Treadmill training with partial body-weight support in children with cerebral palsy: a systematic review

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LIST OF ABBREVIATIONS

AACPDM	American Academy for Cerebral
	Palsy and Developmental Medi-
	cine
ICF	International Classification of
	Functioning, Disability and Health
NDT	Neurodevelopmental treatment
PBWSTT	Partial body-weight support
	treadmill training
PEDI	Pediatric Evaluation of Disability
	Inventory

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RESULTS As two of the eight published articles reported on different outcomes of the same study, this review reports on seven studies with a total of 41 children. The evidence for the functional effects is limited. Statistical significance is not demonstrated in several of the studies, despite reported improvements in gross motor function, functional status, walking performance, and gait parameters.

INTERPRETATION This systematic review is limited by the small number of participants, the heterogeneous level of abilities of participants from Gross Motor Function Classification System levels I–IV, and the low quality of trials. Because of these limitations, we cannot conclude that PBWSTT results in improvements for children with CP. Additional studies and well-established randomized controlled (or clinical) trials are clearly needed before determining the benefits and efficacy that would support continued use of this intervention in the clinical setting.

Cerebral palsy (CP) describes a group of disorders of the development of movement and posture, causing activity limitation, which is attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of CP are often accompanied by disturbances of sensation, cognition, communication, perception, behavior, and/or a seizure disorder.¹

Physical therapy is considered an important part of the management of children with CP. A common functional outcome in physical therapy for children with CP is the attainment of upright locomotion (i.e. walking).² To improve ambulatory function in children with CP, physical therapists often focus on balance and strength training, as well as on gait preparatory tasks during crawling, sitting,

and standing.^{3–5} Children who are able to walk are more successful in social roles, such as participation in the community, and have more functional independence in activities of daily living compared with children who use wheelchairs.²

Gait limitations in children with CP are common. Reduced walking speed and endurance are two of the main functional problems.⁶ In addition, gait deviations including, but not limited to, decreased step and stride length, decreased speed, decreased toe clearance, and timing issues affect the ability of a child with CP to ambulate independently and efficaciously in home and community environments.7 Children with CP at Gross Motor Function Classification System (GMFCS) levels III-V have additional limitations and issues with ambulation, secondary to their increased need for assistance and support during ambulation.⁸ Clinical presentations and preliminary reports about partial body-weight support treadmill training (PBWSTT) have physical encouraged physical therapists to explore this intervention to address gait limitations in children with CP. PBWSTT intervention is also potentially attractive as it may address gait limitations more effectively, because it allows one to address gait to be addressed at multiple levels of the International Classification of Functioning, Disability and Health (ICF). Interest in PBWSTT for children with CP is rapidly increasing. Evidence to support treatment intervention in children with CP should be carefully explored by clinicians before they add it to their treatment repertoires.

Treadmill training is a dynamic system approach for attainment of locomotor skills in children with CP.9-12 It provides therapeutic intervention at the activity level of walking, one of the most important milestones in a child's development. PBWSTT is an active, repetitive, task-specific approach used to facilitate attainment of stepping and locomotion and to achieve a more normalized gait pattern. Treadmill training is based on current theories of motor learning.^{13,14} If a person is to learn to walk, the actual practice of walking is necessary.15 Activation of spinal and supraspinal pattern generators, as described in animal experiments, underpins the theoretical basis of this treatment concept.¹⁶ Physical effects of therapy and taskspecific practice, as well as neuroplasticity after brain injury, are believed to play a role in the mechanics of treadmill training in children with CP. PBWSTT allows the therapist systematically to train patients to walk on a treadmill at increasing speeds with increasing weight-bearing, simulating what will be necessary for household or community ambulation. Therapists provide verbal and tactile cues to facilitate the kinematic, kinetic, and temporal features of walking. It is reasonable to assume that the treadmill locomotor practice sessions affect motor learning and strengthen leg muscles, activate the locomotor control system, and improve functional abilities as the child practices and experiences the task-specific behavior of walking.^{11,15}

During PBWSTT, an overhead harness system is used to support the child's body weight, while the therapist manually guides the foot and leg movements.^{17–20} Although PBWSTT was initially developed to facilitate improved locomotion in ambulators, non-independent walkers, including severely disabled children who will never experience walking in normal conditions, may also practice locomotor movements on a slowly moving treadmill.^{11,21} Types of treadmill and harness systems used, as well as speed, time, and other practice parameters, may all influence actual PBWSTT intervention outcomes.

Physical therapists need to use evidence-based practice in the clinical setting and must take the responsibility for using scientifically acceptable methods of intervention and objective measurements of outcomes.²² Despite evidence supporting the use of PBWSTT as an effective and beneficial intervention to restore gait in adult neurological disorders, i.e. stroke, Parkinson disease, spinal cord injury, and progressive supranuclear palsy,^{13,23-27} the evidence to support its use for those with CP has not been systematically reviewed. The aim of this review is to summarize the current research evidence on PBWSTT in children with CP and its effects on functional outcomes in them. It should guide future research in this area to determine 'where we are now' and 'where we should go next' with PBWSTT for children with CP. PBWSTT has also been researched for children with Down syndrome and infants at high risk for other neurodevelopmental deficits.²⁸⁻³⁰ However, as the outcome measures, characteristics of the motor disability, accompanying disorders, and methodological issues for these disorders differ importantly from those of CP, this review is restricted to treadmill training in children with CP.

METHOD

Search

The clinical questions of this review were: 'What are the effects of PBWSTT in children with CP?' and 'How does PBWSTT play a role in the neurorehabilitation of children with CP?'. The inclusion criteria were as follows: (1) studies including children under 18 years of age with CP; (2) studies with all research designs including case reports; (3) fully published studies (not abstracts) in peer-reviewed journals; (4) studies showing the effectiveness of PBWSTT in children with CP; (5) studies using functional outcome measures; (6) studies written in English. Review papers and studies that addressed only indications for the intervention were excluded from the review.

A literature search used the following electronic and library databases: Medline, PubMed, Google, EmBase, Ovid Medline, Galter Health Sciences Library (http:// www.galter.northwestern.edu), Physiotherapy Evidence Database (PEDRO), COCHRANE Collaboration Database Systematic Reviews, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and the Hooked on Evidence database of the American Physical Therapy (http://www.apta.org). Association Databases were searched from 1950 until July 2007. The keywords used for the search were 'cerebral palsy', 'treadmill training', 'PBWSTT', 'locomotor therapy', 'gait', 'walking', and 'physical therapy methods'. Reference lists in relevant studies and review articles were also examined.

Review method

Four methods were chosen to summarize and review each article. (1) The summary characteristics were determined using the methodology to develop systematic reviews of treatment interventions suggested by the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM).³¹ Summary characteristics were identified and included participant characteristics (number in each group, target population, diagnosis, numbers in each diagnostic subgroup, and ages), intervention used, control used, research design, and outcomes of interest. (2) The level of evidence for each article was identified by 'coding levels of evidence' as described in the AACPDM methodology for developing systematic reviews of treatment interventions.³¹ The grading of levels of evidence was based on Sackett's hierarchy of levels of evidence.³² The level of evidence was based on research design types. Level I evidence is the most definitive for establishing causality, with greatest reduction in bias. Level IV can only hint at it. Level V only suggests the possibility of causality. (3) The research design type of each article was determined using the Guidelines for Critical Review Form - Quantitative Studies by Law et al.³³ There are seven research design types, ranging from highest to lowest quality as explained by Law et al.:³³ randomized controlled (or clinical) trial (RCT); cohort design; single case design; before-after design; case-control design; cross-sectional design; and case-study design. (4) The methodological quality of each article was evaluated using the Critical Review Form - Quantitative Studies and the Guidelines for Critical Review Form - Quantitative Studies by Law et al.33 Methodological Quality Critical Review Forms and Guidelines were chosen as they are commonly used tools in evidence-based practice critical reviews and were developed by the McMaster University Occupational Therapy Evidence-Based Practice Research Group.³³ This method was chosen to evaluate each of the articles in the following categories: study purpose, literature review, study design, sample, outcomes, intervention, results, conclusion, and clinical implications (Table I). The overall quality of each article was evaluated using 15 closed-ended questions, scored as either 1 (completely fulfills the criterion) or 0 (does not fulfill the criterion); scores for all 15 questions were added for a total score. A maximum score of 15 indicated excellent methodological quality.

Coding level of evidence is determined only by study design³² whereas methodological quality indicates quality of articles, including purpose, literature, design, sample, outcomes, intervention, results, and conclusions.³³ For this reason, highest scores in methodological quality do not always show high levels of evidence. Although validity and reliability of the methodological quality critical review form has not yet been ascertained, this form is commonly used in review studies in evidence-based research.^{33,34}

Methodological quality critical review forms were completed by the first and second authors independently; any disagreement was discussed to reach consensus. The other review methods were completed by the first author and then reviewed by the second author; disagreements were discussed.

Table I: Methodological quality of articles: Critical Review Form –
Quantitative Studies ³³

Study purpose

1- Was the purpose clearly stated?

Literature

2- Was relevant background literature reviewed? Design

3- Was the design appropriate for the study question? Sample

4- Was the sample described in detail?

5- Was sample size justified?

Outcomes

6- Were the outcome measures reliable?

7- Were the outcome measures valid?

Intervention

8- Was intervention described in detail?

9- Was contamination avoided?

10- Was co-intervention avoided?

Results

11- Were results reported in terms of statistical significance?

12- Were the analysis methods appropriate?

- 13- Was clinical importance reported?
- 14- Were drop-outs reported?

Conclusions and clinical implications

15- Were conclusions appropriate given study methods and results?

Data analysis

Effect sizes with 95% confidence intervals (CIs) were calculated if raw data were available in the studies. The effect size gives an easy understanding of how big the treatment effect is, and the clinical significance of these statistically significant treatment effects can also be justified. The effect size was calculated by subtracting the means of outcome measures of the pre- and posttreatment groups as the participants were acting as their own controls and dividing it by the SD of difference scores. The 95% CI was approximated by the formula $3 \times \text{SD}/\sqrt{n}$ (*n*, number of participants in the study).³⁵

RESULTS

Initially 22 studies were found through the search strategy. Twelve of the 22 studies were 'published as articles' whereas 10 studies were 'unpublished as articles'. From the 12 published articles found, three were excluded because they did not address the use of treadmill training in individuals with CP, and one of the remaining articles was excluded because it did not meet all the preset inclusion criteria defined above. Eight articles remained, and each of these had 'treadmill training' and 'cerebral palsy' in their titles. Eight of the 10 'unpublished as an article' studies were published in *Pediatric Physical Therapy*, one in *Klinische Neurophysiologie*, and one in *Neuropediatrics* as 'abstracts'. After contact with the authors of those studies, it was determined that none had been published as articles.

As two of the eight published articles^{10,21} reported on different outcomes of the same study, this review reports on a total of seven studies with a total number of 41 children.

Results are summarized in Tables II, III, and Tables SI and SII (supporting information published online).

Results of methodological quality of articles showed that total scores ranged from 10 to 13 (Table II). None of the studies identified met the highest total score. All studies, with the exception of one,¹² consisted of case studies, open non-randomized trials, or case series with/without control participants, indicating that the studies' level of evidence was low (Sackett's level III, IV, V). The studies demonstrated large variability in participants' ages (1.7-18 years) and levels of impairment (GMFCS levels I-IV). In addition, intervention characteristics such as equipment used, percentage of body-weight support, time spent training within a session, sessions in a week, total intervention period, and other concurrent interventions that occurred throughout the study period, showed large variability. Only Richards et al.¹¹ used a customized treadmill in their study; in the other studies, motor-driven commercial treadmill equipment was used. Variability in equipment used, concurrent interventions, and temporal parameters, as well as heterogeneity of the population, precluded meta-analysis.

All the studies explored activity limitation as described in the ICF. In addition, impairment issues were also explored in all studies except two.15,18 Functional outcomes used varied by study, although several studies reported Gross Motor Function Measure (GMFM) and Pediatric Evaluation of Disability Inventory (PEDI) scores. In the studies by Cherng et al. and Schindl et al.,9,18 the standing and walking scores of the GMFM were statistically significant (p < 0.05, p < 0.01). In three studies,^{11,15,21} GMFM scores changed although not significantly. Only two studies^{15,17} used the PEDI outcome measure for functional status. In one of these,17 after the PBWSTT treatment, mobility, social function in the functional skills domain, self-care in the functional skills domain, and the caregiver assistance domain improved significantly (p<0.05) on the PEDI in three participants out of five. In the other,15 pre- and posttreatment PEDI scores showed only small improvements; the amount of improvement, however, did not exceed the standard error for the scaled scores.

Table II: Results of	: Results of methodological quality of articles: Critical Review Form – Quantitative Studies ³³															
Studies	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Total
Begnoche et al. ¹⁷	1	1	1	1	1	1	1	1	NA	0	1	1	1	1	1	13
Cherng et al. ⁹	1	1	1	1	0	1	1	0	NA	0	1	1	1	1	1	11
Day et al. ¹⁵	1	1	1	1	1	1	1	1	NA	0	0	0	1	NA	1	10
Dodd et al. ¹²	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1	13
Phillips et al. ²¹	1	1	1	1	1	0	0	1	NA	1	1	1	1	1	1	12
Provost et al. ¹⁰	1	1	0	1	1	1	1	1	NA	1	1	1	1	1	1	13
Richards et al. ¹¹	1	1	1	1	1	1	1	1	NA	0	0	1	1	1	1	12
Schindl et al. ¹⁸	1	1	0	1	1	1	1	1	NA	0	1	1	1	1	1	12

0, no; 1, yes; NA, Not applicable.

Study	Research design	Level of evidence	Numb particip		Participant characteristics Sample of Convenience	Age range (y)	
			Treatment group	Control group			
Begnoche et al. ¹⁷	Multiple single- subject design Case series	IV	5	5 ^a	Children with spastic CP GMFCS: 2 children in level I, 1 child in level III, 2 children in level IV	2.3–9.7	
Cherng et al. ⁹	Case series	IV			Children with spastic diplegic CP GMFCS: 2 children in level II, 6 children in level III (1 dropout in level III)	3.5–6.3	
	AAB group		4	3 (1) ^a			
	ABA group		4	4 ^a			
Day et al. ¹⁵	Single case design	V	1	1 ^a	Non-walker spastic tetraplegic CP GMFCS: level not identified	9	
Dodd et al. ¹²	Clinical controlled trial (matched pairs)	III	7	7	Children with athetoid quadriplegia, spastic quadriplegia, and spastic diplegia. GMFCS: 4 children in level III and 10 children in level IV	5–14	
Phillips et al. ²¹	Multiple single- subject design	IV	6	6 ^a	Children with spastic hemiplegic and diplegic CP GMFCS: all children in level I	6–14	
Provost et al. ¹⁰	Multiple single- subject design	IV	6	6 ^a	Children with spastic hemiplegic and diplegic CP GMFCS: all children in level I	6–14	
Richards et al. ¹¹	Multiple single- subject design	IV	4	4 ^a	Children with spastic hemiplegic, diplegic and tetraplegic CP; at baseline none were independent walkers, 2 walking with support GMFCS: level not identified	1.7–2.3	
Schindl et al. ¹⁸	Open nonrandomized baseline treatment study	IV	10	10 ^a	Children with spastic diplegic, tetraparesic, and tetraparesic and ataxic CP; 6 non-ambulatory and 4 ambulatory children GMFCS: level not identified	6–18	

^aTreatment group acting as their own control group. Levels of evidence: I, systematic review of randomized controlled trials (RCTs), large RCT with narrow confidence intervals (n > 100); II, smaller RCTs with wider confidence intervals (n < 100), systematic reviews of cohort studies, 'outcomes research' (very large ecologic studies); III, cohort studies (must have concurrent control group), systematic reviews of case control studies; IV, case series, cohort study without concurrent control group (e.g. with historical control group), case-control study; V, expert opinion, case study or report, bench research, expert opinion based on theory or physiological research, common sense/anecdotes. For additional study details, see Tables SI and SII. AAB, first treatment schedule; ABA, second treatment schedule; GMFCS: Gross Motor Function Classification System.

Ambulatory status was measured using gait kinematics, speed of walking, and endurance. Gait parameters were evaluated in three of the studies^{9,11,17} An increase in step length and stride length, and a decrease in double limb

support, were noted.9,17 In addition, hip and ankle movement patterns were closer to normal values.¹¹ Walking performance was assessed in three studies.^{10,12,21} In one of them,¹² when compared with the control group, the seven

treadmill-training participants increased their self-selected walking speed over $10m^{36}$ significantly (*p*=0.048) and increased distance walked over ground in 10 minutes although it did not reach statistical significance (*p*=0.083). In another study,²¹ after the treadmill training the 10m walking velocity significantly increased (*p*=0.035) and there was no change in distance walked for 6 minutes³⁷ (*p*=0.851). Provost el al.¹⁰ indicated a significant difference between pre- and postclinical measures in 10m walking velocity (*p*=0.038) and no significance in the 6 minute endurance walk (*p*=0.851) after treadmill training.

Balance was measured in only one study,¹⁰ which found no significant difference (p=0.221) in pre- and posttreatment group means. No side effect of PBWSTT was reported in any study.

Relative effect size with 95% CIs was available for two studies.^{12,17} Effect size in one of these¹⁷ was calculated using the raw data obtained from the study.

DISCUSSION

This review showed that eight studies evaluated functional outcomes of PBWSTT in children with CP from 1950 to July 2007. As the topic's popularity is advanced within the clinical setting, an increase in publications and evidence is noted. In the past year alone results of five of the seven studies were published, yielding eight papers.

Confidence in evidence-based physical therapy is growing.³⁸ In our review, using the AACPDM guidelines and the methodological quality scale strengthened the quality of this evidence-based literature review of PBWSTT for children with CP. Overall, low levels of evidence for this intervention were found; all studies except one¹² consisted of case studies, open non-randomized trials, or case series with/without comparison participants.

Studies examined in the review addressed outcomes in a heterogeneous and non-standardized way and provided inconclusive results. This systematic review is limited by the small number of participants, the heterogeneous level of abilities of participants from GMFCS I-IV, and the overall low quality of the trials. Functional improvement in standing and walking in gross motor function after PBWSTT may be explained by the increase in lower extremity strength, improved balance, facilitation and repetition of movements, and exposure to increased practice. Treadmill training also resulted in an improvement of functions other than gait (standing, transfers, rising).^{15,18} However, in all of the studies reviewed except two,^{10,21} which both report outcomes on the same study, children underwent co-intervention, and continued with their regular physical and occupational therapies. We do not have any confirmation that it was the PBWSTT rather than these other interventions that may have led to the noted

improvements. In addition, parameters of PBWTT varied in training speeds, percentage of body-weight support, and frequency and duration of training. This is a similar result to that discussed in Dobkin's overview on adults with spinal cord injury.³⁹ Dobkin also noted that duration, frequency, and characteristics of treadmill training, as well as type of treadmill and harness, style of therapy and outcome measures, varied when PBWSTT was undertaken with adult neurological populations.³⁹ Additional research is required to demonstrate the isolated effects of PBWSTT for children with CP and to determine effective parameters for use of this intervention.

This review demonstrates that it is not yet clear whether PBWSTT has an influence on activity levels, participation in social roles, and psychological development of children who have never experienced walking. It might reasonably be suggested that IQ has an impact on the motivation and outcome of a person with CP provided with locomotor therapy, as sufficient cognitive and communicative skills seemed to best predict the outcome of locomotor therapy of children with CP.¹⁴ None of the studies in this review identified or explored IQ levels of children. Future study should consider the effect of IQ on performance and outcome during PBWSTT.

Research findings suggest that PBWSTT is superior to neurodevelopmental treatment (NDT) in enhancing walking capacity after acute stroke.⁴⁰ It may be necessary to compare PBWSTT with other specific interventions for children with CP, such as NDT, as used in for patients with acute stroke. Additional studies in children to compare treadmill training with overground walking, which has had evidence demonstrated in adults,⁴¹ should be undertaken in the next step of research. Randomized clinical trials must be undertaken using scientific experimental designs that measure the impact of PBWSTT on the lives of children with CP and their families. Outcomes specific to locomotor training should include functional independence for walking and for mobility-related self-care and community activities, and should include walking speed, endurance, and the perceptions of participants about health-related quality of life.

The difference between children with CP who are nonambulators and adults after spinal cord injury or stroke is that the children have not previously experienced walking. Locomotor pathways have been clearly established in the adult patient pre-insult. Children with CP in a predominantly non-ambulatory state may have altered neural pathways that subserve locomotion at both spinal and supraspinal levels. However, input from spinal circuits and supraspinal centers, although probably abnormal, may possess sufficient developmental plasticity to benefit from the locomotor training experience. Investigation of the types of change that the children in these studies may have experienced at the spinal or supraspinal level, in addition to changes in muscle performance, cardiovascular endurance, and function as a product of training, is promising and areas of research needed.¹⁴

Task-dependent neuroplasticity is an important mechanism underlying motor recovery after brain injury.²¹ Phillips et al.²¹ focused on the role of neuroimaging in pediatric neurorehabilitation, in the first study on the topic. PBWSTT was conducted with use of pre- and posttraining functional magnetic resonance images (fMRIs). Six participants were included in the study; however, only three of the six were able to complete pre–post intervention fMRIs. The very small number of participants does not allow us to generalize the results to the larger population of children with CP. Perhaps additional fMRI studies, as well as diffusion tension imaging studies in conjunction with PBWSTT in children with CP, could add to the body of knowledge about neuroplasticity and locomotor training.

No side effect of PBWSTT treatment was reported in any study. Psychological impact of interventions in children with disabilities has always been an important but less well-researched perspective. An increase in motivation and self-confidence was observed in the study by Day et al.¹⁵ as a secondary outcome of PBWSTT treatment. Consistent use of health-related quality of life outcome measures in locomotor intervention training studies will add additional insight to determine overall treatment benefits.

PBWSTT may allow physical therapists to foster acquisition of physiologically sound gait patterns in children with CP, and seems to be an adjunct for the other rehabilitation approaches. However, it requires considerable physical therapist training and standardized procedures before use in children with CP. Standardization will require hands-on training of, the therapists who perform PBWSTT before any RCT, a manual to define all aspects of the intervention, a system to grade the performance of the trainers, and monitoring of their skills throughout the RCT.³⁹

Initial studies have suggested that PBWSTT may have a place in treatment for children with CP. However, PBWSTT for this population requires additional study, specifically well-formulated RCTs. High-quality randomized placebo-controlled, clinical trials should be completed to determine whether treadmill training programs have a beneficial effect on functional locomotion and muscle strength for children with CP. RCTs with well-defined methods of PBWSTT for well-defined populations of children with CP must be performed to determine the efficacy of this intervention for this population. Outcomes at all levels of the ICF should be explored to determine the cost-benefit ratio of undergoing such an intensive intervention. Lower-extremity muscle strength should also be measured because lower-extremity strength training has been effective in improving gait parameters and functional abilities in children with CP.⁴²

CONCLUSION

This systematic review is limited by the small number of participants, heterogeneous level of abilities of participants from GMFCS I-IV, and low quality of the trials. Because of these limitations, we cannot conclude that PBWSTT results in improvements for children with CP. The results of this review suggest that, although treadmill training may appear to have benefits within the tested population of children with CP, additional studies and well-established RCTs are clearly needed before determining benefits and efficacy that supports continued use of this intervention within the clinical setting. The treatment does not appear to be harmful to the children. Theoretical support is emerging in adults, as is evidence for the efficacy of this approach for adults with spinal cord injury and stroke. Developing children present a more complicated theoretical substrate than adults with injury to the central nervous system, and further study is warranted before its implementation as an accepted intervention in the standard of care of children with CP. To allow comparison across trials or studies, PBWSTT intervention parameters should be standardized across trial groups to allow for a larger sample size and a stronger study outcome (albeit positive or negative), which will further advance our knowledge of this intervention. In addition, there are no studies with long-term follow-up, which would enable one determination of any long-term gain posttreatment. Future studies, including RCTs, must involve follow-up measurement to determine if gains will have long-term and lasting impact for children with CP.

SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Table SI: Summary of intervention outcome characteristics.

Table SII: Summary of study results (continued).

This material is available as part of the online article from http://www.blackwell-synergy.com/doi/10.1111/ j.1469-8749.2008.03221.x (this will link you to the article abstract).

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