Table 12: Studies included in the evidence review for neurosurgical procedures for spasticity

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Full citation Albright,A.L., Cervi,A., Singletary,J., Intrathecal baclofen for spasticity in cerebral palsy, JAMA, 265, 1418-1422, 1991 **Ref Id** 58579 **Country/ies where the study was carried out** USA **Study type** Randomised cross-over trial **Aim of the study** To assess the effect of ITB on spasticity in people with CP **Study dates** Not reported	**Sample size** N = 7 (aged 15 or older) **Characteristics** Age: 15 to 31 (median 18 years) Ambulant (GMFCS I to III): NR Non-ambulant (GMFCS IV or V): NR Degree of dystonia / spasticity: moderately severe spastic quadriparetic Prior treatment with baclofen pump: NR Adjunct medications: no oral spasmolytics Presence of scoliosis: NR **Inclusion criteria** Moderately severe spastic quadriplegic CP, who used spasticity to maintain erect	**Interventions** Patients treated for 6 days with one lumbar puncture and intrathecal or placebo injection each day. These were done in a paired randomised double blind manner days 1 & 2 : placebo or 25 micrograms baclofen (in a randomised order) days 3 & 4 : placebo or 50 micrograms baclofen (in a randomised order) days 5 & 6 : placebo or 100 micrograms baclofen (in a randomised order)	**Details** Physical therapists assessed upper and lower limb muscle tone before each injection (the baseline value) and at 2, 4, 6 and 8 hours post injection. Upper limb function was assessed before and at 4 hours after injection.	**Outcomes** Tone (follow up 8 hours) **Results** See forest plots in appendix E	**Limitations** Cochrane risk of bias Random sequence generation - low risk (coin toss) Allocation concealment - low risk Blinding of participants and personnel - low risk Blinding of outcome assessment - low risk Incomplete outcome data - low risk Selective reporting - low risk

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Source of funding Grant 5M01RR00084 from the NIH general clinical research center, Bethesda, MD.	posture but whose gait or other movements might improve if spasticity were alleviated. Not candidates for selective posterior rhizotomy. **Exclusion criteria** Not reported				Other sources of bias - not applicable Overall low risk **Other information**
Full citation Bertelli, J. A., Ghizoni, M. F., Rodrigues Frasson, T., Fernandes Borges, K. S., Brachial plexus dorsal rhizotomy in hemiplegic cerebral palsy, Hand Clinics, 19, 687-699, 2003 **Ref Id** 586436 **Country/ies where the study was carried out** Brazil **Study type** Before and after study **Aim of the study**	**Sample size** N=7 (aged 16 or more) **Characteristics** Age: 16 - 20 (Median 19 years) Ambulant (GMFCS I to III): NR Non-ambulant (GMFCS IV or V): NR Degree of dystonia / spasticity: Ashworth 3 or more Prior treatment with baclofen pump: NR Adjunct medications: NR Presence of scoliosis: NR **Inclusion criteria**	**Interventions** Brachial plexus dorsal rhizotomy	**Details** After general anaesthesia induction, the patient was placed prone with the head in a Mayfield pin head-holder. The spinous processes of C2 and C7 were marked and confirmed by fluoroscopy. A midline incision was made across the cervical region. A two- or three-level hemilaminectomy was performed. The yellow ligament was divided and the duramere was opened. The dorsal roots were identified and sectioned; major vessels always were preserved. The duramere was closed with a watertight seal and the yellow ligament sutured. The removed bone chips then were replaced. The muscle and fascial layers were reapproximated and the skin	**Outcomes** Gross motor function Tone (follow up 15 months) **Results** See forest plots in appendix E	**Limitations** EPOC Quality criteria for interrupted time series (ITS) Protection against secular changes - done Data were analysed appropriately - done Sample size calculation performed - not done Shape of the intervention effect was

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To evaluate the effect of brachial plexus dorsal rhizotomy on spasticity and functional use of the hand. **Study dates** 2000 - 2001 **Source of funding** Not reported	Age < 20, hemiplegic CP, with spasticity, capable of understanding instructions, one muscle scoring 3 or more on the Ashworth scale **Exclusion criteria** Not reported		was closed. No postoperative neck immobilization was used. Outcomes were assessed before surgery and at 3 and 15 months after surgery.		specified - not done Protection against detection bias: Intervention unlikely to affect data collection - done Protection against detection bias: Blinded assessment of primary outcome(s) - done **Other information**
Full citation Gerszten,P.C., Albright,A.L., Barry,M.J., Effect on ambulation of continuous intrathecal baclofen infusion, Pediatric Neurosurgery, 27, 40-44, 1997 **Ref Id**	**Sample size** N=24 (21 with CP, 3 with TBI) **Characteristics** Diagnosis: 21/24 CP, 3/24 traumatic brain injusry Age: mean 18 years (range 9 to 30 years)	**Interventions** Intrathecal baclofen pump, mean dose 200 micrograms per day (range 22 to 550 micrograms).	**Details** Pre and postoperative ambulatory status was assessed by a physiotherapist, orthopaedic surgeon or neurosurgeon. Mean postoperative follow-up was 52 months (range 12 to 93 months). Ambulatory status was classified in four levels as follows: community ambulators, household	**Outcomes** Walking Adverse events (mean follow-up 4.3 years) **Results** See forest plots in appendix E	**Limitations** EPOC Quality criteria for interrupted time series (ITS) Protection against secular changes - not clear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
58679 **Country/ies where the study was carried out** USA **Study type** Before-after study **Aim of the study** To asses the effect of intrathecal baclofen on ambulatory status in people with CP **Study dates** 1989 to 1995 **Source of funding** Not reported	Ambulant (GMFCS I to III): all were ambulatory to some extent Non-ambulant (GMFCS IV or V): NR Degree of dystonia / spasticity: moderate or severe Prior treatment with baclofen pump: Adjunct medications: Presence of scoliosis: **Inclusion criteria** Ambulatory to some extent Patients had shown response to a screening trial of intrathecal baclofen (lower extremity improvement of at least 1 on the Ashworth scale - a requirement for pump implantation) **Exclusion criteria** Not reported		ambulators, non-functional ambulators or non-ambulators.		Data were analysed appropriately - done Sample size calculation performed - not done Shape of the intervention effect was specified - not done Protection against detection bias: Intervention unlikely to affect data collection - done Protection against detection bias: Blinded assessment of primary outcome(s) - not clear **Other information**

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					Not applicable
Full citation Meythaler,J.M., Guin-Renfroe,S., Law,C., Grabb,P., Hadley,M.N., Continuously infused intrathecal baclofen over 12 months for spastic hypertonia in adolescents and adults with cerebral palsy, Archives of Physical Medicine & Rehabilitation, 82, 155-161, 2001 **Ref Id** 58767 **Country/ies where the study was carried out** USA **Study type** Before and after study **Aim of the study** To determine if the continuous intrathecal delivery of baclofen will control spastic hypertonia	**Sample size** N=13 **Characteristics** Age: mean 25 years (13 to 43 years) Ambulant (GMFCS I to III): NR Non-ambulant (GMFCS IV or V): NR Degree of dystonia / spasticity: intractable spastic hypertonia and quadriparesis Prior treatment with baclofen pump: NR Adjunct medications: NR Presence of scoliosis: 2 patients required surgery to correct scoliosis **Inclusion criteria** People with CP with intractable spastic hypertonia, aged over 13 years old. The spastic hypertonia functionally	**Interventions** Intrathecal baclofen pump, starting at a dose of 100 micrograms per day. By 12 months the mean dose was 263 micrograms per day (±91 micrograms; range 160 to 470 micrograms)	**Details** The following outcomes were measured at 1, 3, 6, 9 months, and 1-year post-pump placement; The Ashworth (rigidity) scale for tone in both the LEs and the UEs a 4-point scale reflecting the number of spontaneous sustained flexor and extensor muscle spasms per hour a 5-point scale documenting deep tendon reflexes was used at the biceps, patella, and Achilles the current 24-hour infused dosage complications including cognitive dysfunction, urologic problems, infections, problems regarding physical and occupational therapy, as well as equipment malfunction	**Outcomes** Tone Adverse events (follow up one year) **Results** See forest plots in appendix E	**Limitations** EPOC Quality criteria for interrupted time series (ITS) Protection against secular changes - done Data were analysed appropriately - done Sample size calculation performed - not done Shape of the intervention effect was specified - not clear Protection against detection bias: Intervention unlikely to affect

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caused by long-standing cerebral palsy (CP). **Study dates** Not reported **Source of funding** Funded in part by Medtronics, Inc (supplier of intrathecal baclofen pumps).	interfered with their ADLs, sleep, mobility, and positioning, or caused significant contractures or pain. All patients had failed to respond to oral antispasmodic treatment or had untoward side-effects. Patients were only implanted if they responded to a screening intrathecal baclofen injection (decrease of 2 points on the Ashworth scale or reduction in the number of spasms in the affected limbs, without untoward side effects) **Exclusion criteria**				data collection - done Protection against detection bias: Blinded assessment of primary outcome(s) - not clear **Other information** Not applicable
Full citation Motta,F., Antonello,C.E., Stignani,C., Intrathecal baclofen and motor function in cerebral palsy, Developmental Medicine and Child Neurology, 53, 443-448, 2011 **Ref Id** 133141	**Sample size** N=9 (aged 18 or older) **Characteristics** Age: mean age at implant 23.3 years Ambulant (GMFCS I to III): NR by age subgroup Non-ambulant (GMFCS IV or V): NR by age subgroup	**Interventions** Intrathecal baclofen pump	**Details** Patients were evaluated before pump implantation and 12 months after by the same team of rehabilitation therapists and orthopaedic physician	**Outcomes** Gross motor function (follow up one year) **Results** See forest plots in appendix E	**Limitations** EPOC Quality criteria for interrupted time series (ITS) Protection against secular changes - done Data were analysed

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Country/ies where the study was carried out Italy **Study type** Before and after study **Aim of the study** To measure the effect of intrathecal baclofen on motor function in people with CP **Study dates** 2003 to 2008 **Source of funding** Not reported	Degree of dystonia / spasticity: NR by age subgroup Prior treatment with baclofen pump: NR Adjunct medications: protocol implies no additional therapies Presence of scoliosis: NR **Inclusion criteria** Patients with CP who received ITB pump at a single institution **Exclusion criteria** People with learning disabilities that prevented evaluation with the Gross Motor Function Measure (GMFM). Those who underwent additional treatment (for example orthopaedic surgery or botox therapy) in the period 6 months before to 12 months after implantation. Those who did not attend follow-up visits.				appropriately - done Sample size calculation performed - not done Shape of the intervention effect was specified - not clear Protection against detection bias: Intervention unlikely to affect data collection - done Protection against detection bias: Blinded assessment of primary outcome(s) - not clear **Other information** Not applicable
Full citation	**Sample size**	**Interventions**	**Details**	**Outcomes**	**Limitations**

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Reynolds,M.R., Ray,W.Z., Strom,R.G., Blackburn,S.L., Lee,A., Park,T.S., Clinical outcomes after selective dorsal rhizotomy in an adult population, World Neurosurgery, 75, 138-144, 2011 **Ref Id** 132414 **Country/ies where the study was carried out** USA **Study type** Before and after study **Aim of the study** To evaluate the effectiveness of SDR for adults with CP related spastic diplegia. **Study dates** 1989 - 2007 **Source of funding** No commercial or financial relationships influenced the content of the article.	N=21 **Characteristics** Age: mean 26 years (range 18 to 39 years) Ambulant (GMFCS I to III): 21/21 - all had independent ambulation with or without an assistive device Non-ambulant (GMFCS IV or V): 0/21 Degree of dystonia / spasticity: Prior treatment with baclofen pump: Adjunct medications: Presence of scoliosis: **Inclusion criteria** Patients treated by a single surgeon (1989 - 2007) who had cerebral palsy-related spastic diplegia, with independent ambulation with or without an assistive device, and relatively mild orthopedic deformities. All had disabilities which were an obstacle toward achieving an acceptable quality of life. A subjective assessment was	Selective dorsal rhizotomy	The T12-L1 level was verified by plain radiographs of the thoracolumbar junction. After a single-level laminectomy, the conus medullaris was localized under ultrasonographic guidance before dural opening. The operating microscope was then used to separate the dorsal nerve roots from the ventral roots. After identification of the L2-S2 dorsal roots, electromyographic testing was performed to ensure that no ventral roots were included. Electromyographic studies were used to examine the innervation pattern of individual roots. Subsequently, each root was subdivided into three to five rootlets, which were tested in a stepwise fashion and graded for reflex threshold. Rootlets that produced excessive responses were cut. At least 25% to 33% of the rootlets were preserved at each level to avoid a postoperative sensory deficit. Patients were evaluated preoperatively several days before surgery and postoperatively at 4 months. Most patients (11/21) participated in longer periods of postoperative follow-up (mean, 17.6 ± 30.2 months; range, 4-138	Walking Gross motor function Tone Health related quality of life Pain (follow up 4 months – for objective physical assessment; mean 5 years for function self-assessment) **Results** See forest plots in appendix E	EPOC Quality criteria for interrupted time series (ITS) Protection against secular changes - done Data were analysed appropriately - done Sample size calculation performed - not done Shape of the intervention effect was specified - not clear Protection against detection bias: Intervention unlikely to affect data collection - done Protection against detection bias:

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	performed for those patients exhibiting the highest potential for functional gain after SDR and motivation to perform a home exercise program **Exclusion criteria** Not reported.		months). Assessments included baseline ambulatory status, joint ROM, GMFM, degree of spasticity, and adequate conservative therapy. Studies of joint ROM were performed with the use of a 360-degree goniometer . Muscle tone was quantified by use of the modified Ashworth scale. Each patient completed a telephone survey of subjective pre- and postoperative function. All surveys were conducted during the month of July 2007 (62.3 ± 37.4 months after SDR surgery; range, 9-132 months after SDR surgery). The survey consisted of 48 questions, including “pre-operative chief complaint” and “functional status following surgery” (improved, no change, or worse). Assist devices required for ambulation were also assessed pre- and postoperatively. Patients were instructed to estimate the time required to walk 10 feet before and after SDR surgery. Patients were asked to rate the following on a scale of 0 to 10 preoperatively versus postoperatively: ambulatory ability, spasticity, coordination, joint ROM,		Blinded assessment of primary outcome(s) - not clear **Other information** Not applicable

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
			pain, overall quality of life, and independence. Each patient was evaluated with the Katz and Lawton ADL scales		
Full citation Tasseel Ponche, S., Ferrapie, A. L., Chenet, A., Menei, P., Gambart, G., Menegalli Bogeli, D., Perrouin Verbe, B., Gay, S., Richard, I., Intrathecal baclofen in cerebral palsy. A retrospective study of 25 wheelchair-assisted adults, Annals of Physical & Rehabilitation Medicine, 53, 483-98, 2010 **Ref Id** 343952 **Country/ies where the study was carried out** France **Study type** Before and after study **Aim of the study**	**Sample size** N=25 **Characteristics** Age: Mean 29.6 years (±12.66) Ambulant (GMFCS I to III): 6 independent with wheelchair Non-ambulant (GMFCS IV or V): 19 third party dependent with wheelchair Degree of dystonia / spasticity: bilateral spastic CP (N=21), choreo-athetotic CP (N=4). Prior treatment with baclofen pump: Adjunct medications: Presence of scoliosis: **Inclusion criteria**	**Interventions** Intrathecal baclofen pumps. Mean daily dose was 128 micrograms (±97 micrograms) in the first year rising to 401 micrograms in the 5th year.	**Details** All implanted pumps were programmable models, except for one with continuous flow. Most were Medtronic SynchroMed II devices (16) After pump implantation, dose was adjusted and outcomes were recorded at 1, 3, 6 and 9 months post-surgery and then every year after that. Efficacy was measured subjectively using questionnaires	**Outcomes** Tone Adverse events (follow up – up to 5 years) **Results** See forest plots in appendix E	**Limitations** EPOC Quality criteria for interrupted time series (ITS) Protection against secular changes - not clear Data were analysed appropriately - done Sample size calculation performed - not done Shape of the intervention effect was specified - not clear

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
To measure the effectiveness and safety of intrathecal baclofen therapy in wheelchair-dependent adults with cerebral palsy. **Study dates** 1999 - 2009 **Source of funding** Not reported. Authors insist there were no conflicts of interest.	Functional impairment caused by treatment-refractory, generalized spasticity and a modified Ashworth score greater or equal to 3. Patients were selected for implanted pumps using a trial bolus intrathecal injection of baclofen with the aim of decreasing Ashworth score by 1 unit. **Exclusion criteria** Not reported				Protection against detection bias: Intervention unlikely to affect data collection - done Protection against detection bias: Blinded assessment of primary outcome(s) - not clear **Other information** Not applicable
Full citation Van Schaeybroeck, P., Nuttin, B., Lagae, L., Schrijvers, E., Borghgraef, C., Feys, P., Intrathecal baclofen for intractable cerebral spasticity: a prospective placebo-controlled, double-blind study, Neurosurgery, 46, 603-9; discussion 609-12, 2000	**Sample size** N=11, for screening study. N=8 were implanted with baclofen pumps **Characteristics** Diagnosis: 9/11 CP, 1 stroke, 1 craniocerebral trauma Age: 8 to 55 years (median 22 years)	**Interventions** Bolus intrathecal baclofen injection via lumbar puncture. Continuous baclofen infusion via implanted pump.	**Details** Screening trial (N=11) was done to select candidates for implanted baclofen pump. A lumbar puncture was done once daily and injections of 25, 50, 75 or 100 micrograms baclofen or saline were given in random order & double blinded starting with 25, 50 of baclofen or saline. Spasticity of a range of muscle groups was measured before the injection and at 2, 4 and 6 hours.	**Outcomes** Tone Adverse events (follow up 1 year) **Results** See forest plots in appendix E	**Limitations** Cochrane risk of bias Random sequence generation - unclear risk Allocation concealment - unclear risk

Study details	Participants	Interventions	Methods	Outcomes and Results	Comments
Ref Id 339237 **Country/ies where the study was carried out** Belgium **Study type** Randomised cross-over study **Aim of the study** To measure the effectiveness of intrathecal bolus injections and continuous administration of baclofen. To compare spasticity scores with functional evaluations in different muscle groups. **Study dates** Not reported **Source of funding** Not reported	Ambulant (GMFCS I to III): Non-ambulant (GMFCS IV or V): Degree of dystonia / spasticity: Prior treatment with baclofen pump: Adjunct medications: Presence of scoliosis: **Inclusion criteria** Spasticity of cerebral origin. Those with severe quadriparesis as well as those with relatively good motor function were included All had received multiple oral antispasmodics in high doses - which proved ineffective or had intolerable side effects. **Exclusion criteria** Child bearing potential, pregnancy and renal or hepatic dysfunction. Those who did not respond to the baclofen screening trial (N=3) did not have pumps implanted.		8 patients then had an implanted SynchroMed infusion system programmable pump (Medtronic Inc., MN). The tip of the catheter was placed at the 10th thoracic vertebra, using fluroscopy, with the pumps in a hypochodriac subcutaneous pocket. The minimal effective bolus injection dose was doubled to calculate the starting chronic infusion dose and adpated in the days after implantation (range 50 micrograms to 200 micrograms per day). During the first year of follow-up each patient was subjected to a blinded dose reduction test (where the continuous baclofen infusion was reduced to the lowest possible rate - 25 or 50 micrograms per day)		Blinding of participants and personnel - low risk Blinding of outcome assessment - low risk Incomplete outcome data - low risk Selective reporting - low risk Other sources of bias - not applicable Overall unclear risk **Other information** Not applicable

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