.4 (11.0)	29.6 (11.3)	.62	33.4 (11.9)	.92
GMFM-66 total score	39.4 (7.6)	42.1 (8.6)	.84	46.8 (8.0)	2.02
GMFM B (sitting)	53.1 (23.2)	57.3 (23.1)	.37	65.9 (21.3)	.84
GMFM C (crawling)	26.4 (25.5)	31.8 (26.3)	.44	44.3 (23.5)	.84
GMFM D (standing)	7.7 (5.8)	13.4 (12.9)	.60	18.9 (15.5)	.86
GMFM E (walking, running, jumping)	4.6 (5.3)	7.5 (8.5)	.67	11.2 (8.3)	1.31

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

"The large effect size for the ECAB suggests that it is responsive to change in young children with CP after 6 months and may be used as an outcome measure in this population over this duration." (page 498)

"The results of this study support the validity of the ECAB as a measure of postural control in young children with CP." (page 497)

The GMFM-66 total score demonstrated a much higher effect size, with an SRM of 2.02 after 6-months of physical therapy intervention, which reinforces this gold standard tool as an excellent choice for detecting change in this population. Choosing which measurement tool to use should be based of individual factors.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

A checklist for critical appraisal of studies reporting validity, reliability, and responsiveness of outcomes measures by Christina Jerosh-Herold, DipCOT, MSc, PhD was used and this study scores a 8.5/11 total points indicating high internal validity.[11]

Strengths: This study was conducted along with subjects who were enrolled in an RCT, and while this study did not compare the two groups, the rigors associated with an RCT design could strengthen the interpretations of these results. This study compared the ECAB to a gold standard tool which supports the overall internal validity of the study, and the results can be trusted, both by the establishment of the correlation between the two tests and then the comparison of the standard response means for both the new tool being investigated and the gold standard tool which is already backed by significant research studies. The physical therapists administering the tests were provided with training to increase internal validity.

Weaknesses: The sample size was fairly small, n =27, at baseline measurements, then decreased to n =23 at the 6-month testing for both the outcome measures being tests. The authors explain that parents had the option to discontinue the physical therapy treatment after participating 3-months if they wanted to. The four children who did not continue onto the second phase of the study, completing six full months of physical therapy treatment, could have discontinued due to lack of progress or any other reason. Due to the small sample size, the loss of 4 data points could affect statistical calculations. If the children who dropped out did not progress as much as the children who stayed in the physical therapy treatment part of the study, then the effect size calculations could be less than was reported here.

External Validity: This study applies to young children with Cerebral Palsy who present with postural control impairments. Children do not always receive a diagnosis of Cerebral Palsy during infancy and toddlerhood, but the authors clearly explain that children who presented with classic impairments characteristic of Cerebral Palsy were included in the study. This inclusion applies to the real-world settings of pediatric physical therapy, where a diagnosis is not always available in infancy and the toddler years.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

The results are clear that the ECAB is a new outcome measurement tool that can be used in very young children with a diagnosis of CP or postural control impairments. This tool demonstrates good criterion and content validity with excellent correlation with a gold standard tool, the GMFM-66 when comparing total scores. The standing, walking, and running dimensions of the GMFM-66 had a moderate correlation of r =.63 and r =.68, respectively. The last three ECAB individual test items include standing with feet together, a 360-degree turn, and placing alternating feet on a step. Dimension E of the GMFM-66 includes skills that are beyond this developmentally, including; kicking a ball, walking up/down four steps, jumping off a raised surface. The ECAB does not include a "walking" test, whereas dimension E includes walking items. The attainment of walking during the 6-months of PT intervention could have been reflected more in with the GMFM-66 than with the ECAB leading to the much larger effect size seen at 6-months for the GMFM-66. The small sample size could affect the outcome of this study, as well as the loss of 4 participants for the last 3-month of PT intervention. Despite these limitations, the ECAB is a tool that can be used in this population and is responsive to change over time.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

This methodological study has high applicability to the clinical question and scenario. The purpose of the study was to investigate the responsiveness of the ECAB, which is the most critical aspect of the PICO question. The age of the children that participated in the study is nearly identical to the age of the child who inspired the PICO questions. The study participants underwent 6-months of physical therapy intervention, which is similar to the amount of physical therapy a child would generally participate in at this age with these impairments. Six months is the standard time frame used when re-evaluating and re-testing children at this stage of development. The inclusion criteria for the participants is nearly identical to the impairments present in the clinical scenario. The physical therapy interventions are unknown, although we know that the participates were all receiving some form of physical therapy. The study reinforces the use of a gold standard tool, the GMFM, may still be the best choice in this population. The study did not describe the location of the interventions or the location/setting for the testing. The testing location may play a role in performance on the outcome measures used in the study. Practically speaking, either test could be performed in the home or clinic without the need for any significant equipment.

Two crucial aspects to consider for any outcome measure is the minimal clinically significant difference and the availability of reference norms to help detect if the change in the score on the ECAB is due to chance or due to developmental progress. Other studies have investigated these properties and would need to be taken into consideration but are not included in this study.

(2) Description and appraisal of "Sensitivity to change and responsiveness of the Segmental Assessment of Trunk Control (SATCo) in children with spinal cord injury"[6] by Argetsinger et al, 2019

Aim/Objective of the Study/Systematic Review:

The purpose of this study was to determine the SATCo responsiveness and sensitivity to change in comparison to other outcome measures for children aged 1-12 who have either an acute or chronic Spinal Cord Injury at T10 or above, receiving outpatient activity-based locomotor training physical therapy intervention.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Note: For systematic review, use headings 'search strategy', 'selection criteria', 'methods' etc. For qualitative studies, identify data collection/analyses methods.

Design: The study design was a prospective single cohort methodological study to investigate the responsiveness of an outcome measure, the SATCo, participating in an outpatient 5 x per week intensive physical therapy program for 3-months. A total of 21 patients completed the study, and all participants received the same physical therapy program. The following group types were compared to one another:

- Acute SCI (< 1 year) vs Chronic SCI (≥ 1 year)
- Cervical vs. Thoracic level SCI

Inclusion/Exclusion Criteria for Participants:

Inclusion:

1. Between the ages of 1 and 12
2. Diagnosis of SCI either acute or chronic above T10

Exclusion

1. History of surgical interventions for scoliosis, tendon lengthening or transfers
2. Ongoing Spasticity management/medication
3. Ventilator dependent

Data collected:

- An initial evaluation by a physical therapist at baseline was performed and then at approximately ~20 therapy sessions using the following outcome measures: SATco, Pediatric Balance Scale, Modified Functional Reach, Timed Short Sit, Timed Long Sit, Times Stand, and 2-minute walk test.

Data Analyses:

- The primary outcome analysed was the SATco, comparing changes by calculating adjusted estimate mean change scores at 95% confidence intervals for evaluations 1 vs 2, 1 vs 3, 1 vs 4, 3 vs 2, 4 vs 2, and 4 vs 3.

- The secondary outcome measures analysed were the PBS, MFR, Timed Short Sit Test, Timed Long Sit Test, Timed to Stand Test, and 2-minute walk. The change in scores was assessed using mean values and standard error calculations. Change scores were calculated for evaluations 1 vs 2,3, and 4.
- Responsiveness was measured by calculating the *adjusted standardized response mean (ASRM)*, adjusting for age at injury and time between injury and starting the intervention therapy. The outcome measure was considered "significantly responsive" if it's 95% CI did not include 0. The measures that demonstrated statistically significant confidence intervals were then examined for effect size by using Cohens classifications.
- Post hoc power analysis was performed secondary low sample size.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

The intensive therapy took place at an outpatient rehabilitation center.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

N = 21

Acute SCI n = 10; 5-female 5-male

Chronic SCI n = 11; 5-female 6-male

Mean age at injury (SD) = 43.8-months (29.9)

Mean age at start of therapy (SD) = 63.3-months (27.2)

Cervical Injury n= 9; 3-acute, 5-chronic

Thoracic Injury n = 12; 7-acute, 5-chronic

Initial SATCo scores:

Score x/20 – 3 point per level, except level 1 only 2 points	Number of children
0-5/20 – SATCo level 1 and 2, exhibits head to upper thoracic trunk control	8
6-12/20 – SATCo level 3 and 4, exhibits mid thoracic control to lower thoracic control	9
13-20/20 – SATCo level 5, 6, and 7, exhibit upper lumbar control, lower lumbar control, to full trunk control	4

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

No control, all participated enrolled in intensive 5 x week physical therapy program

Experimental

21 pediatric patients with SCI T10 or above participated in 60-sessions (3-months) of intensive 5 x week physical therapy for 1.5 hours per days.

Physical Therapy intervention included:

1. 55-60 minutes of treadmill training standing and stepping via body weight support system and therapist assistance. Assistance provided guided by SATCo level, giving support at or lower than SATCo level score
2. 30-min applying gains, new skill training, and providing HEP for parents

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

SATCo: The patient is seated in short sit on a bench with hips/knees/ankle at 90° angles. Manual support from the therapist was given instead of strapping systems, which has been used in other research studies. SATCo level 1 is maximal support provided at shoulders and forearms resting on a table. The static position was tested first (5-sec hold) with the head in line with the shoulders, then an active position with the patient rotating head to R and L and back to midline head in line with trunk equals full points given (2-points). The therapist then moves hand support down to the next level at the axillae, which included the static position, an active position (described above), and a reactive position where the therapist provides a brief nudge anteriorly, posteriorly, and laterally. The test positions continue to move down the trunk to the next level; inferior scapula, over lower ribs, below ribs, pelvis, and then no supports given at all. The score is the spot at which the patient has complete control, scoring all points at one level.

Modified Reach Forward, Right, Left sitting: no description of procedures

Timed Short Sit: holding time with a maximum of 5-minutes – test ended if achieved 5-minutes (arm support and assistive devices allowed)

Timed Long Sit: holding time with a maximum of 5-minutes – test ended if achieved 5-minutes (arm support and assistive devices allowed)

Timed Stand: holding time with a maximum of 5-minutes – test ended if achieved 5-minutes (arm support and assistive devices allowed)

2-min walk: no description of procedures

All outcomes were tested at initial evaluation, then approximately every 20-days 3 more times, for a total of 4 testing data points.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

- SATCo was the most responsive outcome measure from evaluation one to four and demonstrated a large effect size. **See Table 1.**
- SATCo scores increased for all patients at every evaluation point, $p < .0001$, across each evaluation.
- The average SATCo score at baseline was 7/10, inferior scapula support level, and after 60-sessions the average SATCo score was 13/20, below rib level support level. Average change score from one evaluation to the next was 2 SATCo points ($p < .05$).
- Patient with cervical and thoracic level SCI demonstrated improvements in SATco scores with an average increase of 2-points from one evaluation to the next and not differ based on chronic or acute status.
- Patients with initially low SATCo (0-5/20 points) scores demonstrated larger point increase compared to those with middle to high SATCo (6-12/20 or 13-20/20) scores from evaluation 1 to evaluation 4.
- The Timed Short Sit, Times Long Sit, Timed Stand, and Modified Reach Test demonstrated statistically significant change scores from evaluation 1 to 4, but only small to medium effect sizes.
- The Pediatric Balance Scale did not demonstrate statistically significant change scores across any evaluations.

Table 1: Mean Raw Scores (SD) for Statistically Significant Outcome Measures and Effect Sizes (Cohens Classification)

Outcome Tool	Eval 1	Eval 2	Eval 3	Eval 4	Effect Size (95%CI) Eval 1 to 4
SATCo	7 (1)	11 (1)	12 (1)	13 (1)	1.09 (.92, 1.25)

Modified Reach Forward-sitting	2 (1)	5 (3)	8 (3)	8 (4)	.52 (.35,.68)
Modified Reach Right-sitting	2 (1)	3 (2)	4 (2)	5 (2)	.59 (.42,.72)
Modified Reach Left-sitting	2 (1)	3 (2)	5 (2)	5 (2)	.5 (.22,.69)
Timed Short Sit	112 (37)	152 (35)	143 (35)	162 (33)	.38 (.15,.51)
Timed Long Sit	117 (36)	154 (35)	158 (33)	165 (33)	.22 (-.11,.52)
Timed Stand	31 (16)	41 (21)	55 (25)	57 (26)	.37 (.2, .52)
2-min Walk	7 (6)	11 (7)	11 (7)	16 (10)	.33 (.17,.38)

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

"The significant changes in SATCo scores from baseline to one, two, three months are evidence that it is sensitive to change. Of the outcome measures collected, the SATCo demonstrated the largest responsiveness effect across 3-months of AB-LT." (page 265)

The SATCo is sensitive in detecting change in trunk control to both types of SCI, acute and chronic, and patients demonstrated improvements in SATCo scores regardless of the stage of recovery the patient was in.

Improvements in trunk control can be more carefully measured by using the SATCo for a group of patients who are thought to not make physical recover after 1-year post injury, yet patients in this study demonstrated improvement in their SATCo scores despite length of time since injury.

The SATCo level scores can guide appropriate supports given by therapist to encourage more independence with trunk control by using the scores on the SATCo to guide support level during therapy, and changing support as score increases, allowing for more "muscle activation, neural reorganization, and/or strengthening." (page 266)

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

A checklist for critical appraisal of studies reporting validity, reliability, and responsiveness of outcomes measures by Christina Jerosh-Herold, DipCOT, MSc, PhD was used and this study scores a 8/11 total points indicating high internal validity.[11]

Strengths: This study clearly stated their measurement system using the SATCo and the point system they used for each level to be awarded "complete" control at that trunk level. This study made sure to break down their change scores by SCI chronicity, an essential aspect of rehabilitation potential, and compared the two groups to each other.

Weakness: This study was small in sample size n=21. This study did not have a gold standard tool for this population to compare raw score progress and effect size. This study lacked a full explanation of all the outcome measures used, instead stating that the 2-min walk and the Pediatric Balance Scale were administered as usual. The same therapist performed all the evaluations, which introduces the possibility that bias is present for the SATCo scores given. If the same therapist also provided all the treatments, this therapist would likely have an investment in the child's overall improvement. A separate tester would introduce less bias; however, it is not clear from this study if the tester and the treating physical therapist were the same.

External Validity: This study has good external validity as children with SCI would likely have physical therapy in a rehabilitation center, and the outcome measures used are logical and commonly used in this population. In the real world, however, patients who are 1 year or more out of SCI are unlikely to have access to 5 x week physical therapy session placing into question if the results on the SATco and excellent

effect size is reproducible for patients who have a chronic SCI and are not able to receive weekly physical therapy.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

The SATCo's large effect size of 1.09 is a good indication that this outcome measurement tool is responsive to change for children with an SCI undergoing intensive physical therapy. For children who have an SCI at T10 or higher, trunk control is vital to improvements in overall function and independence. A measurement tool that can directly assess segmental trunk control from the head down to the pelvis is critical in this population, and therefore the results of this study are promising for this the new outcome measurement tool. This study proved that the SATCo is responsive to change over time. A weakness of this study is that the minimal clinically important difference is not part of this study, and the improvements in the SATCo scores as a true change would be more trustworthy if there were also statistical calculations for standard error mean and minimal detectable change.

Additionally, there may be some bias present because it appears that the examiner who tested the children at the four different evaluation points, may also be the treating physical therapist. This introduces bias because the physical therapist would want the patient to improve after intensive physical therapy. A separate blinded tester for the outcome measures used in this study would decrease bias and increased the internal validity of the study.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

This study is only moderately applicable to the PICO question and clinical scenario. Spinal cord injury and neurodevelopmental delays are not clinically similar, and improvements in postural control could be quite different during and after physical therapy treatment. The age range of the patients included in the study is applicable, and the patients received physical therapy treatment over three months, similar to pediatric patients receiving therapy services for developmental delays. However, the patients received intensive 5 x week physical therapy, which is uncommon for children receiving physical therapy in the home or the clinic. The researchers in this study used their hands for support and a bench for the patient to sit on to complete the SATCo test, which is feasible in the home or the clinic. The large effect size detected using the SATCo in this study is promising for this tool; however, more information is needed on minimal clinically important difference to ensure that the progress detected is meaningful to the patient.

SYNTHESIS AND CLINICAL IMPLICATIONS

[Synthesize the results, quality/validity, and applicability of the two studies reviewed for the CAT. Future implications for research should be addressed briefly. Limit: 1 page.]

Synthesis of Evidence: The results of these two methodological non-experimental studies provide evidence that both the ECAB and the SATCo can be used to detect progress in postural control in children who are undergoing physical therapy treatment. Both the SATCo and the ECAB have been used in children with Cerebral Palsy, or patients with impairments consistent with this clinical diagnosis. However, the study that was best suited for review for the SATCo included children who had suffered a spinal cord injury, which is less applicable to this PICO question. Both studies found large effect sizes, and therefore both outcome measures are responsive. No one study compared the two tools together, and therefore the direct comparison is impossible. Instead, the PICO questions must be answered by looking at all the evidence and a review of many different studies that look at reliability, validity, and responsiveness. Based on these two studies reviewed, the ECAB is more applicable and relevant to children who present with neurodevelopmental delays and poor postural control, as an outcome measure that can be used in the home easily. The additional studies reviewed after the article search demonstrated that the ECAB has high inter and intra-rater reliability, high validity when compared to gold standard tools, and large effect size after physical therapy intervention of 6-months.[2,4,5] LaForme Fiss et al. also published longitudinal trajectories on the ECAB for children 18-months to 12-years at different GMFCS levels (I to IV), providing a way to compare mean scores to children of the same age and function level.[7] The SATCo has been studied in preterm and term infants and has demonstrated term infants complete or hit the ceiling of the SATCo by 8 to 9-months of age.8 This same study found that the SATCo can detect reactive control differences between preterm and term infants at 8-months.[8] Therefore, depending on the question, the clinical scenario, and patient demographics, the answer for which outcome measure is best to use may change. For this PICO question

based on the evidence reviewed, the ECAB is the most applicable and has more data available for this specific population making a comparison to peers and detection of true progress possible.

Implications for Clinical Practice: Infants and children with neurologic impairments and developmental delays frequently struggle with sitting balance and postural control. Skill acquisition of independent sitting for an extended period is often delayed or unmet in this population of children. Physical therapists will benefit from having more outcome measures that accurately assess sitting balance and postural control more precisely. Standardized assessment tools, while essential to capturing an overall picture of the child's gross motor skill mastery compared to age-matched peers, generally consider the trunk as a whole. The test items often require that vertical control has been achieved in order to receive credit.[8] These tests may not reflect small changes in sitting balance overtime because the items are credited as "can perform" or "cannot perform." While some standardized assessment tools, like the GMFM-88 or GMFM-66, do award partial credit and are a gold standard tool for children, the test is long and complex to complete. Many children who are significantly delayed will continue to score in the delayed range on these tests as they are unable to "pass" the upright sitting items of the tested. For a child who has not yet mastered neutral vertical upright sitting balance, a measurement tool that breaks down the development of upright posture can be used to monitor progress better, justify the ongoing treatment of this impairment, and help guide clinical decisions. Reaching ability, and object manipulation are enhanced by the mastery of sitting and ready a child for the onset of locomotion.[12] These skills provide the opportunity to learn and grow cognitively. Therefore, pediatric physical therapists should focus their energy on supporting these skills by working towards improved postural control and providing interventions that support the development of sitting balance. Either tool can be used depending on the goal.

Implications for Future Research: Future research that compares these two outcome measures directly will help physical therapists decide between the use of these two outcome measures. Additional research is needed on the minimal clinically important difference for the SATCo in order to fully understand how much change in the scores of the test is needed to detect a truly meaningful change for the patient. One study reported that they assume the MCID is 1 SATCo level, but a study that includes this as part of their investigation is needed.[6] Another study reported that intra-rater reliability was less for patients who had specific trunk alignment issues; however, the study had a small sample size, and therefore studies with more patients will help flush out issues related to reliability for the SATCo.

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