1997

A randomized clinical trial to compare selective posterior rhizotomy plus physiotherapy with physiotherapy alone in children with spastic diplegic cerebral palsy

Paul Steinbok
University of British Columbia

Ann M. Reiner
British Columbia's Children's Hospital

Richard Beauchamp
British Columbia Research Institute for Child and Family Health

Robert Armstrong
Aga Khan University, robert.armstrong@aku.edu

Douglas Cochrane
University of British Columbia

A randomized clinical trial to compare selective posterior rhizotomy plus physiotherapy with physiotherapy alone in children with spastic diplegic cerebral palsy

Paul Steinbok
Ann M Reiner
Richard Beauchamp
Robert W Armstrong
D Douglas Cochrane

A randomized controlled single-blind trial was performed to compare lumbo-sacral selective posterior rhizotomy (SPR) followed by intensive physiotherapy, with intensive physiotherapy alone in improving motor function in children with spastic diplegic cerebral palsy. Fifteen patients were randomly assigned to each treatment modality. Patients in the SPR group had rhizotomy within 1 month, followed by intensive outpatient physiotherapy for 9 months. Patients assigned to physiotherapy alone had identical intensive physiotherapy. There was a statistically significant and clinically important difference in improvement in motor function in favor of the SPR group, with a mean increase in total Gross Motor Function Measure (GMFM) score of 11.3% at 9 months for the SPR group compared with 5.2% for the physiotherapy-only group (P=0.007). Significant improvements in spasticity (P<0.001) and range of movement (P<0.001) were noted in the SPR group compared to the physiotherapy-only group. The results indicate that the improvement in motor function after SPR is more than can be explained by the associated intensive physiotherapy.

Selective posterior rhizotomy (SPR) is currently performed in many centers for the treatment of spasticity associated with cerebral palsy (CP), with the aim of reducing spasticity and increasing range of movement in the lower limbs, with the expectation that this will improve the motor function of the child. Favorable results have been reported after this operation by many workers in the field (Fasano et al. 1980, Peacock and Staudt 1991, Steinbok et al. 1992, Abbott et al. 1993, Park et al. 1993, Peter and Arens 1993, McLaughlin et al. 1994, Albright et al. 1995). None of the above reports has been based on randomized clinical trials, and it has not been possible to determine whether the positive results noted after the rhizotomy procedure are due to the operation itself or to the intensive physiotherapy that is usually given after SPR (Landau and Hunt 1990, Giuliani 1991, Park and Owen 1992, McLaughlin et al. 1994).

The objective of this study was to determine whether lumbo-sacral SPR followed by intensive physiotherapy was more effective than intensive physiotherapy alone in improving motor function in children with spastic diplegic CP.

Method

DESIGN AND SETTING

This was a single-centre randomized single-blind trial comparing two treatments for lower-limb spasticity: SPR plus intensive physiotherapy; and intensive physiotherapy alone. The study was designed to compare the efficacy of these two treatments in improving the gross motor function of children 9 months after treatment.

The total score of the Gross Motor Function Measure (GMFM) was chosen as the primary outcome measure for this study because it was the only functional assessment tool that had been standardized and validated for use in children with spastic CP (Russell et al. 1989, Haley et al. 1991).

The study was conducted at British Columbia's Children's Hospital, the only tertiary care referral children's hospital in the province of British Columbia. The study was approved by the Ethics Committee of the University of British Columbia.

Fifteen children were randomly assigned to each arm of the study. One child in each group dropped out after randomization: the parents of one child assigned to the physiotherapy-only group decided that they were not prepared to wait for surgery later, and the parents of the other child assigned to the SPR group later refused rhizotomy. Children in the SPR group ranged in age from 35 to 75 months (mean 50 months, median 47 months), and in the control group from 35 to 77 months (mean 47 months, median 42 months).

Six children who were potentially eligible were not entered into the study, but went on to undergo a rhizotomy. Three of these patients did not meet all the eligibility criteria: in two cases there was uncertainty about the availability of intensive physiotherapy, and for one child with significant hip subluxation there was concern about the possibility of a delay in surgical treatment. The other three children were eligible for the study but the parents refused to participate, preferring instead to proceed to an electively scheduled rhizotomy.

The comparability of the treatment and control groups was assessed by examining baseline measurements of all the outcome measures, including GMFM, Physiological Cost Index, Peabody Fine Motor Scale, self-care assessment score and 10 measures of range, spasticity and strength. There were no significant differences between the two groups at baseline

(Table I). All children had been receiving active supportive therapy, with a minimum of one session weekly with a physiotherapist, before entry to the study.

The amount of physiotherapy given by a physiotherapist over the 9 months of the study averaged 81.8 hours (range 72 to 90 hours) for the SPR group, compared with 81.3 hours (range 70 to 89 hours) for the physiotherapy-only group.

For the children undergoing SPR, the mean percentages of the posterior roots cut were 58% for L2, L3, L5 and S1 combined, 42% for L4, and 40% for S2.

Potential subjects were reviewed by an orthopedic surgeon, neurosurgeon and physiotherapist to determine whether they were eligible for the study in fulfilling the following criteria: spastic diplegic CP with no athetoid or ataxic component to their neuromuscular problem; 3 to 7 years of age; spasticity severe enough to impair gross motor function; SPR considered to be appropriate for the child; able to sit on the edge of an examining table with arms in the air and able to stand up while holding on with their hands; intensive physiotherapy in accordance with the study protocol available in the child's home community; and parents consented to the child being randomly assigned to one of the two groups. Patients were excluded if there was a planned surgical procedure (orthopedic or otherwise) during the period of the study, or if it was felt by the assessors that the child's problems were of such severity that a 9-month delay in performing a definitive procedure might compromise the child's health (e.g. if the hips were subluxed significantly). Parents were informed that both the physiotherapy alone and the SPR plus physiotherapy had the potential to improve the child, and that if the child was assigned to the physiotherapy-only arm of the study, the child would be able to have SPR at the completion of the study if the physicians and parents felt that this procedure was still indicated. Children who were entered into the study were randomly assigned to either group by using a random numbers table. The randomization was performed by an independent party not involved with the care of the patient.

PROCEDURE

Children selected for SPR had the operation perfomed within 1 month of being assigned to the group. Postoperative management was standardized, with gradual mobilization after 48 hours of bed rest, and discharge on the 6th postoperative day. Children then returned to their home where they received intensive physiotherapy. Children assigned to the physiotherapy-only group started their intensive physiotherapy program within 1 month of being assigned, and received the same amount and type of physiotherapy as the SPR group.

Children in both study groups received intensive physiotherapy 3 times a week for 3 months, and twice a week for 6 months, using equivalent techniques of treatment. Physiotherapy consisted of passive range of motion of the joints of the lower limbs; strengthening to hip abductors and extensors, knee extensors, and ankle dorsiflexors; and for 40 minutes of each 1-hour session, the practice of normal patterns of movement based on neurodevelopmental theory (Bobath 1967). Because the usual protocol after SPR involves much standing and walking, the physiotherapist treating each child in the physiotherapy-only group was instructed to place as much emphasis on weightbearing as if the child had undergone SPR. A home physiotherapy program, as outlined by the study physiotherapist, was taught to parents and monitored by the child's community physiotherapist. Records of the physiotherapy sessions were kept by the parents and by the physiotherapists, and these were provided to the study coordinator.

SPR involved partial posterior rhizotomies from L2 to S2, via laminotomies from L1 to S1. Each posterior root was split into three to six rootlets, each of which was stimulated within 4cm of the root exit foramen with two unipolar electrodes (Modified Insulated Ball Dissectors; Aesculap Surgical Instruments, Burlingame, CA., USA). Recordings were made with silver/silver chloride electrodes applied over the muscle bellies of the hip adductors, vastus medialis, tibialis anterior and gastrocnemius in the lower limbs, deltoids and extensor digitorum communis in the upper limbs, and sternocleidomastoid and masseter. The threshold for a response was identified by

Table 1: Mean baseline values and 95% CI for all outcome measures in both groups.

Assessment	*SPR*	*Physiotherapy*	*SPR*		*Physiotherapy*	
	N	*N*	*Mean*	*(CI)*	*Mean*	*(CI)*
GMFM	14	15	60.7	(51.4–70.0)	62.7	(54.4–71.0)
Physiological Cost Index	6	5	1.07	(0.67–1.47)	1.03	(0.46–1.59)
Peabody score	14	15	513	(484–541)	508	(485–531)
Self-care assessment score	14	15	44.8	(29.7–60.0)	37.4	(24.7–50.1)
Spasticity (Ashworth score)						
Hip adductors	14	15	3.36	(3.0–3.7)	3.1	(2.7–3.5)
Knee flexors	5	5	2.9	(2.2–3.6)	2.6	(1.5–3.7)
Ankle plantarflexors	14	15	4.0	(3.7–4.3)	3.3	(2.9–3.7)
Range of motion (degrees)						
Hip abduction	14	15	25.8	(20.8–30.8)	31.9	(26.9–36.9)
Knee extension	14	15	138.3	(129.5–147.1)	144.3	(136.5–152.0)
Ankle dorsiflexion	7	4	–11.3	(–15.1–7.5)–	–14.1	(–29.5–1.3)
Muscle strength (kg force)						
Knee extensors	5	5	7.0	(4.0–10.0)	6.5	(4.5–8.6)
Hip extensors	5	5	2.1	(0.7–3.5)	1.5	(0.1–3.0)
Hip abductors	5	5	2.5	(1.3–3.8)	2.6	(1.3–3.8)
Ankle dorsiflexors	5	5	1.9	(0.6–3.1)	1.8	(0.3–3.3)

SPR = SPR plus physiotherapy group, Physiotherapy = physiotherapy-only group.

using single stimuli and was defined as the stimulus intensity at which the first visible muscle contraction was noted in the segmental distribution of the posterior rootlet or root being stimulated. Tetanic stimulation at 50Hz was then applied for a duration of 1 second at the threshold level of stimulation, and the electrophysiologic responses were recorded on a 17-channel Nihon-Kohden EEG machine with a printout.

Selection of the nerve rootlets to be cut was based primarily on the clinical assessment of the extent and severity of the spasticity, with a decision made preoperatively about the approximate amount of the posterior root to be cut at each level. In general, the plan was to cut no more than 50% of S2 because of concern about possible bladder dysfunction, 40% to 50% of L4 to avoid excessive hypotonia of the quadriceps, and 50% to 70% of L2, L3, L5 and S1. The responses to electrical stimulation were used to determine which rootlets to cut to achieve the predetermined amount, and the final amount of the root cut was modified from the predetermined amount depending on the extent of abnormal responses to electrical stimulation. If responses were particularly abnormal, up to an additional 20% might be cut, and if the responses were generally normal up to 20% fewer might be cut. The major electrophysiologic criterion used was the extent of spread of the response, with spread contralaterally or to the upper limbs considered to be abnormal. A secondary criterion was the pattern of the response to tetanic stimulation, with incremental and clonic responses being considered to be most abnormal, decremental responses most normal, and flat (square wave) responses somewhat equivocal.

OUTCOME MEASURES

Children were assessed at the start of the study and at 3, 6, and 9 months after the start of treatment by physiotherapists and occupational therapists who were not involved in the ongoing treatment of the study patients. Information about the patients' treatment was withheld from the physiotherapists assessing outcome. The child was dressed in a one-piece leotard for each assessment, so that the therapist could not see

Table II: Scores at baseline and at 9 months after treatment, and the changes between baseline and 9-month assessments for each dimension of the GMFM and for the total GMFM score, for each patient in the study.

Nr	*Lying and rolling*			*Sitting*			*Crawling and kneeling*			*Standing*			*Walking, running, jumping*			*Total GMFM score*		
	Baseline	*9mo*	*Change*	*Baseline*	*9mo*	*Change*	*Baseline*	*9mo*	*Change*	*Baseline*	*9mo*	*Change*	*Baseline*	*9mo*	*Change*	*Baseline*	*9mos*	*Change*
SPR + physiotherapy group																		
1	96.1	100	3.9	96.6	100	3.4	92.8	92.8	0.0	71.8	82.0	10.2	51.4	73.6	22.2	81.7	89.7	8.0
2	86.3	100	13.7	58.3	80.0	21.7	64.3	85.7	21.4	17.9	15.4	-2.5	13.9	9.7	-4.2	48.1	58.2	10.1
3	90.2	100	9.8	80.0	100	20.0	100	100	0.0	59.0	79.5	20.5	16.6	55.5	38.9	69.2	87.0	17.9
4	100	100	0.0	100	100	0.0	95.2	100	4.8	79.5	87.1	7.6	63.9	75.0	11.1	87.7	92.4	4.7
5	88.2	100	11.8	40.0	88.3	48.3	66.6	95.2	28.6	17.9	33.3	15.4	2.8	16.6	13.8	43.1	66.6	23.5
6	100	100	0.0	98.3	100	1.7	88.1	92.9	4.8	35.9	64.1	28.2	16.7	18.1	1.4	67.8	75.0	7.2
7	96.1	96.1	0.0	90.0	91.6	1.6	71.4	88.1	16.7	28.2	28.2	0.0	13.9	13.8	-0.1	59.9	63.6	3.7
8	100	100	0.0	38.3	76.7	38.4	57.1	73.8	16.7	10.3	10.3	-0.1	5.5	5.6	0.0	42.2	53.3	11.0
9	100	100	0.0	93.3	100	6.7	78.6	97.6	19.0	53.8	82.1	28.3	36.1	52.7	16.6	72.4	86.5	14.1
10	94.1	100	5.9	40.0	85.0	45.0	71.4	83.0	11.6	10.2	20.0	9.8	4.2	9.7	5.5	43.9	59.5	15.6
11	96.1	100	3.9	81.6	86.6	5.0	57.1	64.3	7.2	5.1	7.7	2.6	4.2	4.2	0.0	48.8	52.5	3.7
12	98.0	100	2.0	96.6	100	3.4	95.2	97.6	2.4	74.3	84.6	10.3	44.4	70.8	26.4	81.7	90.6	8.9
13	94.1	100	5.9	51.6	93.3	41.7	64.3	85.7	21.4	10.3	43.4	33.1	4.2	16.6	12.4	44.9	67.8	22.9
14	100	100	0.0	86.6	98.3	11.7	71.4	85.7	14.3	23.1	28.4	5.3	12.5	13.8	1.3	58.7	65.2	6.5
Mean	95.7	99.7	4.1	75.1	92.8	17.8	76.7	88.7	12.1	35.5	47.6	12.1	20.7	31.1	10.4	60.7	72.0	11.3
Physiotherapy-only group																		
1	100	100	0.0	98.3	100	1.7	90.5	90.5	0.0	46.2	61.5	15.4	16.7	18.1	1.4	70.3	74.0	3.7
2	86.2	100	13.8	70.0	83.3	13.3	38.1	73.8	35.7	5.1	7.7	2.6	0.0	0.0	0.0	39.9	52.9	13.0
3	100	100	0.0	100	100	0.0	95.2	100	4.8	71.8	82.1	10.3	43.1	66.6	23.5	82.0	89.7	7.7
4	100	100	0.0	95.0	85.0	-10.0	88.1	80.9	-7.2	30.8	38.5	7.7	12.5	9.7	-2.8	65.3	62.8	-2.5
5	96.1	100	3.9	93.3	95.0	1.7	85.7	92.9	7.2	23.1	43.6	20.5	13.9	16.6	2.7	62.4	69.6	7.2
6	100	100	0.0	91.7	93.3	1.6	95.2	95.2	0.0	76.9	84.6	7.7	47.2	55.5	8.3	82.2	85.7	3.5
7	86.3	100	13.7	70.0	81.9	11.9	80.9	78.6	-2.3	10.3	30.8	20.6	15.3	16.7	1.4	52.5	61.6	9.1
8	94.1	100	5.9	85.0	90.0	5.0	83.3	88.1	4.8	33.3	33.3	0.0	16.6	16.6	0.0	62.5	65.6	3.1
9	96.1	100	3.9	100	98.3	-1.7	88.1	92.9	4.8	28.2	42.2	14.0	12.5	12.5	0.0	65.0	69.2	4.2
10	98.0	100	2.0	98.3	100	1.7	95.2	95.2	0.0	43.6	64.1	20.5	16.6	16.6	0.0	70.4	75.2	4.9
11	92.2	100	7.8	83.3	85.0	1.7	85.7	90.1	4.4	17.9	25.6	7.7	12.5	16.7	4.2	58.3	63.5	5.2
12	90.2	100	9.8	68.3	75.0	6.7	61.9	66.7	4.8	17.9	28.2	10.3	4.2	8.3	4.1	48.5	55.6	7.1
13	82.3	82.3	0.0	46.6	51.7	5.1	19.0	23.8	4.8	12.8	12.8	0.0	4.2	8.3	4.1	33.0	35.7	2.7
14	100	100	0.0	100	100	0.0	100	100	0.0	84.6	84.6	0.0	45.8	61.1	15.3	86.0	89.1	3.1
Mean	94.4	98.7	4.3	85.7	88.5	2.8	79.1	83.5	4.4	35.9	45.7	9.8	18.6	23.1	4.4	62.7	67.9	5.1

whether there was an incision on the back, and the parents were specifically instructed not to indicate to the assessor what treatment the child was receiving or had received. The assessors were instructed not to discuss the possible treatment of the child or results of the assessment with the parents. All outcome assessment sessions were monitored for inadvertent breaks in the blinding protocol.

The total score of the Gross Motor Function Measure (GMFM) was chosen as the primary outcome and end point of the study. The validity, reliability and responsiveness of the GMFM have been demonstrated in a population of patients similar to those that were studied (Russell et al. 1989, McLaughlin et al. 1994). Assessments were performed by physiotherapists who had been trained in the use of the GMFM in children with CP.

A number of other parameters were assessed as secondary outcome measures:

1. Muscle strength (kg) of hip extensors, abductors, quadriceps and ankle dorsiflexors with the use of a hand-held myometer (Hyde et al. 1983). This measure was used to assess only those patients who were able to cooperate adequately at the time of the initial assessment.

2. Muscle tone of hip adductors, knee flexors and ankle plantar flexors with the use of a modified Ashworth scale (Bohannon and Smith 1987).

3. Range of motion at hips, knees and ankles measured with a goniometer using standardized anatomical landmarks and the methods as proposed by the American Academy of Orthopedic Surgeons (American Academy of Orthopedic Surgeons 1965).

4. Physiological Cost Index, which monitors speed of walking and heart-rate simultaneously, and combines these two parameters as an index of locomotor function. The measure has been shown to be reliable and sensitive to the increased

Table III: Mean change and standard deviation of the change (SD) between the values at baseline and 9 months for the secondary outcome measures for both groups

Assessment	*SPR*			*Physiotherapy*			*t*	P
	N	*Change*	*SD*	*N*	*Change*	*SD*		
Physiological Cost Index	6	−0.3	0.15	5	−0.27	0.48	−0.14	0.89
Peabody score	14	22.4	20.2	14	17.4	15.4	0.73	0.48
Self-care assessment score	14	10.5	10.1	14	11.5	7.5	−0.28	0.78
Spasticity (Ashworth score)								
Hip adductors	14	−1.4	0.6	14	−0.3	0.6	−4.86	<0.001
Knee flexors	14	−1.1	0.5	14	−0.1	0.7		
Ankle plantarflexors	14	−1.5	0.6	14	0	0.8		
Range of motion (degrees)								
Hip adductors	14	15.8	10.6	14	−3.3	8.6	5.24	<0.001
Knee flexors	14	15.6	15.6	14	−2.1	10.9		
Ankle plantarflexors	7	18	5.9	2	17.5	14.1		
Muscle strength (kg force)								
Knee extensors	5	0.2	1.5	5	0.7	1.5	−0.48	0.64
Hip abductors	5	0.5	1.2	5	−0.2	0.6		
Hip extensors	5	0.9	1.0	5	0.5	1.2		
Ankle dorsiflexors	5	1.3	1.1	5	0.6	1.4		

Positive numerical changes indicate improvement and for all outcome measures except Physiological Cost Index and spasticity. SPR = SPR plus physiotherapy group. Physiotherapy = physiotherapy-only group, N = Number of subjects assessed.

Table IV: Ambulatory status at baseline and at 9 months for both groups

SPR				*Physiotherapy*			
Baseline		*9 mo*		*Baseline*		*9 mo*	
Walking status	*N*	*Walking status*	*N*	*Walking status*	*N*	*Walking status*	*N*
Hands held	5	Hands held	3	Hands held	4	Hands held	4
		Walker	2				
Walker	5	Walker	2	Walker	7	Walker	7
		Crutches	2				
		Unsupported	1				
Unsupported	4		4	Unsupported	3	Unsupported	3

All children could walk and were categorized in order of increasing function, as walking with 'hands held', 'walker', 'crutches' or 'unsupported'. SPR = SPR plus physiotherapy group. Physiotherapy = physiotherapy-only group.

physiological demand of walking in those with spasticity of the lower limbs (Butler et al. 1984). It was used to assess only subjects who were able to walk (independently or with aids) at first assessment.

5. The Peabody Fine Motor Scale, a standardized measure of fine motor function (Stokes et al. 1990).

6. A locally developed, non-standardized, criterion-referenced evaluation of self-care.

7. Ambulatory status.

A sample size of 15 children per group was determined on the basis of expected score changes on the GMFM and the previous work of Russell et al. (1989), who reported that a change in score of 5.1% represented an improvement of moderate to major clinical importance. Because of the invasive nature of the SPR it was felt that to justify the surgery one would need to show a difference between the SPR group and the physiotherapy-only group that was of moderate to major clinical importance in favor of the SPR group. Such a clinically important difference required that there should be an improvement of at least 5.1% in the GMFM score in favor of SPR. From the sample size estimate of Russell et al. (1989) it was estimated that 15 children per group were required to test the hypothesis at a power of 90% and $\alpha = 0.05$.

ANALYSIS

The mean change in GMFM score from baseline to 9 months in the two groups was compared with the *t* test for independent means. A number of secondary outcomes were analyzed, including lower-limb muscle strength, spasticity and range of motion; Peabody Fine Motor Scale; Physiological Cost Index; and the criterion-referenced measure of self-care. In these analyses, continuous measures were compared with *t* tests for independent means. As in our previous work (Steinbok et al. 1995), one measure each of spasticity, range of motion, and muscle strength was chosen beforehand for statistical analysis. For spasticity, hip adductor spasticity was chosen because it is functionally significant and generally representative of the overall degree of lower-limb spasticity. For range of motion, hip abduction was chosen because it is functionally significant and relates to the hip adductor spasticity. For muscle strength, the knee extensors were chosen because these muscles are important for standing and walking. The two treatment groups were compared on each of these three measures, and a Bonferoni correction for multiple comparisons was used ($P = 0.05/4 = 0.0125$ was accepted as significant).

MONITORING OF STUDY PROTOCOL

All children eligible for the study were accounted for, and if they did not enter the study the reasons for this were identified. Children who entered the study but withdrew early were identified and the reasons for withdrawal documented. Caregivers were advised not to institute additional treatments for the children during the course of the study, and this was monitored throughout the study to identify any possible non-compliance.

Results

PRIMARY OUTCOME

The mean increase in the total GMFM score at 9 months was 11.3% (95% CI, 7.4 to 15.2) for the SPR group compared with 5.2% (95% CI, 3.1 to 7.2) for the physiotherapy-only group, for a difference in means of 6.1%. This difference between the means for the two groups was significant ($t = 3.03$, $P = 0.007$). The details of the individual assessments, according to each of the five dimensions that comprise the total GMFM score, are shown in Table II.

SECONDARY OUTCOMES

There was a difference between the two groups in the improvement in spasticity, as measured in the hip adductors, with a mean decrease in spasticity of 1.4 units on the Ashworth scale for the SPR group compared with 0.3 units for the physiotherapy-only group. This difference in means was significant ($P<0.001$). Change in spasticity in other muscle groups followed a similar pattern, as shown in Table III. There was a greater improvement in the range of movement, as measured by hip abduction, in the patients having SPR (15.8°) than in those receiving physiotherapy (–3.3°). The difference in the mean change between the two groups was significant ($P<0.001$). Changes in range of movement at other joints are detailed in Table III. There was no difference in the change in quadriceps strength between the two groups ($P = 0.64$).

There was no significant difference between the SPR group and the physiotherapy-only group with respect to the Physiological Cost Index, Peabody Fine Motor Scale and self-care assessment score (Table III). There were technical problems with the Physiological Cost Index, in that the resting heart rate was variable between assessments, making interpretation of the data difficult. In the SPR group, ambulatory status improved in five of the 10 children who were not walking independently at their initial assessment, whereas no patient in the physiotherapy-only group had an improved level of ambulation (Table IV).

All patients in the physiotherapy-only group went on to have SPR after the conclusion of the study.

There were no complications in the physiotherapy-only group. In the SPR group there was one postoperative infection with a spinal epidural abscess and one case with transient urinary retention, which resolved by the fourth postoperative day. One child, at 9 months after SPR, complained of back pain, which resolved spontaneously within 2 days.

No patient on the study was given additional therapies outside the prescribed study protocol. There was one protocol noncompliance with respect to the blinding process for the outcome assessments, and because that occurred after the final assessment for the patient no corrective measures were necessary.

Discussion

Although there have been no previous randomized, controlled studies, analyses of outcome after SPR have been reported from many centers. Spasticity and range of movement in the lower limbs have consistently been reported to improve after SPR (Peacock and Staudt 1991; Steinbok et al. 1992, 1995; Park et al. 1993; McLaughlin et al. 1994; Marty et al. 1995; Nishida et al. 1995). Improvement in ambulation has been demonstrated qualitatively (Steinbok et al. 1992, 1995; Peter and Arens 1993; Marty et al. 1995; Nishida et al. 1995) and with formal gait analysis techniques (Peacock and Staudt 1991, Vaughan et al. 1991, Boscarino et al. 1993). Functional improvements after SPR have been shown by using assessment tools, such as the Pediatric Evaluation of Disability Inventory and GMFM (Bloom and Nazar 1994; McLaughlin et al. 1994).

In many reports the importance of intensive postoperative physiotherapy is stressed (Peacock et al. 1987, Abbott et al. 1989, Steinbok et al. 1992, McLaughlin et al. 1994), and

although the protocols vary from one center to another. SPR is typically followed by more frequent physiotherapy sessions than was being provided preoperatively (P Steinbok, unpublished data). Furthermore, the postoperative therapy often differs from the usual physiotherapy for children with spastic diplegia, in that more emphasis is placed postoperatively on strengthening the lower-limb musculature and practising standing and walking, as opposed to stretching exercises for lower-limb joints and muscles. Thus, even if one accepts on the basis of the previously described non-randomized studies, that SPR does improve spasticity and range of movement in the lower limbs, and does improve function of the child, it could be that the improvements are not the result of the operation itself but the result of the intensive physiotherapy provided in the postoperative period.

The results of our study showed a significantly greater improvement in functional outcome as assessed by the GMFM in the SPR group compared with children in the physiotherapy-only group.

The mean additional improvement of the SPR group over the physiotherapy-only group of 6.1% on the GMFM scale was not only statistically significant but is considered to be of moderate to major clinical significance (Russell et al. 1989). This is reflected by the finding that, whereas there were no improvements in ambulatory status in the children treated with physiotherapy alone, half of the children in the SPR group, who were not independent ambulators at the start of the study, had improved their level of ambulation at 9 months after SPR.

The mean improvement in GMFM noted in the physiotherapy-only group was 5.2%, and this has to be assessed in the light of expected improvements in GMFM as the child matures. In a study of 34 children with mild or moderate spastic diplegic CP between 3 and 5 years of age, and 24 children aged 6 years or older, the mean improvement in GMFM after an average follow-up of 5.4 months was 2.8% for the younger group and 2.3% for the older children (Russell et al. 1991). This suggests that intensive physiotherapy as typically used after SPR might by itself be of some benefit for children with spastic diplegia. Whether the benefit is more than might be achieved with more standard, less intensive physiotherapy is not known. Neither is it known whether intensive physiotherapy is really necessary to optimize functional outcome after SPR.

One other similar, randomized clinical trial has been reported in abstract form recently (Drake et al. 1995). In that study, SPR plus physiotherapy was compared with physiotherapy alone in the treatment of children with spastic diplegic CP, and a significant improvement in function was noted in the surgically treated patients compared with the physiotherapy-only group, using the GMFM as the primary outcome measure. However, the physiotherapy-only group might have received less physiotherapy than the surgical patients. Another randomized clinical trial to compare SPR plus physiotherapy with physiotherapy alone is in progress in Seattle, Washington.

In the present study there was no difference between the SPR group and the physiotherapy-only group in the other functional assessment measures that were examined as secondary outcomes, but it must be recognized that the study was not designed to show a difference between the two groups with respect to any of the secondary outcomes. Furthermore, the Peabody Fine Motor Scale and the locally developed evaluation of self-care score both reflect primarily upper-limb function, which would not be expected to change much after lumbo-sacral SPR. The lack of change in the Physiological Cost Index might have been related in part to technical problems associated with this test and the small number of children in whom this assessment was done. Spasticity and range of movement in the lower limbs improved significantly more in the SPR group than in the physiotherapy-only group, in keeping with the underlying rationale for doing a SPR, and also consistent with the earlier, non-randomized clinical studies.

Significant complications associated with SPR have generally been few (Fasano et al. 1978, Peacock et al. 1987, Steinbok et al. 1992, Park et al. 1993, McLaughlin et al. 1994), although serious postoperative complications were noted in one center in as many as 15% to 18% of patients (Abbott 1992, Abbott et al. 1993). In the present series there was one serious complication, namely a postoperative epidural abscess. This was the only infection to occur in more than 150 rhizotomies which comprised our entire series. One of the commonly noted effects of SPR, which can be a source of morbidity, is postoperative weakness in lower-limb muscles. This might be of functional importance when weakness is prominent in the muscles important for standing and walking, such as the quadriceps femoris and the hip abductors (Arens et al. 1989). The weakness is most marked immediately after SPR, and the preoperative level of strength is usually regained by 1 year after surgery (Steinbok et al. 1995). In this study, the change in quadriceps strength from baseline to 9 months was the same for patients treated with SPR plus physiotherapy as for those receiving physiotherapy only.

CONCLUSION

In this study, at the relatively short assessment time of 9 months, we showed that SPR followed by intensive physiotherapy improved motor function of children with spastic diplegic CP, an improvement that was not simply the result of intensive physiotherapy. Further studies are needed to confirm these results.

Accepted for publication 24th September 1996.

Acknowledgements

We thank Ruth Milner, who helped to design the study. The study was supported by grants from the British Columbia Health Care Research Foundation.

Authors' appointments

*Paul Steinbok, BSc, MBBS, FRCSC, Division of Neurosurgery, University of British Columbia;
Ann M Reiner, BSR, MA, Department of Physiotherapy, British Columbia's Children's Hospital;
John R Kestle, BSc, MD, MSc, FRCSC, Centre for Evaluation Sciences, British Columbia Research Institute for Child and Family Health, Vancouver, BC;
Richard Beauchamp, MD, FRCSC, Department of Orthopedics,
Robert W Armstrong, MD, PhD, Department of Pediatrics, British Columbia's Children's Hospital;
D Douglas Cochrane, MD, FRCSC, Division of Neurosurgery, University of British Columbia.

**Correspondence to first author at* Division of Pediatric Neurosurgery, British Columbia's Children's Hospital, 4480 Oak Street, Vancouver, BC V6H 3V4, Canada.

References

Abbott R. (1992) Complications with selective posterior rhizotomy. *Pediatric Neurosurgery* **18:** 43–7.

– – Forem SL, Johann M. (1989) Selective posterior rhizotomy for the treatment of spasticity: a review. *Child's Nervous System* **5:** 337–46.

– Johann-Murphy M, Shiminski-Maher T, Quartermain D, Forem S, Gold JT, Epstein FJ. (1993) Selective dorsal rhizotomy: outcome and complications in treating spastic cerebral palsy. *Neurosurgery* **33:** 851–7.

Albright AL, Barry MJ, Fasick MP, Janosky J. (1995) Effects of continuous intrathecal baclofen and selective posterior rhizotomy on upper extremity spasticity. *Pediatric Neurosurgery* **23:** 82–5.

American Academy of Orthopedic Surgeons (1965) *Joint Motion: Method of Measuring and Recording*. Chicago: AAOS.

Arens LJ, Peacock WJ, Peter J. (1989) Selective posterior rhizotomy: a longterm follow-up study. *Child's Nervous System* **5:** 148–52.

Bloom KK, Nazar GB. (1994) Functional assessment following selective posterior rhizotomy in spastic cerebral palsy. *Child's Nervous System* **10:** 84–6.

Bobath B. (1967) The very early treatment of cerebral palsy. *Developmental Medicine and Child Neurology* **9:** 373–90.

Bohannon RW, Smith MB. (1987) Interrater reliability of a modified Ashworth Scale. *Physical Therapy* **67:** 206–7.

Boscarino LF, Ounpuu S, Davis RB, Gage JR, DeLuca PA. (1993) Effects of selective dorsal rhizotomy on gait in children with cerebral palsy. *Journal of Pediatric Orthopedics* **13:** 174–9.

Butler P, Engelbrecht M, Major RE, Tait JH, Stallard J, Patrick JH. (1984) Physiological cost index of walking for normal children and its use as an indicator of physical handicap. *Developmental Medicine and Child Neurology* **26:** 607–12.

Drake JM, Wright FV, Shiel EMH, Naumann S, Wedge JH (1995) Randomized trial of selective dorsal rhizotomy vs therapy alone for children with spastic diplegia. *Child's Nervous System* **11:** 551–2.

Fasano VA, Broggi G, Barolat-Romana G, Sguazzi A. (1978) Surgical treatment of spasticity in cerebral palsy. *Child's Brain* **4:** 289–305.

– – Zeme S, Sguazzi A. (1980) Long term results of posterior functional rhizotomy. *Acta Neurochirurgia (Wien)* **30** (Suppl): 435–9.

Giuliani CA. (1991) Dorsal rhizotomy for children with cerebral palsy. *Physical Therapy* **71:** 80–91.

Haley SM, Coster WJ, Ludlow LH. (1991) Pediatric functional outcome measures. *Physical Medicine and Rehabilitation Clinics of North America* **2:** 689–723.

Hyde SA, Goddard CM, Scott OM. (1983) The myometer: the development of a clinical trial tool. *Physiotherapy* **69:** 424–7.

Landau WM, Hunt CC. (1990) Dorsal rhizotomy: a treatment of unproven efficacy. *Journal of Child Neurology* **5:** 174–8.

Marty GR, Dias LS, Gaebler-Spira D. (1995) Selective posterior rhizotomy and soft-tissue procedures for the treatment of cerebral diplegia. *Journal of Joint and Bone Surgery* **77:** 713–8.

McLaughlin JF, Bjornson KF, Astley SJ, Hays RM, Hoffinger SA, Armantrout EA, Roberts TS. (1994) The role of selective dorsal rhizotomy in cerebral palsy: critical evaluation of a prospective clinical series. *Developmental Medicine and Child Neurology* **36:** 755–69.

Nishida T, Thatcher SW, Marty GR. (1995) Selective posterior rhizotomy for children with cerebral palsy – a 7 year experience. *Child's Nervous System* **11:** 374–80.

Park TS, Gaffney PE, Kaufman BA, Molleston MC. (1993) Selective lumbosacral dorsal rhizotomy immediately caudal to the conus medullaris for cerebral palsy spasticity. *Neurosurgery* **33:** 929–33.

— Owen JH. (1992) Surgical management of spastic diplegia in cerebral palsy. *New England Journal of Medicine*, **326:** 745–9.

Peacock WJ, Arens LJ, Berman B. (1987) Cerebral palsy spasticity. Selective posterior rhizotomy. *Pediatric Neuroscience* **13:** 61–6.

— Staudt LA. (1991) Functional outcomes following selective posterior rhizotomy in children with cerebral palsy. *Journal of Neurosurgery* **74:** 380–5.

Peter JC, Arens LJ. (1993) Selective posterior lumbosacral rhizotomy for the management of cerebral palsy spasticity. A 10-year experience. *South African Medical Journal* **83:** 709–10.

Russell D, Rosenbaum P, Cadman DT, Gowland C, Hardy S, Jarvis S. (1989) The Gross Motor Function Measure: a means to evaluate the effects of physical therapy. *Developmental Medicine and Child Neurology* **31:** 341–52.

– – – Gowland C, Hardy S, Lane W, Plews N, McGavin H, Cadman D, Jarvis S. (1993) *Gross Motor Function Measure Manual*. 2nd ed. Hamilton, Ontario: Neurodevelopmental Clinical Research Unit, McMaster University.

Steinbok P, Gustavsson B, Kestle JR, Reiner A. (1995) Relationship of intraoperative electrophysiological criteria to outcome after selective functional posterior rhizotomy. *Journal of Neurosurgery* **83:** 18–26.

— Reiner A, Beauchamp RD, Cochrane DD, Keyes R. (1992) Selective functional posterior rhizotomy for treatment of spastic cerebral palsy in children. Review of 50 consecutive cases. *Pediatric Neurosurgery* **18:** 34–42.

Stokes NA, Dietz JR, Crowe TK. (1990) The Peabody Developmental Fine Motor Scale: an interrater reliability study. *American Journal of Occupational Therapy* **44:** 334–40.

Vaughan CL, Berman B, Peacock WJ. (1991) Cerebral palsy and rhizotomy. A 3 year follow-up evaluation with gait analysis. *Journal of Neurosurgery* **74:** 178–84.