Long-term effects of spasticity treatment, including selective dorsal rhizotomy, for individuals with cerebral palsy

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ABBREVIATION
SDR Selective dorsal rhizotomy

AIM To understand the long-term effects of comprehensive spasticity treatment, including selective dorsal rhizotomy (SDR), on individuals with spastic cerebral palsy.
METHOD This was a pre-registered, multicenter, retrospectively matched cohort study. Children were matched on age range and spasticity at baseline. Children at one center underwent spasticity treatment including SDR (Yes-SDR, *n*=35) and antispastic injections. Children at two other centers had no SDR (No-SDR, *n*=40 total) and limited antispastic injections. All underwent subsequent orthopedic treatment. Participants returned for comprehensive long-term assessment (age ≥21y, follow-up ≥10y). Assessment included spasticity, contracture, bony alignment, strength, gait, walking energy, function, pain, stiffness, participation, and quality of life.
RESULTS Spasticity was effectively reduced at long-term assessment in the Yes-SDR group and was unchanged in the No-SDR group. There were no meaningful differences between the groups in any measure except the Gait Deviation Index (Yes-SDR + 11 vs No-SDR + 5) and walking speed (Yes-SDR unchanged, No-SDR declined 25%). The Yes-SDR group underwent more subsequent orthopedic surgery (11.9 vs 9.7 per individual) and antispastic injections to the lower limbs (14.4 vs <3, by design).
INTERPRETATION Untreated spasticity does not cause meaningful impairments in young adulthood at the level of pathophysiology, function, or quality of life.

The aim of this study was to understand the long-term effects of spasticity on individuals with spastic cerebral palsy (CP), the most common subtype of CP. It is commonly believed that spasticity leads to deformity, impedes movement, increases energy consumption, and causes pain, resulting in impaired function, reduced participation, and a lower quality of and satisfaction with life. While there is a plausible physiological basis for these beliefs, the evidence to support them is inconclusive. It is true that children with high levels of spasticity present with marked gait deviations, high energy consumption, joint contractures, and low function. However, high levels of spasticity are often accompanied by poor motor control, weakness, and other comorbidities associated with more severe CP. From a causal perspective, it is unclear which deficit is to blame.

Spasticity is not part of typical development and so it is frequently treated. Common treatments for spasticity are selective dorsal rhizotomy (SDR) and botulinum neurotoxin A (BoNT-A) injections.[1,2] The effect of SDR on clinical measures of spasticity appears to be large and permanent. However, there is a lack of strong evidence related to other SDR outcomes. There have been three randomized controlled trials examining SDR short-term outcomes compared to physical therapy alone. These showed a large effect on spasticity and mixed effects on function and other measures.[3–5] However, the clinical relevance of these studies is limited since it is uncommon for children with CP to undergo physical therapy as a sole treatment. Many studies had no control group[6–10] or an inappropriate control group (e.g. poorly matched or typically developing).[11–13] Some authors have compared SDR to orthopedic care with non-randomized designs and small sample sizes.[13,14] A recent systematic review pointed to the urgent need for prospective long-term studies.[15]

Several of the current study authors recently conducted a pilot study on the long-term outcome of SDR.[16] The results suggested a minimal impact of SDR on gait, energy consumption, and function. However, the study was small

and individuals in the control group received multiple antispastic injections, and several had intrathecal baclofen pumps implanted. Therefore, the effects of spasticity were not well isolated. Furthermore, the control cohort consisted of patients drawn from a center with an active spasticity treatment philosophy, raising concerns about possible bias.

What this paper adds

- Untreated spasticity does not cause meaningful long-term impairments in young people with cerebral palsy (CP).
- No evidence of an age-related decrease in spasticity in CP as has been reported.
- Spasticity reduction does not impact strength.

METHOD

This was a pre-registered study. Methodological details and specific hypotheses can be found in the accompanying protocol paper.[17] Our primary hypotheses centered on the premise that untreated spasticity would lead to inferior long-term outcomes across multiple domains compared to early aggressive spasticity reduction.

Study design

This study was approved by the University of Minnesota and Western institutional review boards. Written, informed consent was obtained before study participation. Participant recruitment and evaluation took place between 2018 and 2020.

We examined individuals from three centers divided into two groups based on spasticity treatment. The individuals were identified from medical records and matched retrospectively on diagnosis, age range, and lower limb spasticity during a standard-of-care evaluation (baseline time point). Individuals returned for a single follow-up research evaluation in young adulthood (long-term time point). Between the baseline and long-term time points, one group underwent comprehensive spasticity reduction treatment including SDR (Yes-SDR group; Gillette Children's Specialty Healthcare, St. Paul, MN, USA). Individuals in the Yes-SDR group may have also received antispastic injections and baclofen. The other group did not have SDR (No-SDR group; Shriners Hospitals for Children, Salt Lake City, UT, USA and Shriners Hospitals for Children, Spokane, WA, USA). Individuals were excluded from the No-SDR group if they had a lifetime history of more than three BoNT-A injections or underwent baclofen therapy (oral or intrathecal) for more than 1 year. The restriction on BoNT-A injections did not apply to the Yes-SDR group. We use 'Yes-SDR' and 'No-SDR' as shorthand for these groups to highlight a critical, though not exclusive, difference in treatment. The Yes-SDR center has a history of active and aggressive spasticity reduction treatment, while the No-SDR centers have a distinctly less aggressive spasticity treatment philosophy.

The groups were retrospectively matched on overall lower limb spasticity: 60% severe, 30% moderate, and 10% mild. These ratios are based on the historical distribution of spasticity in children undergoing SDR at the Yes-SDR center.[17] Individuals in the No-SDR group were further selected so that their age at baseline visit was between 3 years 6 months and 10 years 6 months, which is the 10th to 90th centile of the baseline age for the Yes-SDR group. Individuals were randomly contacted from the pool of eligible participants meeting study criteria (Fig. S1, online supporting information). Participants returned to their respective baseline center for a single follow-up research evaluation.

We measured outcomes across a wide range of domains spanning body structures, mobility, function, pain, and quality of life.

Spasticity was quantified as mild, moderate, or severe using an overall lower limb spasticity score across plantarflexors, hip adductors, hamstrings, and rectus femoris.[17] Subsequent treatments after SDR (Yes-SDR) or after baseline (No-SDR) were counted. Individual orthopedic procedures, excluding instrumentation removal and antispastic injections (BoNT-A or phenol) were each counted separately. It is common for multiple procedures to occur during a single surgery and for multiple injections to occur during a single session.

Three-dimensional gait kinematics were measured at baseline and long-term evaluation using three to five barefoot walking trials, collected at self-selected speed. Each motion analysis laboratory used modern gait analysis equipment and methodology, employed highly experienced staff, and were accredited by the Commission for Motion Laboratory Accreditation.[18] The Gait Deviation Index, which measures overall deviations in gait compared to typical development, was calculated from individual trials and averaged.[19]

Net walking energy consumption was assessed during a 6-minute walk test with a cardiorespiratory diagnostic system using a uniform protocol and data processing.[20]

Contracture, bony torsion, and strength were assessed during a clinical examination performed by a licensed physical therapist at the baseline and long-term assessments.

Function was assessed by a physical therapist using the Gross Motor Function Measure dimensions (GMFM) D (standing) and E (walking, running, and jumping) and the Gross Motor Function Classification System (GMFCS).[21]Patient-reported function was measured via the Functional Mobility Scale (FMS).[22]

Participation was measured using a questionnaire assessing community enfranchisement measures of importance of and control over participation.[23]

Quality of life was assessed using the Abbreviated World Health Organization Quality of Life assessment and the Satisfaction with Life Scale.[24,25]

Pain, discomfort, and stiffness associated with spasticity were assessed using two domains of the Multiple Sclerosis Spasticity Scale.[26] The Multiple Sclerosis Spasticity Scale is a National Institute of Neurological Disorders and Stroke common data element.

Statistical analysis

All analyses were performed in R software, version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria). Graded strength measures were truncated ('+' and '–' dropped) and an overall strength score was computed, using polychoric principal component analysis, as a weighted average of bilateral plantarflexor, knee extensor, and hip extensor strength.[27] Missing data were excluded on a pairwise basis.

In accordance with guidance of the American Statistical Association, we present the results with an emphasis on the magnitude and direction of changes, consistency across individuals, and clinical interpretation of the data.[28] We use a slightly conservative critical type I error rate of α=0.01, without additional adjustments for multiple comparisons and non-parametric Wilcoxon signed-rank (paired) or Mann–Whitney *U* (unpaired) tests for scale variables. Categorical survey response and GMFCS level data were assessed using Fisher's exact test. Individual surgical procedure counts were modeled using a Poisson generalized linear model.

RESULTS

Results are presented as mean [2.5, 97.5 centiles] unless otherwise noted.

Matching

The groups were well matched at baseline on many important clinical variables (Table 1). Screening for SDR is the primary reason to collect gait data on children younger than 5 years old resulting in a slightly younger Yes-SDR group. Time from baseline evaluation to SDR was 6.5 [0.4, 13.2] months. At long-term assessment, the groups were the same age in years (Yes-SDR 26 [22, 30] vs No-SDR 26 [22, 32], p=0.47).

Spasticity reduction

At long-term assessment, 100% of participants in the Yes-SDR group were in the mild spasticity category, while the distribution of spasticity in the No-SDR group was essentially unchanged (65% severe, 25% moderate, 10% mild spasticity).

Prior and subsequent treatment

Rates of prior orthopedic treatment were low and matched between groups (Fig. 1). Every participant in the Yes-SDR group and 93% of participants in the No-SDR group underwent subsequent orthopedic surgery between the baseline and long-term evaluations. The rate of subsequent orthopedic surgery in the Yes-SDR group was 11.9 [10.9, 13.1] procedures per participant compared to 9.7 [7.7, 12.2] in the No-SDR group. Bone surgery was much more common in the Yes-SDR group (Yes-SDR 6.1 [3.8, 9.7] vs No-SDR 2.1 [1.7, 2.6]), while soft-tissue surgery was slightly less common (Yes-SDR 5.9 [4.4, 7.9] vs No-SDR 7.6 [6.8, 8.5]). There was a distinct difference in soft-issue surgery rates between the two No-SDR centers. As a result, soft-tissue surgery rates were matched between the Yes-SDR group and one of the No-SDR centers (Yes-SDR 5.9 [4.4, 7.9] vs No-SDR-Center-1 5.9 [4.1, 8.5] vs No-SDR-Center-2 9.3 [6.7, 13.0]). Bone surgery did not differ between the two No-SDR centers. Surgery rates for individual procedures can be found in (Fig. S1). Participants in the Yes-SDR group received an average of 14.4 antispastic injections in the lower limbs post-SDR, while participants in the No-SDR group received no more than three injections as part of participant selection criteria.

Table 1: Descriptive patient characteristics at baseline

	SDR	No-SDR	SMD	*p*
n	35	40		
Sex, % male	51	43		0.49
Age (y:mo)	5:5 (1:5)	7:4 (1:10)	1.22	<0.01
Height (cm)	105.0 (10.6)	118.0 (13.3)	1.s08	<0.01
Weight (kg)	18.1 (5.8)	23.3 (9.6)	0.66	0.01
Spasticity level (%)				
Severe	51	60		0.69
Moderate	40	30		
Mild	9	10		
Passive ankle dorsiflexion [°]	0.1 (11.1)	5.0 (11.3)	0.44	0.07
Popliteal angle [°]	49.9 (16.1)	48.5 (14.3)	0.09	0.51
Passive knee extension [°]	–0.4 (5.4)	1.0 (7.1)	0.22	0.74
Passive hip extension [°]	5.0 (6.3)	5.3 (5.9)	0.05	0.86
Passive hip internal rotation [°]	64.4 (12.6)	68.4 (14.0)	0.30	0.23
Bimalleolar axis angle [°]	12.0 (10.0)	12.8 (13.1)	0.07	0.62
Gait Deviation Index (dimensionless)	65.0 (8.1)	66.0 (11.2)	0.11	0.65
Speed (dimensionless)	0.31 (0.13)	0.37 (0.12)	0.42	0.07
Net walking energy (dimensionless)	2.3 (0.9)	2.2 (0.6)	0.14	0.63

Values presented as mean (SD). SDR, selective dorsal rhizotomy; SMD, standardized mean difference. Passive ankle dorsiflexion: positive = dorsiflexion; passive knee extension: positive = flexion; passive hip extension: positive = flexion.

Contracture and bony torsion

Levels of contracture at the ankle, knee, hamstrings, and hip did not differ meaningfully between the treatment groups (Fig. 2). Ankle dorsiflexion and knee flexion contractures remained constant from the baseline to long-term assessments, popliteal angle worsened slightly (Yes-SDR 6.5°, No-SDR 10.4°), and hip flexion contractures improved slightly (SDR −3.9°, No-SDR −2.9°).

Bony torsion at the femur and tibia did not differ meaningfully between the treatment groups (Fig. 2). Passive internal hip rotation improved markedly (Yes-SDR −23°, No-SDR −22°), while the bimalleolar axis angle remained essentially unchanged.

Strength

Strength increased approximately 1SD from baseline to long-term assessment in both groups (Yes-SDR −0.4 [−1.3, 0.6] to 0.5 [−1.3, 1.8] vs No-SDR −0.4 [−1.8, 1.5] to 0.3 [−1.2, 1.4]). Overall strength did not differ between treatment groups at either time point (p=0.96 baseline, 0.19 long-term).

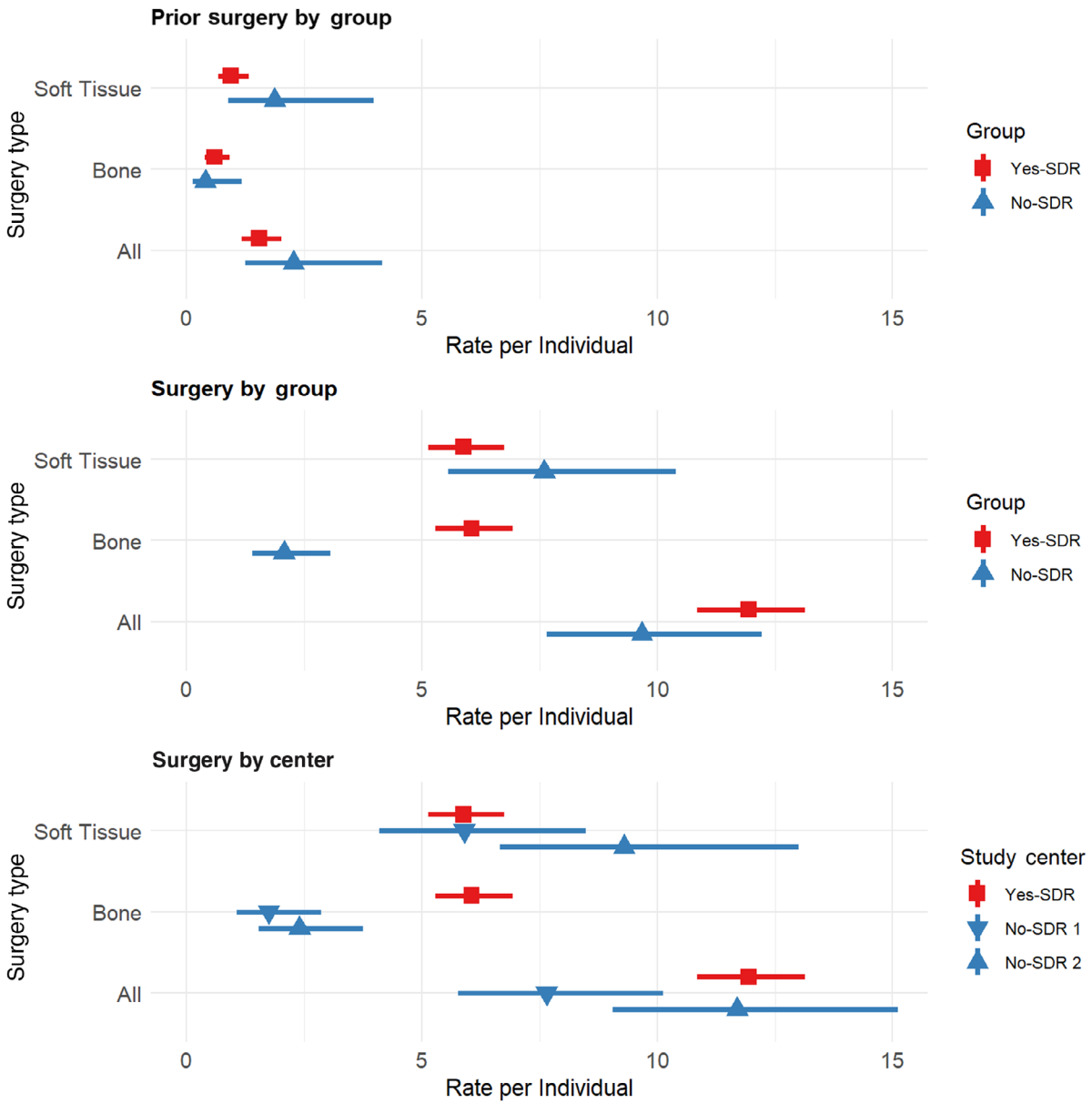

Figure 1: Surgery distribution. Orthopedic surgery before baseline evaluation was rare and well matched (top). There were slightly more soft-tissue surgery procedures in the No-SDR group, and many more bone surgery procedures in the Yes-SDR group (middle). Soft-tissue surgery rates differed between the two No-SDR centers (bottom). SDR, selective dorsal rhizotomy.

Gait deviations

Overall gait deviations did not differ statistically between treatment groups at baseline (Yes-SDR 65 [55, 82] vs No-SDR 66 [45, 88], p=0.58) or long-term time points (Yes-SDR 76 [59, 93] vs No-SDR 71 [46, 89], p=0.10). However, the Yes-SDR group improved by 6 points more than the No-SDR group. Dimensionless walking speed was slightly lower at baseline in the Yes-SDR group (0.31 [0.05, 0.54] vs No-SDR 0.37 [0.11, 0.55], p=0.04). The Yes-SDR group maintained walking speed at long-term assessment, while the No-SDR group decreased (Yes-SDR 0.33 [0.18, 0.43] vs No-SDR 0.26 [0.08, 0.40], p<0.01).

Energy

Net dimensionless walking energy as a fraction of typically developing norms was matched at baseline at just over 2 times typical (Yes-SDR 2.3 [0.90, 4.2] vs No SDR 2.2 [1.6, 3.0], p=0.63) and improved to around 1.5 times typical at long-term assessment in both groups (Yes-SDR 1.7 [1.0, 2.9] vs No-SDR 1.4 [0.8, 2.5], p=0.06).

Function

Neither GMFCS, Gross Motor Function Measure, nor Functional Mobility Scale were standard clinical procedures at baseline, so only long-term results are reported.

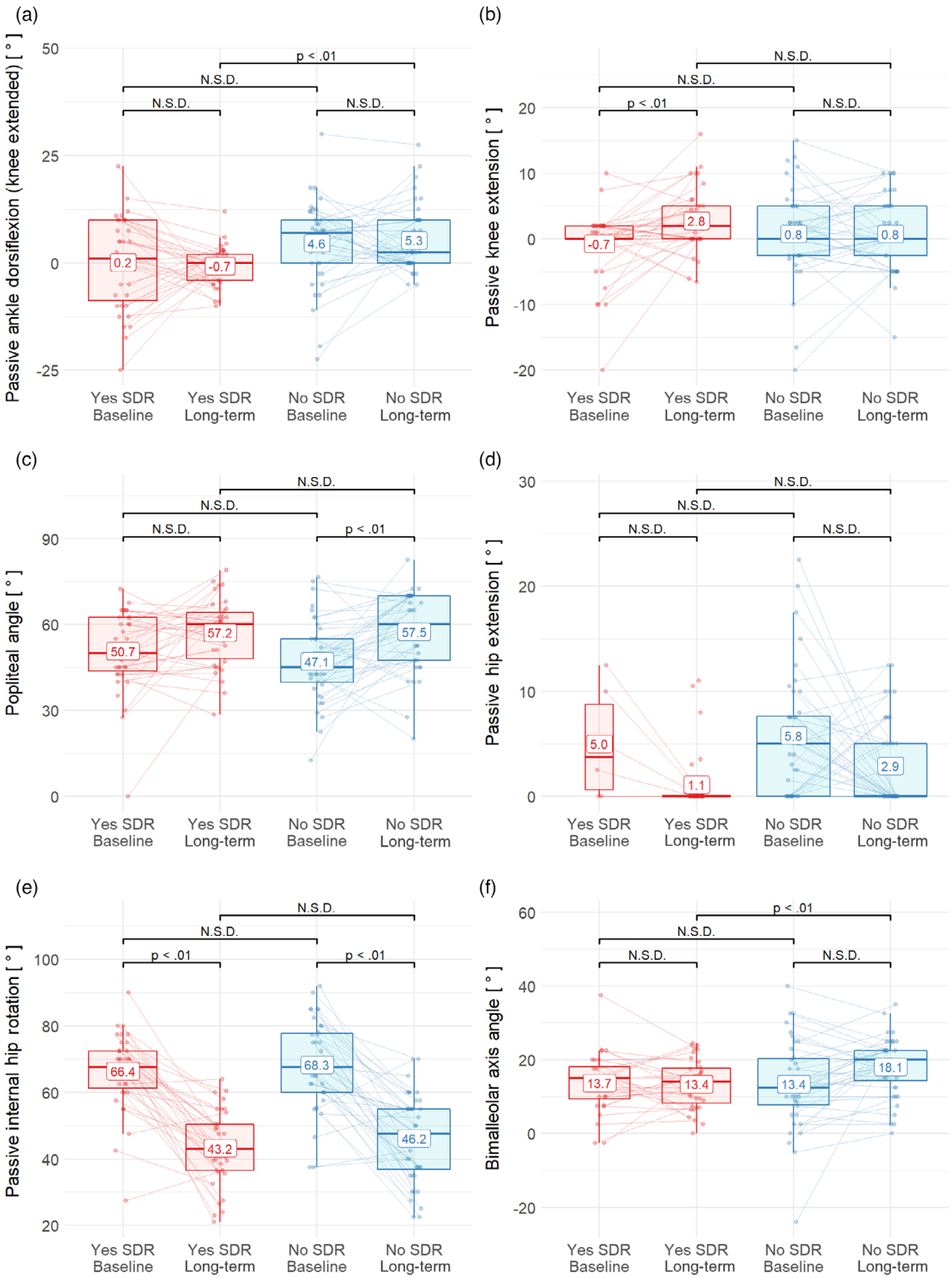

Figure 2: Contracture and bony torsion. Groups were matched at baseline for all contracture measures. Passive extension at the ankle (a) and knee (b) were largely unchanged. Popliteal angle (c) worsened slightly in both groups, while passive hip extension (d) improved slightly in both groups. Groups were matched at baseline for both torsion measures. Both groups exhibited improved femoral anteversion, reflected in passive internal hip rotation (e), and neither group showed a change in tibial torsion, reflected by bimalleolar axis angle (f). Observed changes arose from a combination of surgical treatment and bony remodeling. NSD, no statistical difference.

GMFCS

At long-term assessment, there was no difference between groups regarding GMFCS level (p=0.33). Percentages of participants functioning at GMFCS levels I to IV were 29%, 44%, 26%, and 0% for the Yes-SDR group and 22%, 60%, 15%, and 3% for the No-SDR group.

Gross motor function measure

At long-term evaluation, there was no difference between groups in dimension D (Yes-SDR 76 [33, 97] vs No-SDR 76 [44, 95], p=0.99) or dimension E (Yes-SDR 63 [12, 96] vs No-SDR 62 [18, 93], p=0.79).

Functional Mobility Scale 5m, 50m, 500m

At long-term assessment, there was no difference between groups on the Functional Mobility Scale 5m, 50m, or 500m (p=0.54, p>0.99, p=0.91 respectively). Independent walking on all or level surfaces at 5m was possible for 74% of Yes-SDR and 88% of No-SDR participants. At 50m, the percentages dropped to 60% and 63%, and at 500m to 43% and 58% respectively.

Spasticity-related pain, discomfort, and stiffness

At long-term evaluation, there was no difference between groups in spasticity-related pain and discomfort, or spasticity-related stiffness (p=0.30, p=0.15 respectively). Pain and discomfort scores were 16 [9, 29] and 17 [9, 33], while stiffness scores were 24 [12, 43] and 27 [13, 48] for the Yes-SDR and No-SDR groups respectively. These scores reflect being 'a little bothered' by pain, discomfort, and stiffness.[26]

Participation

At long-term assessment, there was no difference between the groups in participation involvement and control over participation (p=0.46, p=0.23 respectively). Involvement scores were 52 [46, 58] and 49 [45, 55] and the control over participation scores were 56 [49, 62] and 59 [57, 63] for the Yes-SDR and No-SDR groups respectively. These levels are at the 76th centile compared to disabled adults.[23]

Quality of life

At long-term evaluation, there was no difference between groups in quality of life. On each of the four Abbreviated World Health Organization Quality of Life assessment domains the Yes-SDR group scored slightly lower than the No-SDR group (Physical 59 [53, 69] vs 62 [55, 69], p=0.29; Psychological 58 [55, 65] vs 63 [56, 69], p=0.07; Social 59 [51, 67] vs 64 [59, 69], p=0.06; and Environment 61 [57, 70] vs 66 [61, 71], p=0.11). The same trend was observed in overall quality of and satisfaction with life questions, where the percentage of respondents indicating they were very satisfied or satisfied with life in the Yes-SDR and No-SDR groups was 69% and 78% respectively, while those indicating they were very dissatisfied or dissatisfied made up 6% and 2.5% respectively. Similarly, the percentage of respondents indicating they had a very high or high quality of life was 85% and 95% for the Yes-SDR and No-SDR groups respectively, while those indicating they had a very poor or poor quality of life was 6% and 0%. On the Satisfaction with Life Scale, total scores were 24 [15, 30] for the Yes-SDR and 27 [23, 31] for the No-SDR groups (p=0.26). These values reflect being 'satisfied'.

DISCUSSION

Significant spasticity reduction leads to long-term improvements in gait quality, but has minimal long-term impact on contracture, torsion, energy, function, participation, pain, stiffness, or quality of life.

At long-term assessment, clinically measured spasticity was clearly and substantially reduced in the Yes-SDR group and unchanged in the No-SDR group. From this perspective, comprehensive spasticity reduction treatment achieves its primary technical goal. Importantly, participants in the Yes-SDR group underwent 14.4 antispastic injections after having SDR, while those in the No-SDR group had a maximum of three such injections, by design. This result merits further investigation, especially considering recent findings related to potential harm arising from repeated BoNT-A injections.[29] Finally, we found no evidence of an age-related decrease in spasticity in CP as has been reported.[30]

The differences in surgery rates between groups is open to competing explanations. One explanation is that spasticity reduction leads to differences in deformity, which in turn leads to differences in surgery. The second interpretation is that differences in surgery arise because of local treatment philosophies, such as overall aggressiveness, reticence to do muscle lengthening, or changes in treatment approaches over time. The impact of treatment culture is widely recognized and was demonstrated by Skaggs et al. who showed that consistent identification of deformity did not necessarily lead to consistent rates of recommended soft-tissue surgery or osteotomies.[31]

Spasticity does not appear to affect contracture or bony torsion. Note that while hamstrings surgery differed substantially between the groups (Fig. S2, online supporting information), surgery affecting other contractures did not. The hamstrings findings cannot be dismissed entirely, but, as we discuss above, it is likely that center-dependent treatment culture influenced this finding. The 14.4 antispastic injections, which frequently target the hamstrings, may also influence this result. Passive internal hip rotation (femoral anteversion) and bimalleolar axis angle (tibial torsion) were substantially reduced in both groups from a combination of derotation osteotomies (slightly more in the Yes-SDR group) and bony remodeling. Atypical loading of the femur and tibia are believed to contribute to alterations in bony remodeling.[32] Our study demonstrates that the component of atypical loading due to spasticity does not appear to play a role in the remodeling process.

Overall strength improved by around 1SD for both groups and there were no differences between groups at long-term evaluation. Thus, we conclude that spasticity

reduction does not impact strength, aligning with previous findings for SDR.[12]

Speed and overall gait quality (Gait Deviation Index) were similar between the two groups at the long-term time point. However, the changes from baseline to long-term assessment for both measures favored the Yes-SDR group. The Yes-SDR group maintained its speed, while the No-SDR slowed by 25%. The Yes-SDR group started with a slightly lower Gait Deviation Index and improved 6 points more than the No-SDR group, which is viewed as a clinically meaningful difference.[19] The Yes-SDR group received approximately two more orthopedic procedures per individual, which may have contributed to these results.

We found that spasticity does not lead to elevated walking energy. This confirms earlier findings based on matched cohorts and contradicts a widely held view.[33] High energy consumption is a significant problem for individuals with CP; however, spasticity is not the cause. It is also noteworthy that walking energy was significantly lower at long-term assessment compared to baseline. More research is clearly needed to understand the mechanisms causing elevated walking energy in CP.

We asked a battery of questions aimed specifically at spasticity related pain and stiffness and found no significant effect, though we did observe a small magnitude trend towards more stiffness in the No-SDR group. We also observed a small magnitude trend towards higher self-reported quality of life in the No-SDR group that was highly consistent across a number of measures. Both the stiffness and the quality of life trends should be viewed with caution since the differences were small, and unmeasured variables (e.g. socioeconomic factors) may have a large impact on these domains.

Limitations

We carefully designed our study to assess the role of spasticity on a broad range of outcomes. The matching scheme worked well, but not perfectly, since the Yes-SDR group ended up being 2 years younger at baseline. The age mismatch may have impacted some baseline measures. For example, dimensionless speed rises until around the age of 6 years in typically developing children due to neuromaturation. The lack of routine intermediate follow-up between the baseline and long-term time points is unfortunate, since it means that we cannot judge possible differences in outcome trajectories during childhood. It would be valuable to know if outcomes reach their final levels earlier in one group, despite not showing superiority in young adulthood. We chose to report subsequent treatment data according to its clinical importance. However, we urge caution regarding the interpretation of these results, and we have been explicit about our belief that cultural factors almost certainly have a significant impact on these data. Finally, several outcome measures were not part of routine evaluation at baseline, and thus could only be judged at the long-term assessment. We have assumed these measures would have been reasonably well matched at baseline, based on the overall quality of baseline matching on other measures.

CONCLUSION

In this study we examined the role of spasticity and its treatment, primarily with SDR. We measured outcomes at a variety of levels ranging from body structures and function to participation and quality of life. Our results indicate that untreated spasticity does not cause meaningful impairments in young adulthood at the level of pathophysiology, function, or quality of life.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

SUPPORTING INFORMATION

The following additional material may be found online:

Figure S1: Recruitment flow chart.

Figure S2: Rates of surgical procedures by center.

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