NICE National Institute for Health and Care Excellence

Surveillance report 2016 – Spasticity in under 19s: management (2012) NICE guideline CG145

Surveillance report

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Contents

Surveillance decision

We will not update the guideline at this time.

Reason for the decision

We found 52 studies through surveillance of this guideline.

This included new evidence on:

- principles of care
- physical therapy (physiotherapy and/or occupational therapy)
- orthoses
- oral drugs
- botulinum toxin type A
- intrathecal baclofen
- orthopaedic surgery
- selective dorsal rhizotomy.

None of the new evidence considered in surveillance of this guideline was thought to have an effect on current recommendations.

Other clinical areas

We also found new evidence in areas not covered by the original guideline that was not thought to have an effect on current recommendations. This evidence related to:

- magnetic stimulation, electrical stimulation, vibration training and shock wave therapy
- umbilical cord blood cell therapy
- scoliosis and kyphosis.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the new evidence and views of topic experts, we decided that this guideline should not be updated.

See how we made the decision for further information.

Commentary on selected new evidence

With advice from topic experts we selected 2 studies for further commentary.

Selective dorsal rhizotomy – predictors of benefit

We selected the prospective cohort study by Funk et al. (2015) for a full commentary because the study was highlighted as important by topic expert feedback. Selective dorsal rhizotomy is an irreversible procedure, and predicting which children might benefit would be useful.

What the guideline recommends

NICE's guideline on spasticity in under 19s recommends considering selective dorsal rhizotomy to improve walking ability in children and young people with spasticity at Gross Motor Function Classification System (GMFCS) level II or III. It also adopts the recommendation from NICE's interventional procedure guidance on selective dorsal rhizotomy for spasticity in cerebral palsy that patient selection and treatment should be carried out by a multidisciplinary team with specialist training and expertise in the care of spasticity. However, NICE's guideline on spasticity in under 19s does not currently make any recommendations specifically related to suitability of patients based on preoperative factors such as age or motor function.

Methods

The prospective cohort study (n=54) by Funk et al. (2015) assessed whether preoperative age, BMI, strength, spasticity and motor function can determine functional outcome of selective dorsal rhizotomy in children (mean age 6.9 years). Children (GMFCS level I or II) who could perform a complete Gross Motor Function Measure (GMFM)-88 assessment were recruited from a cerebral palsy clinic at a German paediatric centre.

Approved inclusion criteria (Peacock and Staudt 1991) for the surgery were applied. The authors noted the main prerequisites were a predominantly spastic bilateral subtype of cerebral palsy, some ambulatory ability, good cognitive function, interest in activity and locomotion, no musculoskeletal deformities or contractures, and no prior multilevel surgery. A single neurosurgeon performed all rhizotomies. At least 3 weeks of inpatient rehabilitation began on the first day after surgery, focussing on locomotive training after the first postoperative week.

Data were collected before surgery and at 12 and 24 months. Standardised assessment of outcomes was conducted by the same team of physicians and therapists. Evaluators performed examinations before consulting the chart for previous information to minimise bias. Possible

predictors of functional outcome were correlated against a clinically significant improvement in GMFM of 4% or more. Analysis was done on anonymised data by investigators not involved with clinical examination.

Results

A significant decrease in spasticity (Modified Ashworth scale) of hip adductors and hamstrings was seen at 12 months ($p<0.001$) and sustained at 2 years. Motor function (GMFM-88) had significantly increased from 79% to 84% ($p<0.001$) at 12 months (stated to be clinically significant by the authors) and increased by a further 2% at 24 months ($p=0.002$). Functional improvement was even more pronounced in subdomains D (standing) and E (walking, running and jumping) of the GMFM, with the score for both dimensions significantly increasing from 60% at baseline to 74% at 2 years ($p<0.001$).

Muscle strength (maximal force function test) at 12 months improved significantly for knee extension ($p=0.008$) and ankle dorsiflexion ($p=0.006$), but was unchanged for hip extensors, abductors and ankle plantar flexors. No muscle groups decreased in strength, and no complications of surgery were seen (urinary tract function or skin sensitivity).

At both 12 and 24 months after surgery, improvement in GMFM correlated moderately with age. Namely children achieving a clinically significant improvement in GMFM of >4% were significantly younger (mean age 5.6 years) than children with an improvement in GMFM of ≤4% (mean age 8.4 years; $p=0.004$). A similarly positive correlation with gain in GMFM was seen with baseline GMFM. Namely children achieving an improvement in GMFM of >4% had a lower mean initial GMFM (73%) than children with an improvement in GMFM of ≤4% (mean initial GMFM 87%; $p<0.001$). Conversely, improvement in GMFM correlated weakly with BMI, preoperative dorsiflexor and plantarflexor strength, reduction in spasticity of the hamstrings, and preoperative spasticity of adductors and hamstrings. The authors concluded that children who may benefit most from selective dorsal rhizotomy are 4–7 years old with a preoperative GMFM of 65–85%.

Strengths and limitations

Strengths

- Factors that could influence success of surgery were measured against a clinically significant improvement in GMFM. Topic experts noted this would be useful to help parents decide what surgery means for their child.

- Topic experts further noted that correlating functional improvements with degree of spasticity reduction (which was found to be low) encourages consideration of what other factors determine strength, contracture and function.

Limitations

- Without a control group, the improvements seen cannot definitively be attributed to surgery, particularly in children of GMFCS level I or II who the topic experts noted could expect further motor progress along cerebral palsy development centiles.
- The study population of GMFCS I or II is also not fully relevant to NICE's guideline on spasticity in under 19s, which recommends considering selective dorsal rhizotomy in children with a greater level of disability (GMFCS level II or III). Nor are results fully transferable to the NICE research recommendation 'Does selective dorsal rhizotomy followed by intensive rehabilitation performed between the ages of 3 and 9 years in children who are at GMFCS level II or III result in good community mobility as a young adult?'.
- Topic experts noted there is no evidence specifically for ambulation so no comment about endurance or capacity can be made.
- The actual amount of rehabilitation received by patients was not reported or factored into analyses, which could bias findings.
- Follow-up was 2 years, therefore longer-term outcomes were not assessed.
- Outcome assessors were not blinded to the intervention.
- Only 54 patients were included in the study.

Impact on guideline

The study found that after selective dorsal rhizotomy, spasticity decreased while function (particularly, standing, walking, running and jumping) increased, with no accompanying loss of strength. Although the study population is not directly transferable to the guideline, and follow-up was short, this evidence provides indirect support to the recommendation to consider selective dorsal rhizotomy to improve walking ability in children and young people with spasticity at GMFCS level II or III. The evidence also suggests that this type of surgery could have benefits for standing, walking, running and jumping, which topic experts noted goes beyond the wording in the guideline that discusses only improvement in walking ability as a consideration.

In terms of the correlation data, the study found that most functional gain after surgery was seen in younger children of around 6 years and those with a lower baseline GMFM of around 70%. This could help to refine factors for patient selection, the guidance on which currently notes only that it should be carried out by a multidisciplinary team with specialist training and expertise in the care of spasticity.

Additionally, the topic experts agreed that an important finding was the lack of correlation between reduction in spasticity and functional improvement. They stated that evidence refuting spasticity as the main reason children do not progress could encourage researchers to look more holistically at the upper motor neurone lesion, and to consider other factors – not simply reduction in spasticity. They pointed out that this reinforces the need for the NICE research recommendation 'What are the greatest inhibitors of functional ability in children and young people with upper motor neurone lesions?'.

Although this evidence may suggest potential modifications to current guidance are needed, it should be noted that there is an ongoing NHS England Commissioning through evaluation of selective dorsal rhizotomy. This process enables the formal collection and evaluation of clinical and patient experience data in a limited number of patients for treatments that are not funded by the NHS, but show significant promise for the future. Any changes to NICE's recommendations on selective dorsal rhizotomy would ideally be informed by the outcome of this process, which is unlikely to be published until 2017/18. Therefore no impact on the guideline is currently expected at this time. The progress of the 'commissioning through evaluation' process will be monitored and its impact on the guideline will be considered in full when results are available.

Selective dorsal rhizotomy – long-term outcomes

We selected the prospective cohort study by Tedroff et al. (2015) for a full commentary because the study was highlighted as important by topic expert feedback. It could help answer questions about long-term effects of selective dorsal rhizotomy on mobility in children with bilateral spastic cerebral palsy.

What the guideline recommends

NICE's guideline on spasticity in under 19s recommends considering selective dorsal rhizotomy to improve walking ability in children and young people with spasticity at GMFCS level II or III. It further recommends discussing the irreversibility of the treatment, the known complications and the uncertainties over long-term outcomes with children and young people, and their parents and/or carers.

Methods

The prospective cohort study (n=18, median age 22 years) by Tedroff et al. (2015) investigated long-term outcomes 15–19 years after selective dorsal rhizotomy in children (mean age at surgery 4.6 years) with bilateral spastic cerebral palsy. Inclusion criteria for the original surgery were reported in an earlier follow-up study of the same cohort by Tedroff et al. (2011) and comprised: age 2–9 years; significant spasticity in the lower extremities with a slow increase or plateau in gross motor development within 6 months, or subluxation or luxation of the hips; normal or mildly impaired cognitive development; and some method of independent locomotion. Exclusion criteria were: major rigidity, dyskinesia, dystonia, ataxia, or hypotonia; marked weakness in antigravity muscles; fixed joint contractures; or previous surgery for tendon lengthening or neurectomy.

All rhizotomy was performed by the same neurosurgeon. Participants were confined to bed for 5 days after surgery but physiotherapy started after 3 days comprising daily sessions for 2 weeks, twice-weekly intensive physiotherapy for 6 weeks, and finally 1 weekly session for 6 months. For 10 years after the original surgery, the cohort was prospectively assessed by the same research team. In 2011, 15–19 years after the original surgery, all participants were invited to an additional follow-up. The assessments were made by the same team following the patients since their original surgery.

GMFCS at baseline was not recorded. At the time of the present evaluation, GMFCS levels of participants were: level I=3; level II=5; level III=3; level IV=6; and level V=1. All individuals used wheelchairs, 8 used insoles or orthoses, and 4 used assistive walking or standing devices. During the period after selective dorsal rhizotomy, 89% of individuals had undergone various orthopaedic surgeries (mean 3.6 procedures per person) and 50% had used botulinum toxin A. Three individuals took anti-epileptic drugs and 2 regularly used analgesics.

Results

After a median of 17 years, the reduced spasticity (Modified Ashworth scale) in the lower extremities first recorded at 3-year follow-up was sustained, and no participants used any form of oral spasticity medication. Motor function (GMFM-88) after 17 years was not significantly different to baseline. The best functional capacity was seen at 3-year follow-up (median change in GMFM=25, p=0.001) followed by a gradual decline after 10 years (median change 3–10 years=−13, p=0.022) and 17 years (median change 10–17 years=−4, p=0.005). Median physical activity score was 2 (low activity): 7 individuals were classified as inactive, 7 as having low physical activity and 4 as physically active.

For health-related quality of life (SF-36v2), the physical component score was 42 (slightly lower than a norm sample; significance of difference not reported), and the mental health component score was 52 (slightly higher than a norm sample; significance of difference not reported). For pain, 9 out of 18 participants reported pain with the Brief Pain Inventory, though both pain interference and pain severity score (1.3 and 1.4 respectively) were low (for reference, the authors stated a score of 1–4 is considered 'mild' in oncology patients). For the Bodily Pain domain of SF-36v2, the normalised base score of 49 was well within the normalised reference.

The study also assessed aspects of the participants' lifestyles. Fifteen lived with parents and 3 lived independently (1 with support). Eight needed no assistance with personal care. All were single, but 6 had had a relationship and 1 was a single mother. Ten participants were studying, 3 had completed university and 8 were employed.

Strengths and limitations

Strengths

- Topic experts noted that the existence of such a long-term study demonstrates that follow-up after selective dorsal rhizotomy into young adult life (after full skeletal maturity) is possible.
- Experts also noted the study attempted to assess a wide variety of outcomes as well as spasticity (participation, quality of life, independence, pain, and function) that are important in examining the impact of this surgery, and that were considered to be key outcome priorities during development of the original guideline.
- The study included participants across the spectrum of GMFCS levels (although baseline scores were not reported).

Limitations

- Only 18 patients were included in the study, therefore the number of people at each of the 5 levels of GMFCS was very small. Topic experts stated that this meant the evidence for functional change was less reliable.
- There was no control group, therefore any improvements seen cannot definitively be attributed to surgery.
- Since selective dorsal rhizotomy, most individuals had undergone more than 1 orthopaedic surgery, half had used botulinum toxin A, and participants' use of medications for pain and other conditions varied. This may have introduced bias into the findings.

Impact on guideline

The study found that reduced spasticity following selective dorsal rhizotomy as a young child appears to be sustained into adulthood, but initial improvements in function do not seem to continue in the long term, nor are contractures prevented. However, outcomes for independence, quality of life and particularly pain appear to be relatively good. The results should be considered alongside the limitations of the study, notably the small size and lack of control group.

Topic experts stated that pain is consistently reported as affecting quality of life by young people with spasticity and cerebral palsy, and a positive effect on pain control in the long term may be as important a reason to use selective dorsal rhizotomy as increase in function. Within its limitations, the evidence goes towards answering the NICE research recommendation 'Does selective dorsal rhizotomy followed by intensive rehabilitation performed between the ages of 3 and 9 years in children who are at GMFCS level II or III result in good community mobility as a young adult?'. However, it also provides evidence of additional outcomes such as pain reduction that may be of equal importance when considering the procedure.

Although this evidence may suggest potential modifications to current guidance are needed, it should be noted that there is an ongoing NHS England Commissioning through evaluation of selective dorsal rhizotomy. Any changes to NICE's recommendations on selective dorsal rhizotomy would ideally be informed by the outcome of this process, which is unlikely to be published until 2017/18. Therefore no impact on the guideline is currently expected at this time. The progress of the 'Commissioning through evaluation' process will be monitored and its impact on the guideline will be considered in full when results are available.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 4 years after the publication of spasticity in under 19s (2012) NICE guideline CG145.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual'.

Previous surveillance update decisions for the guideline are on our website.

New evidence

We found 38 new studies in a search for systematic reviews and randomised controlled trials published between 1 July 2014 and 16 May 2016. We also considered 7 additional studies identified by members of the guideline committee who originally worked on this guideline.

Evidence identified in previous surveillance 2 years after publication of the guideline was also considered. This included 7 studies identified by search.

From all sources, 52 studies were considered to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: summary of new evidence from surveillance and references for all new evidence considered.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline and other correspondence we have received since the publication of the guideline.

Views of stakeholders

Stakeholders commented on the decision not to update the guideline. Overall, 5 stakeholders commented. See appendix B for stakeholders' comments and our responses.

Five stakeholders commented on the proposal to not update the guideline: 2 agreed with the decision and 3 disagreed with the decision.

One stakeholder suggested updating several review questions, including those relating to motor interventions, anti-spasticity treatments, hip screening, therapy approaches, and impact of treatments for motor disorders on functional outcomes. However, surveillance includes all new evidence relevant to the scope and no evidence to suggest these questions should be updated was identified.

Extensions to the scope were suggested by 2 stakeholders; however, no evidence to suggest the scope should be extended was identified. The proposed areas to be added to the scope were:

- Scoliosis:
    - Surveillance found limited evidence in this area, and scoliosis can be caused by conditions other than spasticity. NICE's guideline on spasticity in under 19s may not therefore be the most appropriate place for guidance on scoliosis.
- Pure dystonia:
    - Surveillance found no evidence in this area, and dystonias are not limited to people with spasticity. NICE's guideline on spasticity in under 19s may not therefore be the most appropriate place for guidance on pure dystonia.
- 19–25 year olds:
    - Surveillance found no evidence to support extending the scope in this area, and increasing the age limit of the guideline introduces some questions about managing long-term aspects of spasticity. Currently it is not clear how much evidence is available on this to inform recommendations. Managing spasticity in people aged 19 and over with cerebral palsy will be considered for inclusion in the forthcoming NICE guideline on cerebral palsy in adults.

No new ongoing or published studies were identified by the stakeholders to support views that the guideline should be updated or that the scope should be extended.

See ensuring that published guidelines are current and accurate in 'Developing NICE guidelines: the manual' for more details on our consultation processes.

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