NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of selective dorsal rhizotomy for spasticity in cerebral palsy

The aim of selective dorsal rhizotomy is to ease muscle spasticity and improve mobility in people with cerebral palsy. It involves cutting nerves in the lower spine that are responsible for muscle rigidity.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in July 2010.

Procedure name

- Selective dorsal rhizotomy for spasticity in cerebral palsy
- Limited dorsal rhizotomy
- Selective posterior rhizotomy

Specialty societies

- British Orthopaedic Association (BOA)
- British Paediatric Neurosurgical Group (BPNG)
- British Society for Children's Orthopaedic Surgery
- Society of British Neurological Surgeons (SBNS).

Description

Indications and current treatment

Cerebral palsy describes a group of permanent brain disorders originating during fetal development, birth or early childhood. It is associated with abnormalities of movement, balance and posture, and people with cerebral palsy can have language and visual difficulties. Lower limb spasticity affects 80% of people with cerebral palsy, which can impair walking and sitting, and can cause discomfort, cramps and spasms.

Current treatments for lower limb spasticity include oral muscle relaxant medication, orthotic devices, physiotherapy, and repeated intramuscular injections of botulinum toxin. Surgical procedures include tendonotomy, tendon lengthening, peripheral neurotomy, osteotomy, electrical stimulation of the muscles or dorsal spinal cord, and continuous intrathecal baclofen infusion.

What the procedure involves

The aim of selective dorsal rhizotomy is to achieve a long-term reduction in sensory input to the sensory–motor reflex arcs responsible for increased muscle tone, by dividing some of the lumbar sensory nerve roots.

Muscle tone (tension) is normally determined by:

• a sensory-motor reflex comprising input from sensory nerves in the

muscles to spinal motor nerves, which in turn send contracting stimuli to

the muscles, increasing muscular tone, and

• modulation (mainly down-regulation) of this reflex by nuclei in the brain.

In people with central nervous system dysfunction (as is the case in cerebral palsy) the 'damping down' effect of brain nuclei can be diminished. In these people muscle tone is largely determined only by the sensory–motor reflex arc between the affected muscles and the (under-regulated) spinal cord, resulting in abnormally high muscular tone (spasticity).

With the patient under general anaesthesia, a laminectomy of one or more vertebrae is performed to expose the dural sac, which is opened to display the spinal conus with or without the cauda equina. Intraoperative neurophysiological assessment is commonly used to identify the sensory nerve rootlets judged to be most responsible for the excess motor tone. Selected sensory rootlets are divided, preserving some sensory supply and the motor roots responsible for voluntary movements.

Intensive physiotherapy and aftercare is usually given for several months after the procedure. Patients who were previously able to walk may have to learn different walking skills.

Instruments to assess efficacy

A range of validated instruments are used to evaluate the efficacy of spasticity treatments including:

- Modified Ashworth Scale: measures spasticity and improvement in tone on a 5-point scale (0 = no increase in muscle tone, 5 = affected part(s) rigid in flexion or extension).
- Gross Motor Function Classification System (GMFCS): a 5-level classification system that describes the gross motor function of children with cerebral palsy on the basis of their self-initiated movement.
- Gross Motor Function Measure (GMFM): evaluates change in gross motor function in children with cerebral palsy. The current version has 66 items covering: lying, rolling, sitting, crawling, kneeling, standing, walking, running and jumping. Each item is scored on a 4-point scale. A higher score indicates good gross motor functioning.
- Gross Motor Performance Measure (GMPM): used to evaluate quality of movement in children with cerebral palsy. Twenty items assess alignment, coordination, dissociated movement, stability and weight shift. Each item is scored on a 5-point scale.
- Pediatric Evaluation of Disability Inventory (PEDI): measures self-care, mobility and social skills using scores obtained by a combination of parent interview and direct observation. Scores range from 0 to 100 with a higher score indicating greater independence and less reliance on the caregiver.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to selective dorsal rhizotomy for spasticity in cerebral palsy. Searches were conducted of the following databases, covering the period from their commencement to 7 July 2009 and updated 27 July 2010: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

| Characteristic | Criteria |
|-------------------|--|
| Publication type | Clinical studies were included. Emphasis was placed on identifying good quality studies. |
| | Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. |
| | Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature. |
| Patient | Patients with spasticity in cerebral palsy |
| Intervention/test | Selective dorsal rhizotomy |
| Outcome | Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy. |
| Language | Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base. |

Table 1 Inclusion criteria for identification of relevant studies

List of studies included in the overview

This overview is based on 1048 patients from 1 meta-analysis¹, 6 non-randomised comparative studies^{2, 3, 4, 5, 6, 7} and 6 case series^{8, 9, 10, 11, 12, 13}. There is some overlap between the 30 and 14 patients in the last 2 case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on selective dorsal rhizotomy for spasticity in cerebral palsy

Abbreviations used: BTA, botulinum toxin type A; CP, cerebral palsy; EPG; electrophysiological guidance; GMFCS; Gross Motor Function Classification System; GMFM, Gross Motor Function Measure; GMPM, gross motor performance measure; ITBP; intrathecal baclofen pumps; MDT, multidisciplinary team; PT, physical therapy; RCT, randomised controlled trial; ROM, range of motion; SDR, selective dorsal rhizotomy; SPR, selective posterior rhizotomy

| Study details | Key efficacy findi | ngs | | Key safety findings | Comments |
|---|---|---|--------------------------------------|---------------------------------|---|
| McLaughlin J (2002) ¹ | Number of patients Operative parame | • | | No safety data from the primary | Reported in table 2 in the original overview |
| Meta analysis (three RCTs) USA and Canada | between the basel | tically significant inverse ine GMFM-66 score and sal rootlets cut (p = 0.000 dy site. | the | studies is presented. | Follow-up issues: Completeness of follow-up is not reported Study design issues: |
| Recruitment period: RCTs up to December 2000. | Clinical outcome | 5 | | | Medline, Cochrane and meeting abstracts searched for RCTs up to December 2000. No further details of search strategy provided. |
| Study population: Children with spastic diplegia CP – inclusion criteria varied between study sites | SDR multivariate a | | | | Multiple regression undertaken to assess factors of treatment group, study site, age, sex, birth weight, ambulatory status, and baseline clinical scores. |
| n = 90 (number having SDR not stated) | Outcome Modified Ashworth Scale | Change scores* -1.23 (indicating a reduction in spasticity) | p value < 0.001 | | In one study less dorsal root tissue was transected (25%) than in the other two studies (41% and 45%). Used two measures of gross motor function: GMFM |
| Age: 5.5 years (mean) Sex: 53% male | GMFM | 4.53 (indicating increase in gross motor | 0.002 | | and GMFM-66 (updated version). Functional GMFM outcome scores were assessed blindly in all patients. |
| Patient selection criteria: see above | GMFM-66 | function) 2.66 (indicating increase in gross | 0.002 | | Method for data pooling used – blocked Wilcoxon's test. Study population issues: |
| Technique: SDR and physiotherapy (the use of electrophysiological monitoring to select dorsal roots for sectioning varied across the studies) versus physiotherapy alone. | unclear in the paper [IP A weak inverse co percentage of dors | motor function) | veen the hange in | | Baseline data: mean gestational age = 31.7 weeks, mean birth weight = 1849 g, prenatal cause of CP = 87% (78/90), baseline GMFM score = 62.5 , proportion who were non-ambulatory = 57% . No difference in baseline characteristics between the two groups. Other issues : |
| Follow-up: 9 months (1 study) and 12 months (2 studies) Conflict of interest/source of funding: funding provided by a foundation | A small but statisti physiotherapy ove scores improved b groups and 8% in (data read from fig | | nd. GMFM py-only nerapy group: | 3 | Primary researcher was also the author of one of the studies included, allowing for analysis of unpublished raw data, and ability to recalculate variables, but potential subjectivity. |
| | important. | her this benefit was clini | cany | | |

| Study details | Key efficacy findings | , - , 2000 | Key safety findings | Comments | | |
|---|---|-----------------|------------------------|-------------------|--|---|
| Kan P (2008) ² | Number of patients analysed: | 142 (71 vs 71 | Not reported | Follow-up issues: | | |
| Non-randomised comparative study | Outcome | SDR (n = 71) | ITBP (n = 71) | p value | | Completeness of follow-up is not reported |
| USA | Improvement in tone Modified Ashworth Scale | -2.52 | -1.23 | < 0.0001 | | Study design issues: Prospective data collection |
| Recruitment period: | Lower extremity PROM | -0.77 | -0.39 | 0.0138 | | Only children who had SDR before |
| SDR group: up to 1997 | GMFCS | -0.66 | -0.08 | < 0.0001 | | introduction of ITBP were eligible t avoid selection bias. Authors state |
| ITBP group: 1997 onwards Study population: | Proportion requiring subsequent orthopaedic | 19.1 | 40.8 | 0.0106 | | since ITBP was introduced, SDR is only performed in a small number select patients. |
| SDR group: children with severe spasticity with GMFCS score 3+ | procedures (%) | | | | | Authors note that they were not ab |
| ITBP group: children matched by age and GMFCS score. | Patient satisfaction at 1 year | atual atual a | | -1) | | control for comorbidities, concurre medication and postoperative phys therapy which might have had an impact on the results. |
| n = 142 (71 vs 71) | SDR group: 93.5% satisfied (a ITBP group: 95.8% satisfied (a | | • | | | |
| Age: 5.6 years (mean) | TTBP group. 95.6% satisfied (a | | s not reporte | (p = 0.71) | | Study population issues: |
| Sex: not reported | | | | | | Proportion of dorsal nerve rootlets divided in the SDR group: 50–60% |
| Patient selection criteria: see above | | | | | | |
| Technique: SDR (description of method not reported) vs ITBP implantation (infusion started at 50 micrograms/day and doses then titrated to achieve maximal reduction in spasticity in each individual. Mean: 274 micrograms/day). | | | | | | |
| Follow-up: 1 year | | | | | | |
| Conflict of interest/source of funding: not reported | | | | | | |

| Study details | Key efficacy findings | | | | | | | Comments |
|---|--|--------------------|---|--------------|-------------------|----------|--|---|
| Engsberg JR (2006) ³ | Number of patient | s analysed | | Not | Follow-up issues: | | | |
| Non-randomised comparative study USA Recruitment period: not reported Study population: SDR and physical therapy group: ambulatory | SDR group: n = 3 physical therapy c outcomes). <i>Italics</i> (p<0.05) difference (SDR+PT and PT | reported | Nine other children with CP were original included in the study but dropped out (5 in | | | | | |
| children with spastic diplegic CP enrolled through one SDR clinic; physical therapy-only group: ambulatory children with spastic diplegic | | SDR + p therapy | hysical | Physica only | l therapy | Controls | | SDR + physical therapy group and |
| CP found through local and national adverts; Controls: age-matched children with no disabilities recruited by contacting parents within the | Outcome | Pre-op | 20 months | Pre-op | 20 months | (n = 40) | | 4 in the physical therapy only |
| hospital community. | Knee spasticity (measured with isokinetic | 0.008‡ | 0.002* | 0.01 | 0.006 | 0.003 | | group). |
| n = 108 (31 vs 37 vs 40) | dynamometer) | | | | | | | Study design issues: |
| ge: SDR group:9 years (mean); physical therapy group: 9.7 years nean); controls: 9.4 years ex: SDR group: 48.4% (15/31) male; physical therapy group: 51.4% 9/37) male; controls: 52.5% (21/40) male | Maximum knee flexor strength (torque) scores | 0.52 | 0.64 | 0.54 | 0.66‡* | 0.92 | | Prospective study |
| | (nm/kg) | | | | | | | Study population issues: |
| Patient selection criteria: patients aged 4+ years with spastic diplegic CP with level I to III GMFCS, able to walk, minimum level of cognitive skills for active participation, no surgical intervention in the last year or Botox/casting procedures in last 6 months, hypertonicity of lower | Maximum knee extensor strength (torque) scores (nm/kg) | 0.86 | 1.14* | 0.92 | 1.06‡ | 1.66 | No significant differences between the three | No significant |
| extremities, exaggerated deep-tendon leg reflex, Babinski sign and abnormal posture when sitting, standing and walking. Exclusions: | Gait speed (cm/sec)† | 81‡ | 101* | 91‡ | 93‡ | 113 | | weight and sex. No significant |
| children with motor deficits resulting from neurological injury or illness beginning after the first month of life and those with malformation of | Stride length (cm) | 79 | 96* | 85 | 90 | 110 | | differences between the two |
| the nervous system. Patients with moderate to severe dystonia, athetosis, ataxia and severe cognitive delay were also excluded. | Cadence (steps/min) | 122 | 126 | 129 | 124 | 124 | | CP groups for GMFCS level and |
| Technique: SDR plus physical therapy (electrical stimulation was used to grade a reflex response from the lower extremity muscles and rootlets were cut according to the response) versus physical therapy | Knee flexor/extensor ROM† | 44‡ | 52‡* | 45‡ | 47‡ | 61 | | gait status. The percentage of dorsal nerve |
| only versus a control group (age-matched children with no | GMFM | 87 | 92* | 89 | 91* | - | | rootlets sectioned |
| disabilities). Follow-up: 20 months Conflict of interest/source of funding: funded by the National Institute of Neurological Disorders and Stroke | *p < 0.05 comparing with pre-op; $\dagger p$ < 0.05 for comparisons of difference from baseline to follow-up between the SDR+PT and the PT groups; $\ddagger p$ < 0.05 comparing with control group | | | | | | | in the SDR group was not reported. |

| Study details | Key efficacy findings | | | | | | Key safety findings | Comments |
|--|--|---|--------------|-------------|-------------|--------------|------------------------|--|
| Wong A M K (2005) ⁴ | Number of patients analysed: 81 (20 vs 22 vs 20 vs 19) No safe were provide the set of t | | | | | | | Reported in table 2 in the original overview |
| Non-randomised comparative study | Gait analysis | | | | | | in the study | Follow-up issues: |
| Taiwan | Group | | e 3 month | value | 20 month | p s value | report | Completeness of follow-up not reported. |
| Recruitment period: not reported | | | dy height/ | | | | | Study design issues: |
| Study population: ambulatory children with | SDR | 33.5 | 25.3 | < 0.05 | 38.9 | < 0.05* | | Parents chose therapy group. |
| spastic diplegia CP and healthy control children. | BTA | 31.3 | 35.7 | N/S | 32.5 | N/S | | Unclear how healthy controls were |
| | Rehab | 35.5 | 36.6 | N/S | 40.3 | N/S | | recruited. |
| | Control | 66.2 | - | - | - | - | | No details of blinding of outcomes |
| n = 81 (20 vs 22 vs 20 vs 19) | Gait cade | nce (steps | s/min) | | | • | | assessors. |
| Age: SDR group: 5.4 years (mean), BTA group: | SDR | 88.5 | 76.4 | N/S | 94.9 | N/S | | Outcomes assessed by a computer- |
| 4.9 years (mean), rehabilitation group: 5 years | BTA | 92.0 | 100.8 | N/S | 92.8 | N/S | | assisted gait analysis system measuring gait velocity, cadence, and step length (corrected for patient height) |
| (mean) and control group: 5.1 years (mean) Sex: 56.3% (45/80) male | Rehab | 93.0 | 90.0 | N/S | 85.6 | < 0.05* | | |
| | Control | 118.6 | - | - | - | - | | No between-groups analysis was |
| atient selection criteria: children with CP had | Step leng | th (% bod | y height) | | | | | performed (only within groups). |
| received regular rehabilitation for 6+ months | SDR | 21.4 | 16.0 | N/S | 27.8 | < | | |
| with good compliance. CP patients had to be | | | | | | 0.01* | | Study population issues: |
| able to walk with a spastic gait, have bilateral spasticity without noticeable fixed contracture | BTA | 26.0 | 26.2 | N/S | 24.7 | N/S | | Proportion of patients relying on walking |
| and have an Modified Ashworth Scale score of | Rehab | 25.6 | 26.0 | N/S | 25.2 | N/S | | aid = 51%. |
| 2 or 3. Exclusions: children with Modified | Control | 35.0 | - | - | - | - | | No statistically significant difference |
| Ashworth Scale scores 1 and 4, significant leg | *Comparis | on with 3-n | nonth resul | ts | | | | between groups in terms of age, height, |
| length discrepancy, previous surgery of lower | | | | | | | | weight, sex, ambulation ability, or other |
| limbs or presence of athetoid movements. | The BTA g | | | | | | | baseline gait parameters. |
| | 6 months, | | | | | | | Percentage dorsal nerve rootlets |
| Technique: SDR (description of method not | 31.3 ± 10.2 | | | | | | | sectioned in the SDR group was not |
| reported) vs BTA injection vs rehabilitation only | difference | | | | 5 < 0.05 | but the | | reported. |
| vs controls (all patients with CP received regular | unerence | ulu not per | sisi pasi 12 | 2 11011015. | | | | Other issues: |
| rehabilitation therapy for 6 months before | The SDR g | Iroup show | ed a signif | icant dete | rioration | in gait | | |
| baseline). | velocity at | | | | | | | During the study period SDR treatment secta ware paid for by insurance while |
| | second vs | | | | | | | costs were paid for by insurance while BTA was not. |
| Follow-up: 20 months | | | | | | | | Further study of SDR in children in |
| Conflict of interest/source of funding: Study supported by a national grant. | was better | baseline. However this score recovered at 6 months and was better than baseline at 12- and 20-month follow-up (not a significant difference). | | | | | | • Further study of SDR in children in whom repeated BTA injection produced a ceiling effect may be warranted. |

| Study details | Key efficacy | findings | | | Key safety findings | Comments | | | |
|---|---------------------------------------|-----------------------|-----------------|----------------|-------------------------------|--|--|--|--|
| Steinbok P (2009) ⁵ | Number of pa | tients analysed | : 44 (22 vs 22 |) | No safety data were presented | Follow-up issues: Completeness of follow-up not reported. | | | |
| Non-randomised comparative study | Change in sco | ore from baselir | ne to 1-year fo | llow-up: | in the study | | | | |
| Canada | | EPG group (n = 22) | No EPG group | p value | report | Study design issues: Retrospective study. Patient in the no-EPG group were | | | |
| Recruitment period: not reported | | | (n = 22) | | | matched to patients who had EPG with | | | |
| Study population: children with spastic diplegia CP | GMFCS Ashworth hip adductors | 0.14 1.2 | 0.09 0.9 | 0.764 0.307 | - | respect to GMFCS and age (however the authors also state that the controls were chosen randomly). No details of blinding of outcome | | | |
| n = 44 (22 vs 22) | ROM hip | 5.4 | 4.8 | 0.825 | | No details of blinding of outcome assessors. | | | |
| Age: EPG group: 5.2 years (mean); No EPG group: 5.7 years (mean) Sex: not reported Patient selection criteria: all children who had SDR without EPG and matched controls who had SDR with EPG Technique: SDR with EPG vs SDR without EPG (all multilevel laminectomies from L1 to S1) Follow-up: 1 year Conflict of interest/source of funding: not reported | abductors | | | | | Study population issues: Populations were no different at baseline in terms of GMFCS Ashworth and ROM scores. Mean % of L2 to S1 dorsal roots cut: EPG group: 56.8; no EPG group: 52.8 (p = 0.12) Operating time: EPG group: 3.55 hours; no EPG group: 3.23 hours (p = 0.006) | | | |

| Study details | Key efficacy findings | | | | | | Key safety findings | Comments |
|---|------------------------------|---|---------------|---|-------------------|------|---|--|
| Mäenpää H (2002) ⁶ | Number of | f patients ar | nalysed: 4 | 2 (21 vs 21 |) | | SPR + PT group: transient pain | Reported in Appendix A in original overview |
| Non-randomised comparative study | SPR + PT | group: Mo | dified As | hworth Sc | ale score | | due to | Follow-up issues: |
| Finland | Muscle groups | Preop | 1 year | Postop 3 years | Postop 5 years | | hyperaesthesia: 19% (4/21) | 9.5% (2/21) of patients in both groups lost to follow-up between 3 and 5 years |
| Recruitment period: 1991–1998 | Hip flexor Hip | s 4.2 4.3 | 2.4* 2.0* | 2.9* 2.6* | 3.1* 2.9* | | Incontinence: 4.8% (1/21) | Study design issues: |
| Study population: children with spastic CP. | rotators Hip | 4.05 | 2.2* | 3.6* | 3.8** | | Timing and | Prospective study. |
| n = 42 (21 vs 21) Age: both groups: 6 years (mean) | adductors Knee flexors | 4.15 | 2.0* | 3.2* | 3.4* | | treatment of complications not | Different selection criteria for treatment groups. Unclear if outcome assessors blinded to |
| Sex: SPR + PT group: 76.2% (16/21); PT-only group: 71.4% (15/21) | Plantar flexors | 4.3 | 2.3* | 2.8* | 2.8* | | reported | treatment allocation. Functional skills assessed using Illinoi: St Louis score. Lower scores indicate |
| Patient selection criteria: | | compared w compared | | | atively | | Statistic scores indicate better functioning. Spasticity not measured in PT-only | |
| SPR + PT group: functionally disruptive spasticity in lower limbs (diplegia), 6 months' arrest of motor development or spasticity- dependent difficulties in daily care (quadriplegia). | | Follow-up | fu s (1 | lean unctional kills Illinois-St .ouis score) | GMFC | S | | group. The post-surgical physiotherapy care was not standardised between the groups. |
| PT-only group: ongoing motor development | | Preop (n = | 21) 6 | .71 ± 1.62 | 3.8 ± (| | | Study population issues: |
| ypotony or severe weakness of trunk or lower | | 1 year (n = | | .86 ± 2.05 | 3.47 ± | | | No statistically significant difference |
| mb muscles; or muscle contractures or rigidity. | | 3 years (n | | .57 ± 2.35 | 3.52 ± | | | between groups in terms of age, sex, |
| echnique: SPR + PT (bipolar constant current | PT | <u>5 years (n :</u> Baseline (r 21) | | <u>.24* ± 2.83</u> .66 ± 1.97 | 3.57 ± 3.42 ± | | | spasticity of lower limbs, numbers with diplegia/quadriplegia, mean Illinois-St |
| timulation used to grade a reflex response as | | 1 year (n = | 21) 5 | .76 ± 2.03 | 3.41 ± | 0.77 | | Louis scale and mean GMFCS at baseline. |
| ither normal or pathological and rootlets were ut according to the response) vs PT only. | | 3 years (n : | | .33* ± 2.58 | | | | Mean proportion of dorsal nerve rootlets |
| at according to the response) vs PT only. | | 5 years (n : | | .4* ± 2.51 | 3.25 ± | 0.98 | | sectioned in the SDR group: 44.8% |
| Follow-up: 5 years | *Significar baseline. | it change co | ompared v | vith preope | ratively or | | | |
| Conflict of interest/source of funding: not eported | | | | | | | | |

| Study details | Key effica | cy finding | S | | | | | | Key safety findings | Comments |
|---|---------------------------|-----------------------------|------------------------|--------------|---|-----------------------------|-----------------|--|-------------------------------------|--|
| Buckon C E (2004) ⁷ | Number of | ⁱ patients ar | nalysed: 2 | 25 (18 vs 7) | | | | | No safety data was | Reported in table 2 in the original overview |
| Non-randomised controlled trial USA | | SDR baseline (n = 18) | SDR 2 years | p value | Ortho surgery baseline (n = 7) | Ortho surgery 2 years | p value | Betwe en- group p value | presented in the study report | Follow-up issues:Completeness of |
| Recruitment period: over 3 years (dates not reported) Study population: children with spastic diplegia | GMPM total | 54.6 ± 7.0 | 63.4 ±7.2 | < 0.001 | 54.1 ± 7.8 | 60.7 ± 9.4 | < 0.061 | 0.751 | | follow-up not reported. Study design issues: |
| study population: children with spastic diplegia n = 25 (18 vs 7) | GMFM total | 82.1 ± 13.2 | 89.5 ± 11.1 | 0.011 | 78.2 ± 13.0 | 85.7 ± 7.1 | 0.048 | 0.540 | | Prospective study. The post-surgical physiotherapy care |
| Age: SDR group: 71.3 months (mean); orthopaedic surgery group: 78.6 months (mean) | Self- care* | 73.7 ± 13.1 70.5 | 84.1 ± 14.2 77.8 | < 0.001 | 75.2 ± 12.7 69.3 | 83.4 ± 14.2 76.7 | < 0.014 | 0.932 | | physiotherapy care was not standardised between the groups as it was focused to the remedial need, and |
| Sex: 76% (19/25) male | Mobility* Social | 70.5 ±10.1 69.2 | 77.8 ± 10.4 75.0 | < 0.001 | 69.3 ± 12.6 67.5 | 76.7 ± 16.1 75.1 | < 0.042 < | 0.511 | | |
| Patient selection criteria: children found by an MDT to be appropriate for SDR or orthopaedic soft tissue | skills* | ± 8.8 | ± 7.9 | < 0.0004 | ± 6.9 | ± 11.6 | 0.006 | 0.903 | | may have influenced outcome. |
| procedures. SDR patients had to be aged between 4 and 10 years, predominantly spastic, have good trunk control, history of prematurity, no significant ataxia or athetosis, good lower extremity antigravity strength, no significant scoliosis, ambulatory with or without assistive devices, cooperative, ability to isolate lower extremity movements and lower extremity contracture < 10° . | *Measured using the PEDI. | | | | | | | All outcomes were evaluated by two investigators who were trained in using the scales. Assessors were not blinded to treatment allocation. Study population issues: | | |
| Technique: SDR (at L2, 30–50% rootlets were sectioned without electrical stimulation and from L3 to S1 selective electrical stimulation of each nerve rootlet was performed before decision to section) vs aponeurotomy/tenotomy with post-surgical physiotherapy in both groups. Parents chose the treatment therapy after discussions with clinicians. | | | | | | | | | | Ambulatory = 92% There were no significant differences between groups at baseline in any of the clinical outcomes measured. Mean proportion of dorsal nerve rootlets |
| Follow-up: 2 years Conflict of interest/source of funding: no commercial party conferred a benefit on the author. | | | | | | | | | | sectioned in the SDR group: 43.3% [calculated by IP analyst] |

| Study details | Key efficacy findings | | | | Key safety findings | Comments | | |
|---|---|--|---|--|---|---|--|--|
| Kim D-S (2001) ⁸ | Number of patients ana Ability to walk | 5 | | | ComplicationsBack pain: experienced by all patients | Reported in table 2 in the original overview | | |
| Case series South Korea | Patients showed an imp grading) from 4.2 points (p < 0.001). 81.3% (169 ambulatory function. | s at baseline | e to 5.19 poi | nts at 1 year | but well controlled by intravenous fentanyl for 3 days in most patients. 3.4% (7/208) had long-standing back pain at final follow-up. | Follow-up issues: 36.5% (76/208) lost to follow- | | |
| Recruitment period: 1990–1999 Study population: selected patients meeting criteria for posterior rhizotomy. | Muscle tone As measured by the Mo standard deviation). | Baseline | vorth Scale (1 year (n = 208) | (mean and 4 years (n = 132) | Postoperative spinal deformity (radiographic findings only and no functional findings, relating to excessive laminectomy): 6% (12/208). Scoliosis (radiologically observed): 9% (5/58) of patients who had | up between 1 and 4 years. Study design issues : • Retrospective study. • No value for degree of | | |
| n = 208 (198 patients with spastic CP) Age: 5.9 years (mean) Sex: not reported Patient selection criteria: Spastic diplegia or quadriplegia with CP, spastic hemiplegia of cerebrovascular cause, or spastic quadriparesis due to incomplete spinal cord. | Hip adductors2Hamstrings3Quadriceps2Gastrocnemius3 | 9 ± 1.45 ($.2 \pm 1.32$ ($.4 \pm 1.05$ ($.6 \pm 0.77$ ($.8 \pm 0.25$ ($.8 \pm 0.25$ ($.10 \pm 0.25$ (.10 | 0.4 ± 0.72 0.2 ± 0.39 0.5 ± 0.69 0.4 ± 0.55 0.07 ± 0.21 asticity of all at difference | $\begin{array}{c} 0.4 \pm 0.84 \\ 0.2 \pm 0.53 \\ 0.6 \pm 0.53 \\ 0.7 \pm 0.51 \\ 0.15 \pm 0.29 \\ \text{tested muscles} \\ \text{in results between} \end{array}$ | laminectomy, and 1.3% (2/150) who had laminoplasty. Hypotonia: most SDR patients had temporary hypotonia following the surgery but this resolved over 2 to 3 months of scheduled physical therapy for most, although 3% (7/208) still had hypotonia at final follow-up. Urinary retention because of decreased bladder tone and hyporeflexia: 9.6% (20/208). This | certainty of statistical results are given for most outcomes. Postoperative physiotherapy regimen (if any) is not described. Study population issues: Study includes 8 patients with spastic hemiplegia after cerebrovascular insult and 2 patients with spastic | | |
| Technique: SPR. Access either by laminectomy or later in the cohort by laminoplasty. Posterior nerve root cut into three or four and stimulated, with 50 to 70% of abnormal rootlets cut. Procedure repeated from S2 to L2 and at L1 50% of the bilateral root cut without testing. Follow-up: 4.2 years (mean) Conflict of interest/source of funding: not stated | ROM: changes in passive ROM in degreesROM: changes in passive ROM in degreesROM: changes in passive ROM in degreesr and 0% of rocedure and at L1 cutFlexion contracture of the hips1 year (n ± 12.23 4 years ± 208)Flexion contracture of the hips -10.5 ± 12.23 -3.3 ± 5.26 -4.6 ± 6.33 Abduction of the hips 37.5 ± 16.44 59.5 ± 17.56 62.5 ± 15.56 Popliteal angle of the ± 15.23 ± 14.25 ± 13.75 14.25 ± 13.75 Dorsiflexion of the ankle -1.3 ± 7.76 5 ± 6.76 All patients showed an overall improvement (over 95%) in the | | $(n = 132)$ -4.6 ± 6.33 62.5 ± 15.56 -27.9 ± 13.75 4.8 ± 5.95 //er 95%) in the of the ankles, a | resolved spontaneously within 4 weeks in 18 patients, but 2 patients had long-term incontinence due to atonic bladder. This was effectively treated with clean intermittent catheterisation in 1 patient. Transient sensory changes: 7% (15/208); 5 of these patients had sensory changes to final follow-up but these were not functionally important. Aspiration pneumonia: 1% (2/208). Involuntary arm movement: 1% (2/208). 2 patients required orthopaedic surgery for progressive hip migration. | quadriparesis after cervical cord injury. The percentage of patients with scoliosis preoperatively was not reported Other issues: Authors state that other causes other than spasticity can influence child ambulation. Long-standing spasticity in older children resulted in more severe musculoskeletal contracture, which was more difficult to correct with SDR. | | | |

| Study details | Key efficacy findings | Key safety findings | Comments | | | | | |
|---|-----------------------|--|---|----------------|---|--|--|--|
| Steinbok P (2005) ⁹ | Not reported | Scoliosis (n=104) | | | Reported in Appendix A in the original overview | | | |
| Case series | | | Preop | Follow-up | 5 | | | |
| Canada | | Mean Cobb angle for scoliosis (standard deviation) | 6.6° (6.2°) | 12.5° (15°) | Follow-up issues: Preoperative anterioposterior radiograph not available for | | | |
| Recruitment period: 1987 - 2001 Study population: children < | | % with scoliosis ≥ 10° | - | 54.8% (57/104) | one patient. | | | |
| 18years with spastic cerebral palsy in whom pr- and post- | | % with scoliosis ≥35° | - | 5.8% (6/104) | Study design issues:Retrospective study. | | | |
| operative spine radiographs were available | | 1 patient underwent spin patient underwent fusion | | | Postoperative physiotherapy regimen (if any) is not described. | | | |
| n = 105 | | Kyphosis (n=44) | | | Study population issues: | | | |
| Age: 5.2 years (mean) | | | Preop | Foll □ w-up | 59% (62/105) patients had | | | |
| Sex: 53.3% (56/105) male Patient selection criteria: see | | Mean Cobb angle for kyphosis (standard deviation) | 34.8° (13.3°) | 38.2° (13°) | spastic diplegia, 32.4% (34/105) had spastic quadriplegia and 8.6% (9/105) | | | |
| above | | % with kyphosis ≥39.5° | - | 40.9% (18/44) | had quadriplegia and intellectual delay. | | | |
| Technique: SDR (via multilevel laminectomies or laminoplasties, usually from L1 to S1 with 20-90% of dorsal roots cut. | | Lordosis (n=47) | Preoperative ambulatory status: 25.7% (27/105) used a wheelchair, 19% (20/105) could commando crawl, 17.1% | | | | | |
| Electrophysiology used during the | | | Preop | Follow-up | (18/105) 4 point crawling, | | | |
| procedure) | | Mean Cobb angle for lordosis (standard deviation) | 30.8° (13.5°) | 41.2° (15.2°) | 23.8% (25/105) walked using a walker, 1.9% (2/105) used crutches and 12.4% (13/105) | | | |
| Follow-up: 4.3 years (mean) | | % with lordosis >54° | - | 21.3% (10/47) | walked independently. | | | |
| Conflict of interest/source of funding: not reported | | | | | | | | |
| | | | | | | | | |

| Study details | Key efficacy findings | Key safety findings | Key safety findings | | | | | | |
|---|-----------------------|--|---|--|--|--|--|--|--|
| Golan JD (2007) ¹⁰ | Not reported | Scoliosis | Scoliosis | | | | | | |
| Case series | | Mild scoliosis in patients wit bearing radiograph: 42.8% (| | 4.1% (4/98) did not have postoperative radiographs 11.2% (11/98) did not have | | | | | |
| Canada | | For patients with pre- and po | | postoperative weight bearing radiographs. | | | | | |
| Recruitment period: 1991–2001 Study population: children with | | radiographs (n=35): Preope | rative Follow-up | • 64.3% (68/98) did not have | | | | | |
| spastic cerebral palsy | | Mean Cobb 6.4° angle | 8.3° | pre- and post-operative weight-bearing radiographs. | | | | | |
| n = 98 | | % scoliosis ≥10° 31.4% (11/35) | 42.9% (15/35) | Study design issues:Retrospective study. | | | | | |
| Age: 5.1 years (mean) Sex: 61.2% (60/98) male Patient selection criteria: all | | | Of the 15 cases at follow-up, 6 cases had improved by $\geq 10^{\circ}$ and 9 had worsened by $\geq 10^{\circ}$ in comparison to the preoperative radiograph. | | | | | | |
| patients who underwent SDR, had pre- and post-operative | | confirm): | | | | | | | |
| radiographic spinal studies and a minimum of 1 year follow-up were | | Preope (n=10) | (n=50) | radiculopathy. | | | | | |
| included. Technique: SDR (multilevel L1 to | | % kyphosis 20% (2 exceeding upper limit of normal | /10) 12% (6/50) | Study population issues:Preoperative ambulatory | | | | | |
| S1 laminectomy with mean 53.8% rootlets cut) followed by 6 weeks of intensified inpatient | | Lumbar lordosis (requires s confirm): | Lumbar lordosis (requires standing radiograph to confirm): | | | | | | |
| rehabilitation. | | Preope (n=17) | rative Follow-up (n=53) | point crawlers: 9.2% (9/98) and commando crawlers: 5.1% | | | | | |
| Follow-up: 5.8 years (mean) | | Mean lordotic -34.2° angle | -47.7° | (5/98) | | | | | |
| Conflict of interest/source of funding: not reported | | % curve exceeds 5.9% (upper limit of normal | /17) 32.1% (17/53) | | | | | | |
| | | Spondylolisthesis: 19.1% (| 18/94) at follow-up | | | | | | |

| Study details | Key efficacy findings | Key safety findings | | | | Comments |
|--|--------------------------|--|---|---|--|---|
| Li Z (2008) ¹¹ | Not reported | Lumbar spine radio | ographs | | | Follow-up issues: |
| Case series China | | Mean angle of hyperlordolysis | Preop 17.9 ^o ± 4.5 ^o | Follow-up 29.3° ± 4.6° | p value < 0.05 | • 219 patients treated during recruitment period. It is unclear why only 27.9% (61/219) had postoperative lumbar spine radiographs or how these patients were selected. |
| Recruitment period: 1992–2002 Study population: subset of patients with spastic CP who underwent SDR and had follow-up lumbar spine radiographs in 2004/5 | | Lumbar hyperlordosis | 1.6% (1/61) | 16.4% (10/61) [knee hyperexten sion in 3 cases] | Not reported | Study design issues: Retrospective study Study population issues: |
| n = 61 Age:6.9 years (mean) Sex: data are unclear Patient selection criteria: unclear Technique: SDR (selection of rootlets sectioned based on electrophysiology response to intraoperative electrical stimulation) | | Of the 10 patients all showed distinct developed spondy and 5 years after the lumbar kyphosis de In addition, one can spondylolysis were | ively abnorma lolysis and gra ne procedure eformity 7 yea se of scoliosis | al walking posture ade-I spondylolis . One patient dev ars after surgery. s and two cases o | e, 4 patients thesis at 3, 4 reloped of L_5 | Percentage of dorsal nerve rootlets sectioned in the SDR group was not reported. |
| Follow-up: 6.3 years (mean) Conflict of interest/source of funding: not reported | | | | | | |

| Study details | Key efficacy findings | Key safety findings | | Comments |
|---|---|---|---|---|
| Langerak NG (2009a) ¹² | Long term follow-up: | | % with scoliosis | Follow-up issues: |
| Case series | ODI (N=30) | Short-term follow-up (median 4 years)[n=28] | 0% | • 47 eligible patients, of whom 78.7% (37/47) were tracked down by the |
| South Africa | Minimal disability due to back pain (score 0–20%): 76.7% (23/30) | Long-term follow-up (median 21.4 years) [n=30] | Curve <35°: 50% (15/30) Curve 35°: 6.7% | researchers. Of these, 81.1% (30/37) agreed to take part in the study. |
| Recruitment period: SDR procedure: 1981–1991, follow-up: 2008 | Moderate disability due to back pain (score 20–40%): 23.3% (7/30) | p value | (2/30) <0.01 | 6.7% (2/30) patients did not participate in the short-term follow- |
| Study population: patients with spastic | Other pain scores | | % with kyphosis | up. |
| CP. | 3–10% of patients reported pain in their upper extremities | Short-term follow-up (median 4 years)[n=28] | 0 | Study design issues:Retrospective study |
| n = 30 Age: at SDR procedure: 5.2 years (median), at follow-up: 26.8 years | 23–4% of patients reported pain in their lower extremities.20% reported pain at the cervical | Long-term follow-up (median 21.4 years) [n=30] | 6.7% (2/30) | Patients had X-rays at short-term follow-up. Patients had X-ray and MRI scans of the spine at long-term |
| (median) Sex: 56.7% (17/30) male | spinal level 67% reported pain at the lumbosacral level. | p value | 0.32 | follow-up in 2008. Unclear whether assessment was made by |
| Patient selection criteria: inclusion: diagnosis of cerebral palsy with | | Short-term follow-up | % with lordosis 20% (6/30) | independent reviewers. |
| spasticity mainly with involvement of lower limbs, ambulant before 4 years of age, goal of SDR is functional | | (median 4 years)[n=28] Long-term follow-up (median 21.4 years) | 40% (12/30) | Study population issues: Position of laminectomies: 70% L1/2 to S1, 10% L1 to L5, 10% L2 to L5, 3% L2 to S2 and 7% L3 to |
| improvement and improvement gait pattern. Patients had to have lived | | [n=30] p value | 0.13 | All patients ambulant at follow-up. |
| within 100km of Cape Town when they had the procedure to be included in this study. Exclusion: dystonic, athetotic, | | | % with spondylolysis | 66.7% (20/30) walked without walking aids, 13.3% (4/30) used 1 |
| ataxia or hypotonic cerebral palsy, diagnosis of other neuromuscular | | Short-term follow-up (median 4 years)[n=28] | 16.7% (5/30) | or 2 crutches when outdoors only and 20% (6/30) always used crutches. |
| disorders. | | Long-term follow-up (median 21.4 years) | 36.7% (11/30) | Before SDR 48% had muscle releasing surgical procedures and |
| Technique: SDR | | [n=30] p value | 0.13 | 10% had osteotomies of the femur or foot/toes. |
| Follow-up: 21.4 years (median) Conflict of interest/source of funding: none | | In addition, MRI scans sho 26.7% (8/30) of patients; b (6/30) of patients and disc (2/30) of patients. | lack discs in 20% | After SDR, 60% (18/30) had a surgical procedure: 59% had muscle releasing procedures and 31% had osteotomies. |

| Study details | Key efficacy findings | | | | Key safety findings | Comments | | | |
|---|---|------------------|--------------------------------|-----------------------|------------------------|--------------------------------|-------------------------------------|--|--|
| Langerak NG (2009b) ¹³ | Number of patients analysed: 14 | | | | Not reported | Overlap with Langerak 2009a | | | |
| Case series | <u>GMFCS</u> 71.4% (10/14 |) improved l | by 1 level on | GMFCS, 2 | 1.4% (3/14 | 4) remaine | ed unchanged | | Follow-up issues: |
| South Africa | and 1 patient | deteriorated | d from level 3 | to 5 at 20- | year follov | v-up. | | | Complete follow-up for all patients |
| Recruitment period: 1985 - 1986 | | Median pre-op | Median 1 year post | Median 20 year | p value pre-1 | p value pre-20 | p value 1 yr-20 yr | | Study design issues: |
| Study population: Patients with spastic diplegia of congenital origin | | score | op score | post op score | yr | yr | | | Patients were all treated by the same |
| n = 14 | Muscle tone | 3.1 | 2.1 | 2.0 | <0.001 | <0.001 | 0.859 | | neurosurgeon at one hospital. |
| Age: 28 years (mean) | Joint stiffness | 1.9 | 1.2 | 1.3 | 0.001 | 0.019 | 0.972 | | Video of follow-up assessment reviewed by 2 physicitherepiste |
| Sex: 57.1% (8/14) male | Voluntary movement | 3.6 3.1 | 2.3 | 1.9 | 0.001 | 0.002 | 0.021 | | by 2 physiotherapists blinded to the 1-year |
| Patient selection criteria: patients had to be ambulant preoperatively and have | Functional movement | 3.1 | 1.9 | 1.8 | <0.001 | <0.001 | 0.328 | | follow-up outcome to confirm final scores.GMFCS percentages |
| access to intensive physiotherapy before and after surgery. | |) had at leas | t 1 further ort | | | | don procedure: | | are reported as 64% (n=10) improved by 1 |
| Technique: Selective dorsal rhizotomy | | ny: 6 patients | s and femur o | steotomy: | 1 patient). | No patie | dure: 1 patient, nts received an | | level on GMFCS, 29% (n=3) remained unchanged and 7% |
| Follow-up: 20 years | antispasmod | | | n toxin inje | | alleni use | u orar | | (n=1) deteriorated from level 3 to 5 in the |
| Conflict of interest/source of funding: None | <u>Activities of d</u> All patients si 78.6% (11/14 | aid they did | not need helf loyed or stud | o with daily ying. | activities a | at 20 year | follow-up. | | papers. Interventional Procedures analyst has assumed the raw data is correct and adjusted the percentages accordingly. |
| | | | | | | | | | |

Efficacy

Reduction in spasticity (Modified Ashworth Scale)

A meta-analysis of 3 randomised controlled trails (RCTs) including a total of 90 patients reported a mean change in Modified Ashworth Scale score of -1.23 (p < 0.01), indicating a reduction in spasticity following selective dorsal rhizotomy at 9-month follow-up (1 study) and 12-month follow-up (2 studies)¹.

A non-randomised comparative study of 142 patients reported that 71 patients treated by selective dorsal rhizotomy had an improvement in mean Modified Ashworth Scale score of -2.52 compared with -1.23 for 71 patients treated by intrathecal baclofen pumps (ITBP) (p < 0.0001) at 1-year follow-up².

A non-randomised study of 44 patients reported that 22 patients treated by selective dorsal rhizotomy using electrophysiological guidance had a similar change in Ashworth hip adductors score from baseline to 1-year follow-up as the 22 patients treated by selective dorsal rhizotomy without using electrophysiological guidance $(1.2 \text{ vs. } 0.9, \text{ p} = 0.307)^5$.

A case series of 208 patients (198 with cerebral palsy) reported a significant improvement in the spasticity of all tested muscles at 1- and 4-year follow-up⁸.

Gross motor function

The meta-analysis reported a mean change in GMFM score of 4.53 (p = 0.002), indicating an increase in gross motor function following treatment with selective dorsal rhizotomy. The same study showed that GMFM scores improved by 8% in the selective dorsal rhizotomy plus physical therapy group compared with 4% in the physical therapy-only group (p = 0.008) at 9-month follow-up (1 study) and 12-month follow-up (2 studies)¹.

The non-randomised comparative study of 142 patients reported that 71 patients treated by selective dorsal rhizotomy had mean GMFCS scores of -0.66 compared with -0.08 for 71 patients treated by ITBP (p < 0.0001) at 1-year follow-up².

A non-randomised comparative study of 108 patients reported that 31 patients treated by selective dorsal rhizotomy had a mean improvement in GMFM score from 87 preoperatively to 92 postoperatively (p < 0.05) at 20-month follow-up³.

A non-randomised study of 44 patients reported that 22 patients treated by selective dorsal rhizotomy using electrophysiological guidance had a similar change in GMFCS from baseline to 1-year follow-up as the 22 patients treated by selective dorsal rhizotomy without using electrophysiological guidance (0.14 vs. 0.09, p = 0.764)⁵.

A non-randomised comparative study of 42 patients reported no significant change in GMFCS between baseline and 5 years in 21 patients treated by IP overview: selective dorsal rhizotomy for spasticity in cerebral palsy selective dorsal rhizotomy (referred to as selective posterior rhizotomy in study) plus physical therapy or in 21 patients treated by physical therapy only⁶.

A non-randomised comparative study of 25 patients reported improvement in mean GMFM from 82.1 at baseline to 89.5 (p = 0.011) in 18 patients treated by selective dorsal rhizotomy and 78.2 at baseline to 85.7 (p = 0.048) in 7 patients treated by orthopaedic surgery. There was no significant difference in improvement between groups (p = 0.54) at 2-year follow-up⁷.

A case series of 14 patients reported that 71% (10/14) improved by 1 level on the GMFCS, 21% (3/14) remained unchanged and 1 patient deteriorated from level 3 to level 5 at 20-year follow-up¹³.

Patient satisfaction

The non-randomised comparative study of 142 patients reported that 94% of 71 patients treated by selective dorsal rhizotomy and 96% of 71 patients treated by ITBP (absolute figures not reported) were satisfied at 1-year follow-up $(p = 0.71)^2$.

A case series of 14 patients reported that all patients did not need help with daily activities and 79% (11/14) were employed or studying at 20-year follow-up¹³.

Safety

Spinal deformity

The case series of 208 patients reported radiologically observed scoliosis in 9% (5/58) of patients who had laminectomy and 1% (2/150) of patients who had laminoplasty at a mean follow-up of 4.2 years. The percentage of patients with scoliosis preoperatively is not reported⁸.

A case series of 105 patients reported that 55% (57/104) of patients with pre- and postoperative spinal radiographs had scoliosis of 10° or greater at mean 4.3-year follow-up. The same study reported that 21% (10/47) of patients with pre- and postoperative spinal radiographs had lordosis greater than 54° at mean 4.3-year follow-up⁹.

A case series of 98 patients reported scoliosis of 10° or greater (for patients who had both pre- and postoperative weightbearing spinal radiographs) in 31% (11/35) of patients pre-operatively and 43% (15/35) of patients at mean 5.8-year follow-up. The same study reported that 6% (1/17) of patients with a pre-operative standing radiograph and 32% (17/53) with a postoperative standing radiograph had hyperlordosis at mean 5.8-year follow-up¹⁰.

A case series of 61 patients reported an increase in the mean angle of hyperlordosis from 17.9° at baseline to 29.3° at a mean follow-up of 6.3 years

(p < 0.05). This study reported 10 patients with lumbar hyperlordosis (with distinctively abnormal walking posture) after the procedure (1 patient had this condition at baseline). Four patients developed spondylolysis and grade-I spondylolisthesis at 3, 4 and 5 years after the procedure and 1 patient developed lumbar kyphosis 7 years after the procedure¹¹.

A case series of 30 patients reported a significant increase in the proportion of patients with scoliosis, from 0% at median 4-year follow-up after selective dorsal rhizotomy to 50% (15/30) with a curve of less than 35° and 7% (2/30) with a curve greater than 35° at median 21.4-year follow-up (p < 0.01). The same study reported a non-significant increase in the proportion of patients with lordosis, from 20% (6/30) at median 4-year follow-up to 40% (12/30) at median 21.4-year follow-up (p = 0.13)¹².

Bladder problems

The non-randomised comparative study of 42 patients reported that 1 patient of 21 treated by selective dorsal rhizotomy (referred to as selective posterior rhizotomy in the study) plus physical therapy had incontinence following the procedure. Timing, duration and treatment for this complication were not reported⁶.

The case series of 208 patients reported urinary retention due to decreased bladder tone and hyporeflexia in 10% (20/208) of patients. This resolved spontaneously within 4 weeks in 18 patients but 2 patients had long-term incontinence due to atonic bladder⁸.

Back pain

The case series of 208 patients reported 3% (7/208) of patients had longstanding back pain at a mean follow-up of 4.2 years⁸.

A case series of 30 patients reported that 23% (7/30) patients had moderate disability due to back pain (ODI score of 20 to 40%) at median 21.4-year follow-up¹².

Validity and generalisability of the studies

- Most of the studies (5 of 8) reported in table 2 appeared in the original overview.
- Different comparator treatments (physical therapy, orthopaedic surgery and ITBP) are used in the available studies.

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

The Australian Medical Services Advisory Committee published an assessment for nationally funded centre (NFC) status on selective dorsal rhizotomy (SDR) in November 2006. The Committee recommended that:

- one NFC for SDR should be established.
- the cost estimates from the NFC should be reviewed according to the patient referral base.
- a national protocol for the management of patients with SDR should be developed and implemented with agreement between the NFC and referral centres.
- high-quality prospective data with long-term follow-up on all patients treated with SDR and other management options should be collected using a common protocol for data collection to ensure a common dataset across Australia is established. Data collection should allow for monitoring of possible adverse events such as spinal deformity.
- an accelerated review of the number of centres is required in view of the likelihood that this service will diffuse in the future due to the availability of appropriate technical expertise and multidisciplinary spasticity management services and the opportunity to improve patient access¹⁴.

Interventional procedures

 Selective dorsal rhizotomy for spasticity in cerebral palsy. NICE interventional procedures guidance 195 (2006). Available from <u>www.nice.org.uk/guidance/IPG195</u> (Current guidance)

Specialist Advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society.

Professor MS Eljamel (Society of British Neurosurgical Surgeons), Mr Martin Smith and Mr Richard Edwards (British Paediatric Neurosurgical Group) and Mr Andrew Roberts (British Orthopaedic Association).

- One Specialist Adviser performs the procedure regularly, two have never performed the procedure and the other did not report his level of experience.
- Three Specialist Advisers stated that this is established practice.
- Two Specialist Advisers stated that there is only one UK centre where this procedure is performed. Three other centres have expressed an interest in performing this procedure.
- The comparators are intrathecal baclofen infusion, multi-level orthopaedic surgery and physiotherapy.
- Theoretical adverse events: death, worsening motor function and/or paraplegia, dislocation of the hips, back pain, sensory disturbance, urinary incontinence, constipation, weakness, chronic pain, wound infection, cauda equina, scoliosis, spinal deformity, cerebrospinal fluid leakage, late arachnoiditis and/or syringomyelia and meningitis.
- Efficacy outcomes: reduction in lower limb spasticity, improvement in gross motor function, improved gait and walking, reduction in number of subsequent orthopaedic procedures, level of independence and quality of life.
- Training and facilities: specialised neurosurgical centres and multidisciplinary teams including neurosurgeon, neurologist, paediatric anaesthesiologist, physiotherapist, spinal neurophysiology monitoring facilities, specialised equipment for surgery and intra-operative management, paediatric rehabilitation facilities and specialist orthotic services. Training should be a specific fellowship in paediatric neurosurgery at a centre undertaking the procedure.
- Two Specialist Advisers highlighted the importance of appropriate case selection (1 pointed out that the procedure is irreversible).
- One Specialist Adviser indicated that long-term follow-up data (5+ years) is required on this procedure.

Patient Commentators' opinions

• NICE's Patient and Public Involvement programme were unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

 A systematic review of 'Selective dorsal rhizotomy in the management of children with spastic cerebral palsy' by the Cochrane Collaboration is currently in development¹⁵.

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- 10. Golan JD, Hall JA, O'Gorman G et al. (2007) Spinal deformities following selective dorsal rhizotomy. Journal of Neurosurgery 106:Suppl-9.
- 11. Li Z, Zhu J, and Liu X. (2008) Deformity of lumbar spine after selective dorsal rhizotomy for spastic cerebral palsy. Microsurgery 28:10-12.
- 12. Langerak NG, Vaughan CL, Hoffman EB et al. (2009) Incidence of spinal abnormalities in patients with spastic diplegia 17 to 26 years after selective dorsal rhizotomy. Childs Nervous System 25:1593-1603.

- Langerak NG, Lamberts RP, Fieggen AG et al. (2009) Functional status of patients with cerebral palsy according to the International Classification of Functioning, Disability and Health model: a 20-year follow-up study after selective dorsal rhizotomy. Archives of Physical Medicine & Rehabilitation 90:994-1003.
- Australian Medical Services Advisory Committee. (1-11-2006) Selective Dorsal Rhizotomy (SDR): Assessment for Nationally Funded Centre Status (A report by the Medical Services Advisory Committee to the Australian Health Ministers' Advisory Council). 1-82.
- 15. Narayanan UG and Howard AW. (2009) Selective dorsal rhizotomy in the management of children with spastic cerebral palsy (protocol). Cochrane Database of Systematic Reviews

Appendix A: Additional papers on selective dorsal rhizotomy for spasticity in cerebral palsy

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non- inclusion in table 2 |
|--|--|--|---|
| McLaughlin JF, Bjornson KF, Astley SJ et al. Selective dorsal rhizotomy: efficacy and safety in an investigator- masked randomized clinical trial. Developmental Medicine & Child Neurology 1998 Apr; 40:220-232. | RCT n = 38 (21 SDR +PT vs 17 PT only) Follow-up= 2 years | SDR + PT provided a greater mean reduction in spasticity than PT only (p = 0.02) | Included in McLaughlin (2002) meta analysis in Table 2 [Reported in appendix A in original overview] |
| Graubert C, Song KM, McLaughlin JF et al. (2000) Changes in gait at 1 year post-selective dorsal rhizotomy: results of a prospective randomized study. Journal of pediatric orthopedics 20:496-500. | RCT n = 32 (18 SDR+PT vs 14 PT only) Follow-up = 1 year | Changes in ankle dorsiflexion, foot progression angle and hip and knee extension were greater with SDR + PT than PT only (p < 0.05) | Same cases as those Included in McLaughlin (1998) study above [Reported in appendix A in original overview] |
| Steinbok P, Reiner AM, Beauchamp R et al. (1997) A randomized clinical trial to compare selective posterior rhizotomy plus physiotherapy with physiotherapy alone in children with spastic diplegic cerebral palsy. Developmental Medicine and Child Neurology 39:178-184. | RCT n = 30 (15 SPR + PT vs 15 PT only) Follow-up = 9 months | Gross motor function measure improved significantly more in the SDR group (11.3%) than the physiotherapy group (5.2%) ($p = 0.007$). Significant improvements in spasticity ($p < 0.001$) and range of movement ($p < 0.001$) were noted in the SPR + PT group in comparison with the PT- only group. | Included in McLaughlin (2002) meta analysis in Table 2 [Reported in appendix A in original overview] |
| Wright FV, Sheil EMH, Drake JM et al. (1998) Evaluation of selective dorsal rhizotomy for the reduction of spasticity in cerebral palsy: A randomised controlled trial. Developmental Medicine and Child Neurology 40:239-247. | RCT n = 24 (12 SDR + PT vs 12 PT only) Follow-up = 1 year | Gross motor function measure improved significantly more in the SDR group (12.1%) than the physiotherapy group (4.4%) ($p < 0.02$) | Included in McLaughlin (2002) meta analysis in Table 2 [Reported in appendix A in original overview] |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non- inclusion in table 2 |
|---|--|---|--|
| Abbott R. (1992) Complications with selective posterior rhizotomy. Pediatric Neurosurgery 18:43-47. | Case series n = 200 for efficacy outcome and 250 for safety Follow-up = 12 moths for | Spasticity was significantly reduced in ambulatory and non- ambulatory patients. Severe postoperative complications experienced by 15% of patients. Complications: | Old study [Kim 2001 is a more up to date case series of a similar size] [included in table 2 in original overview] |
| Abbott R, Johann- Murphy M, Shiminski- Maher T et al. (1993) Selective dorsal rhizotomy: outcome and complications in treating spastic cerebral palsy. Neurosurgery 33:851- 857. | efficacy outcomes and up to 2+ years for safety outcomes | Intraoperative bronchospasm: 5% (13/250) Aspiration pneumonia:1% (3/250) Urinary retention5% (13/250) Constipation:20% (49/250) Ileus:1% (3/250) Severe postoperative pain: 58% (145/250) Dysthaesia:40% (100/250) Proprioceptive loss:1% (3/250) Pain / temperature loss: 1% (2/250) | |
| Chicoine MR, Park TS, and Kaufman BA. (1997) Selective dorsal rhizotomy and rates of orthopedic surgery in children with spastic cerebral palsy. Journal of Neurosurgery 86:34- 39. | Case series n = 178 Follow-up = 44 months | Children treated later with SDR had a higher rate of subsequent orthopaedic surgery than those treated younger | Larger studies are included in table 2 [Reported in appendix A in original overview] |
| Kim HS, Steinbok P, and Wickenheiser D. (2006) Predictors of poor outcome after selective dorsal rhizotomy in treatment of spastic cerebral palsy. Childs Nervous System 22:60- 66. | Case series n = 178 Follow-up = 44 months | 6.3% (11/178) had a poor outcome. Type of cerebral palsy (p < 0.001) and intellectual delay (p = 0.015) were significant predictors of outcome | Larger studies are included in table 2 |
| O'Brien DF, Park TS, Puglisi JA et al. (2005) Orthopedic surgery after selective dorsal rhizotomy for spastic diplegia in relation to ambulatory status and age. Journal of Neurosurgery 103:5-9. | Case series n = 158 Follow-up = 7.5 years | Orthopaedic surgery is more likely in patients destined to be non- ambulators. | Larger studies are included in table 2 [Reported in appendix A in original overview] |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non- inclusion in table 2 |
|---|---|--|--|
| Steinbok P and Schrag C. (1998) Complications after selective posterior rhizotomy for spasticity in children with cerebral palsy. Pediatric Neurosurgery 28:300- 313. | Case series n = 158 Follow-up = 29.5 months | Aspiration pneumonia was the most common intraoperative complication occurring in 2 patients. Perioperative complications: Sensory changes in 8.9% and transient urinary retention in 4.4%. 6 months after surgery: Back pain:10.8% Sensory changes: 13.9% Neurogenic bladder or bowel problems: 12.7% | Larger studies are included in table 2 [Reported in appendix A in original overview] |
| Salame K, Ouaknine GE, Rochkind S et al. (2003) Surgical treatment of spasticity by selective posterior rhizotomy: 30 years experience. Israel Medical Association Journal: Imaj 5:543-546. | Case series n = 154 Follow-up = 11 years | Painful spasms alleviated in 80% of cases, and reduction of spasticity achieved in all cases | Larger studies are included in table 2 A mixed cohort of patients with spasticity only 60 had cerebral palsy. Data not analysed separately [Reported in appendix A in original overview] |
| Trost JP, Schwartz MH, Krach LE et al. (2008) Comprehensive short- term outcome assessment of selective dorsal rhizotomy. Developmental Medicine & Child Neurology 50:765-771. | Case series n = 136 Follow-up = 18.3 months (mean) | Spasticity improved | Larger studies are included in table 2 |
| Peter JC and Arens LJ. (1993) Selective posterior lumbosacral rhizotomy for the management of cerebral palsy spasticity. A 10- year experience. South African Medical Journal Suid-Afrikaanse Tydskrif Vir Geneeskunde. 83:745-747. | Case series n = 100 Follow-up = to 10 years | Satisfactory tone reduction in 95% of cases | Larger studies are included in table 2 [Reported in appendix A in original overview] Overlap with Langerak 2009a and Langerak 2009b |
| Morota N. (2007) Functional posterior rhizotomy: the Tokyo experience. Childs Nervous System 23:1007-1014. | Case series n = 98 Follow-up = 1+ years | 39% (20/51) followed for 1+ year showed improved locomotion after functional posterior rhizotomy 59% (30/51) demonstrated suprasegmental effects after FPR. | Larger studies are included in table 2 |
| Konya D, Gercek A, Dagcinar A et al. (2009) | Case series | Severity of spasticity reduced (mean | Larger studies are included in table 2 |

| Article | Number of patients/follow-up | Direction of conclusions | Reasons for non- inclusion in table 2 |
|--|--|---|---|
| Prevention of brisk hyperactive response during selective dorsal rhizotomy in children with spasticity: isoflurane versus sevoflurane maintenance anesthesia. Journal of Clinical Neuroscience 16:241-245 | n = 54 Follow-up = 30 days | Ashworth score dropped from 3.4 to 1.77, p < 0.001) | |
| Grunt S, Becher JG, van SP et al. (2010) Preoperative MRI findings and functional outcome after selective dorsal rhizotomy in children with bilateral spasticity. Childs Nervous System 26:191- 198. | Case series n = 36 Follow-up: 5 years and 4 months (mean) | The best improvement in gross motor function was seen in patients with normal MRI, and a slight improvement was seen in patients with hydrocephalus. | Larger studies are included in table 2 |
| Nordmark E, Josenby AL, Lagergren J et al. (2008) Long-term outcomes five years after selective dorsal rhizotomy. BMC Pediatrics 8:54- | Case series n = 35 Follow-up = 5 years | Muscle tone was immediately reduced in adductors, hamstrings and dorsiflexors (p < 0.001) with no recurrence of spasticity over 5 years. | Larger studies are included in table 2 |
| Chan SH, Yam KY, Yiu- Lau BP et al. (2008) Selective dorsal rhizotomy in Hong Kong: multidimensional outcome measures. Pediatric Neurology 39:22-32. | Case series n = 20 Follow-up = 12 months | Statistically significant reduction in spasticity, functional improvements in mobility and self care and increased participation in social situations | Larger studies are included in table 2 |
| Cole GF, Farmer SE, Roberts A et al. (2007) Selective dorsal rhizotomy for children with cerebral palsy: the Oswestry experience. Archives of Disease in Childhood 92:781-785. | Case series n = 19 Follow-up = 18 months | UK study Children walked on average 0.15 m/s faster with length step improvement of 0.11m after SDR. 0.3 grade improvement in knee extension power. 78.9% (15/19) children improved by at least one level on the GMFCS. | Larger studies are included in table 2 |

| Article | Article Number of I patients/follow-up c | | Reasons for non- inclusion in table 2 |
|---|--|---|---|
| | | | |
| Horinek D, Hoza D, Cerny R et al. (2008) Two cases of improvement of smooth pursuit eye movements after selective posterior rhizotomy. Childs Nervous System 24:1283-1288. | Case reports n = 4 Follow-up = 6-12 weeks | Improvement in eye response to stimulus following SPR in 2 patients due to suppression of spontaneous fixation nystagmus | Larger studies are included in table 2 |
| Grunt S, van der Knaap MS, van Ouwerkerk WJ et al. (2008) Effectiveness of selective dorsal rhizotomy in 2 patients with progressive spasticity due to neurodegenerative disease. Journal of Child Neurology 23:818-822. | Case reports n = 2 Follow-up = 3 years | Leg spasticity effectively and persistently reduced in both patients, however, spasticity of the arms and other motor disturbances such as spontaneous extension spasm and ataxia increased gradually over time. | Larger studies are included in table 2 |
| Albright AL and Tyler- Kabara EC. (2007) Combined ventral and dorsal rhizotomies for dystonic and spastic extremities. Report of six cases. Journal of Neurosurgery 107:Suppl-7. | Case reports n = 6 (only 2 related to cerebral palsy) Follow-up = 3 years and 6 months | Case 1: no hypertonicity after procedure and care was significantly easier. Case 2: No spasticity or dystonia in lower extremities following procedure. Care became significantly easier and comfort improved. | Larger studies are included in table 2 |
| Spijker M, Strijers RL, van Ouwerkerk WJ et al. (2009) Disappearance of spasticity after selective dorsal rhizotomy does not prevent muscle shortening in children with cerebral palsy: a case report. Journal of Child Neurology 24:625- 627 | Case reports n = 1 Follow-up = 5 years | SDR improved walking abilities however the patient did develop muscle shortening during growth. | Larger studies are included in table 2 |
| Sitthinamsuwan B, Chanvanitkulchai K, Nunta-Aree S et al. (2010) Combined ablative neurosurgical procedures in a patient with mixed spastic and dystonic cerebral palsy. Stereotactic & Functional Neurosurgery 88:187-192. | Case report n = 1 Follow-up: 1 year | Spasticity and cervical dystonia totally disappeared following SDR plus selective peripheral denervation and microsurgical dorsal root entry zone lesion. | Larger studies are included in table 2 |

| Guidance | Recommendations |
|---------------------------|---|
| Interventional procedures | Selective dorsal rhizotomy for spasticity in cerebral palsy. NICE interventional procedures guidance 195 (2006) [current guidance] |
| | 1.1 Current evidence on the safety of selective dorsal rhizotomy (SDR) for spasticity in cerebral palsy appears adequate; however, there is evidence of only limited efficacy. Therefore, the procedure should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake SDR for spasticity in cerebral palsy should take the following actions. o Inform the clinical governance leads in their Trusts. o Ensure that patients or their parents/carers understand the uncertainty about the efficacy of this procedure, that it is irreversible and that there is a risk of serious complications. They should also be counselled on the extensive physiotherapy and rehabilitation required after this procedure and clinicians should provide them with clear written information. Use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG195publicinfo). o Audit and review clinical outcomes of all patients having SDR for spasticity in cerebral palsy (see section 3.1). 1.3 Patient selection should be carried out in the context of a multidisciplinary team with specialist expertise in various treatment options for spasticity in patients with cerebral palsy. This should normally include a physiotherapist, a paediatrician, an orthopaedic surgeon and a neurosurgeon. 1.4 Further evidence on the efficacy outcomes of the procedure will be useful. The Institute may review the procedure upon publication of further evidence. |

Appendix B: Related NICE guidance for selective dorsal rhizotomy for spasticity in cerebral palsy

Appendix C: Literature search for selective dorsal

rhizotomy for spasticity in cerebral palsy

| Database | Date searched | Version/files |
|------------------------------|---------------|--------------------------|
| Cochrane Database of | 27/07/2010 | July, 2010 |
| Systematic Reviews – CDSR | | |
| (Cochrane Library) | | |
| Database of Abstracts of | 27/07/2010 | n/a |
| Reviews of Effects – DARE | | |
| (CRD website) | | |
| HTA database (CRD website) | 27/07/2010 | n/a |
| Cochrane Central Database of | 27/07/2010 | July, 2010 |
| Controlled Trials – CENTRAL | | |
| (Cochrane Library) | | |
| MEDLINE (Ovid) | 27/07/2010 | 1950 to July Week 2 2010 |
| MEDLINE In-Process (Ovid) | 27/07/2010 | July 26, 2010 |
| EMBASE (Ovid) | 27/07/2010 | 1980 to 2010 Week 29 |
| CINAHL (NLH Search 2.0) | 27/07/2010 | n/a |
| Zetoc | 27/07/2010 | n/a |

| Websites | Date searched | Title, year and link |
|--|------------------|---|
| NICE ('published' and 'in development' guidance) | 07/07/2009 | Selective dorsal rhizotomy for spasticity in cerebral palsy, 2005 |
| FDA (MAUDE database) | 07/07/2009 | Nothing found. |
| ASERNIP | 07/07/2009 | Nothing found. |
| ANZHSN | 07/07/2009 | Nothing found. |
| National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database | 07/07/2009 | Nothing found. |
| Current Controlled Trials <i>meta</i> Register of Controlled Trials - <i>m</i> RCT | 07/07/2009 | Phase II Randomized Study of Selective Dorsal Rhizotomy and Physiotherapy Vs Physiotherapy Alone for Spastic Diplegia |
| Clinicaltrials.gov | 07/07/2009 | Wavelet Analysis of Electromyography (EMG) in Cerebral Palsy |
| General internet search | 07/07/2009 | Nothing found. |

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

| 1 | Cerebral Palsy/ |
|----|--|
| 2 | (cerebr* adj3 pals\$).tw. |
| 3 | spasticit*.tw. |
| 4 | (spastic* adj3 diplegia*).tw. |
| 5 | (spastic* adj3 quadripleg*).tw. |
| 6 | Quadriplegia/ |
| 7 | Muscle Spasticity/ |
| 8 | (increase* adj3 muscle* adj3 tone*).tw. |
| 9 | CP.tw. |
| 10 | (little* adj3 diseas*).tw. |
| 11 | tetraplegia*.tw. |
| 12 | quadripare*.tw. |
| 13 | (lock* adj3 in adj3 syndrom*).tw. |
| 14 | Muscle Rigidity/ |
| 15 | (muscle* adj3 rigidit*).tw. |
| 16 | gegenhalten*.tw. |
| 17 | or/1-16 |
| 18 | exp Rhizotomy/ |
| 19 | Rhizotom*.tw. |
| 20 | ((spin* or sensor*) adj3 nerve* adj3 interrupt*).tw. |
| 21 | or/18-20 |
| 22 | (dors* or posterior or functional).tw. |
| 23 | Ganglia, Spinal/ |
| 24 | (gangli* adj3 spin*).tw. |
| 25 | or/22-24 |

| 26 | 21 and 25 |
|----|----------------------------------|
| 27 | 17 and 26 |
| 28 | limit 27 to ed=20060101-20090703 |