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Patient- and Caregiver-Reported Outcome Measures after Single-Level Selective Dorsal Rhizotomy in Pediatric and Young Adult Patients with Spastic Cerebral Palsy

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Keywords

Selective dorsal rhizotomy · Cerebral palsy · Quality of life · Subjective functional outcome · Patient-reported outcome measures · Pediatric neurosurgery

Abstract

Introduction: The aim of this cohort study was to assess the outcome of single-level selective dorsal rhizotomy (SDR) in children and young adults with spastic cerebral palsy (CP) treated at our institution, focusing on patient-reported outcome measures (PROMs) and quality of life (QoL) of patients and their caregivers. **Methods:** We included consecutive patients undergoing SDR from 2018 to 2020 at our institution. Subjective outcome was measured through PROMs, while functional outcome was measured through baseline characteristics, operative outcome, as well as short- and long-term follow-up. Furthermore, the effect of age at the time of surgery on patient/caregiver satisfaction was analyzed. **Results:** Seven patients (3 female, 43%) with a median age at surgery of 11.9 years (IQR 8.7–15.5) were included. All patients had a Gross Motor Function Classification (GMFCS) score of at least IV

before surgery. Five surgeries were palliative and two non-palliative. Based on PROMs, SDR showed very good QoL and health-related outcome measures for both palliative and non-palliative patients. Patient/caregiver satisfaction was higher for the early subgroup (age ≤ 11) than the late subgroup (age > 11). Functional outcome showed reduced spasticity in both groups. Blood transfusions were never needed, while no cerebrospinal fluid leak, infection, or permanent morbidity was seen. **Conclusion:** Based on PROMs, SDR leads to high satisfaction and improved QoL, especially if done at an early age. Further studies with larger cohorts are necessary to underline and confirm our observations.

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Introduction

Cerebral palsy (CP) usually presents with slow motor development, hypertonia, and pathological posture, leading progressively to different severity levels of spasticity [1]. The Gross Motor Function Classification (GMFCS) is

an established measurement scale for the severity of movement disability in individuals with CP [2]. Single-level selective dorsal rhizotomy (SDR) is a procedure aiming to reduce spasticity in these patients. In patients with GMFCS level I–III, it improves mainly motor function, while in patients with GMFCS IV–IV (“palliative” SDR [pSDR]), it improves overall care and comfort [3–9]. To date, the data on the outcome of patients treated with pSDR are sparse. Moreover, the impact of the subjective outcome and improvement in quality of life (QoL) of the patients and/or caregivers is rarely assessed [10–12]. The assessment of patient-reported outcome measures (PROMs) can help identify issues and improvements in health-related QoL as well as social, functional, and overall well-being [13].

This cohort study aimed to assess the outcome of SDR in CP patients, focusing on the PROMs and QoL of the patients and their caregivers. In addition, we aimed to assess whether age influences the functional and subjective outcome of SDR.

Methods

In this single-center cohort study, all consecutive patients under the age of 25 years undergoing SDR between the years 2018 and 2020 at our institution were included. Data were captured through our medical information system. The subjective outcome and QoL were assessed prospectively through PROMs, which were completed through a standardized telephone interview with the caregiver/parent of the patient (see online Suppl. Material; for all online suppl. material, see <https://doi.org/10.1159/000530748>). Existing questionnaires were used as a basis for the construction of the PROMs [14, 15]. Consequently, a survey, consisting of 5-point Likert-type items and open-type questions, was designed to allow a caregiver evaluation on availability of information, general satisfaction, general and functional QoL, and further aspects. Additionally, the caregivers could add free-text information, so that more context to the single Likert items that were perhaps ambivalent could be provided. The primary outcome was the subjective satisfaction and QoL.

Secondary outcome measures were objective assessments at short term (within 3 months) and long term (at least 6 months) of spasticity improvement (improved, unchanged, worsened), the need for redo surgery, the need for further spasticity treatments despite of SDR, duration of surgery, hospitalization and rehabilitation time, intraoperative complications, as well as transient and permanent postoperative morbidity.

Surgical Procedure

The planning and preparation of each surgical case is composed of an interdisciplinary evaluation by pediatric neurosurgeons, physiotherapists, pediatric neurologists, and rehabilitation physicians. Before surgery, a consensus together with the pediatric neurologists is reached, as to which segments should be treated based on the clinical picture of each patient. Surgery is performed

under general anesthesia. Intraoperative neuromonitoring (inomed® Medizintechnik GmbH, Emmendingen, Germany) probes for motor evoked potential (MEP) and somatosensory evoked potential are installed in addition to bulbos-cavernosus reflex and MEP of sphincter muscle. Baseline MEP thresholds for each segment-indicating muscle are estimated using transcranial stimulation for constant monitoring throughout the whole surgical procedure.

The patient is positioned in prone position. Conus level is identified in a preoperatively obtained MRI scan and confirmed through fluoroscopy before surgery. The spine is approached through an approximately 4–5 cm midline incision and subperiosteal dissection of the muscles. The exact position of the conus medullaris is then verified with intraoperative ultrasound guidance. A single-level laminectomy or interlaminotomy, to prevent secondary instability, is performed and the dura is opened by a midline incision. The conus medullaris with the out-bounding roots is exposed. Using direct bipolar neurostimulation, the motor and sensory roots (L1–S1) as well as the spinal nerve roots (S2–S4) can be identified. By bipolar stimulation of the roots for 0.2 ms and 3 Hz in 0.1 mA steps, an anatomical distinction of motor and sensory roots can be done. Motor fibers usually show a response starting from 0.1 mA, whereas sensory fibers often show a threshold of 1 mA or greater. After separation of all sensory roots from motoric roots, the stimulation thresholds of each level are identified. The dermatomal-assigned sensory roots are carefully dissected into rootlets. Using direct neurostimulation of each sensory rootlet, oversensitive rootlets, defined by an exceeded stimulation threshold in comparison to the estimated threshold of the root and an elicitable tetanic 1-s-stimulus response with the prior estimated threshold, can be detected. The oversensitive rootlets are then cut, while approximately 40–60% of each sensory root is cut under constant MEP and somatosensory evoked potential control. Meticulous hemostasis is completed, followed by watertight closure of the dura. Fascia and subcutaneous suturing is followed by the skin closure using DERMABOND® (PRINEO® Ethicon U.S., LLC, Somerville, NJ, USA).

Postoperatively, the patients are ordered flat bed rest for 48 h to prevent cerebrospinal fluid (CSF) fistula. All patients receive inpatient physio- and ergotherapy as early rehabilitation. Anti-spastic drug therapy is continued orally and reduced stepwise according to pediatric neurologist’s recommendations. All patients are discharged to a rehabilitation center with follow-up scheduled for 2 and 12 weeks after surgery. Thereafter, patients are seen regularly in our interdisciplinary spasticity clinic.

Data Management and Statistical Analysis

Study data were collected and managed using REDCap (Research Electronic Data Capture) [16, 17]. Outcome data were analyzed descriptively and presented as ordinary average, mean (\pm SD), median (IQR), and range. For comparative statistics, we dichotomized the cohort to an early group (age \leq 11) and late group (age $>$ 11). The ordinary average difference of the two subgroups Likert scale data was analyzed for significance using two-tailed unpaired *t* test with a 95% confidence interval. Due to the small amount of patients in each group, these calculations were rather explorative to analyze potential trends. All statistical analyses and visualization were done using R (R Core Team [2020], Foundation for Statistical Computing, Vienna, Austria) and its packages [18]. The study protocol

Table 1. Summary of patient characteristics

	N	%	Mean	SD
Sex				
Female	3	43		
Male	4	57		
GMFCS level preop				
I	0	0		
II	0	0		
III	0	0		
IV	4	57		
V	3	43		
GMFCS level postop				
I	0	0		
II	0	0		
III	2	29		
IV	2	29		
V	3	43		
Form of spasticity				
Monoplegia	0	0		
Diplegia	2	29		
Tetraplegia	5	71		
ITB removal	6	86		
Failed test catheter	2	29		
Prior history of ITB explantation	2	29		
ITB removal within SDR surgery	2	29		
No baclofen pump history	1	14		
Follow-up questionnaire after OP, mon			16	8

GMFCS, Gross Motor Function Classification System; ITB removal, Intrathecal Baclofen Pump removal before SDR; mo, months; SD, standard deviation.

was approved by the Local Ethics Committee, Ethikkommission Nordwest- und Zentralschweiz EKNZ, Basel, Switzerland, approval number 2021-01131.

Results

Patient Characteristics

Seven consecutive patients (3 female, 43%), with a median age at surgery of 11.9 years (IQR 8.7–15.5), were included in this single-center cohort (Tables 1, 2). The late group consisted of 3 patients with a median age at surgery of 17 years (age >11 years, Table 3), while the early group consisted of 4 patients with a median age at surgery of 9.1 years (age ≤11 years, Table 3). All the patients had a GMFCS score of IV or higher (Table 1). The 2 youngest patients underwent SDR with the goal to improve ambulation (non-palliative SDR), while the 5 other patients underwent pSDR. Four (57%) patients were treated with baclofen pump before SDR, and it was discontinued due to treatment effect, side effects,

or complications. In two (29%) patients, a test catheter for baclofen was placed without showing sufficient effect; therefore, SDR was indicated rather than the insertion of a baclofen pump. (Table 1).

Patient- and Caregiver Reported Outcome Measures

Questionnaire data were collected from parents or caregivers of all 7 patients. The mean time for the questionnaire follow-up was 16 months (±8 months) after surgery (Table 1). The section “Availability of Information” showed a tendency to the answer option “Strongly or Somewhat Agree” with a mean of 71.4% (±14.3%) as well as the section “General Satisfaction” with 64.3% (±17.1%). Questions regarding the “General Quality of Life” showed no trends with 35.8% (±16.0%) of the participants have chosen “Strongly or Somewhat Agree” and 39.5% (±11.6%) have chosen “Strongly or Somewhat Disagree.” “Further Aspects,” addressing the necessity of rehabilitation after surgery and postsurgical period without unexpected complications, were mainly answered with “Strongly or Somewhat Agree” in 85.7% (±0%). The breakdown of the questions and their answer rates are displayed in Figure 1a–e.

Three caregiver comments (43%) mentioned that the amount of care needed was not reduced but easier due to less spasticity and rigidity in the thigh area, which resulted in easier patient transfer and hygienic care of the patient. Three caregivers (43%) stated that although spasticity decreased, muscle strength was also weakened. One caregiver (14%) of a non-palliative patient mentioned that their child could walk again with additional aid, thus leading to higher QoL and social inclusion.

Comparison between Early and Late SDR

The early group showed greater general satisfaction (78.6% early group vs. 38.1% late group, $p < 0.05$), greater improved general QoL (50% early group, 16.7% late group, $p = 0.10$), and greater improved functional QoL (63.9% early group, 33.3% late group, $p = 0.29$, Table 4).

Operation and Rehabilitation

The mean duration of the surgery was 321 min (±57.7, Table 2). Two patients had an intrathecal baclofen pump (ITB) removal within the same procedure before performing SDR. The mean intraoperative blood loss was 132 mL (±98.9). No intra- or postoperative blood transfusion was needed. The median hospitalization time was 11 days (IQR 10.5–14.5), and the median rehabilitation time was 89 days (IQR 56–112, Table 2).

Reduced spasticity was reported in all patients during hospitalization and rehabilitation at short-term

Table 2. Inferential statistical summary of the operative outcome

	Mean (SD)	Median (IQR)	Range	n	%
Age at surgery, years	13.1 (6.4)	11.9 (6.8)	6.5–24.9		
Duration of surgery, min	321 (57.7)	305 (73)	245–410		
Blood loss, mL	132 (98.9)	100 (127.5)	20–300		
Hospitalization time, days	15.3 (11.4)	11 (29.5)	6–40		
Rehabilitation time, days	83 (49.9)	89 (56)	12–143		
Transient morbidities				5	71
Permanent morbidities				0	0

yr, years; min, minutes; mL, millilitres; d, days; SD, standard deviation; IQR, interquartile range.

Table 3. Patient characteristics

No.	Age at surgery, years	Sex	Form of spasticity	GMFCS preop	GMFCS postop	Previous ITB treatment	Indication palliative	Follow-up, mo
1	10	f	Tetraplegia	IV	IV	Yes	Yes	20
2	24	m	Tetraplegia	V	V	Yes	Yes	8
3	11	m	Tetraplegia	IV	IV	Yes ^a	Yes	16
4	17	f	Tetraplegia	V	V	Yes ^a	Yes	13
5	6	m	Diplegia	IV	III	No	No	16
6	14	f	Tetraplegia	V	V	Yes	Yes	9
7	7	m	Diplegia	IV	III	Yes	No	31

No., number; yr, years; f, female; m, male; GMFCS, Gross Motor Functions Classification System; Previous ITB treatment, previous Intrathecal Baclofen Pump treatment; mo, months. ^aIndicating ITB removal during SDR surgery.

follow-up. At long-term follow-up, reduced spasticity was noted in all patients except 2. One of these patients showed recurrence of spasticity at long-term follow-up at a different spinal root level indicative for redo surgery. For the oldest patient, reduced spasticity was described after short- and early long-term follow-up. However, 1 year after SDR, the patient developed enhanced spasticity, while the parents refused further treatment. One preoperatively non-ambulatory patient showed reduced scissor gait, improvement in drop-foot pathology after non-palliative SDR surgery and was able to walk using a posterior walker.

Morbidity and Mortality

No intraoperative complications were recorded. Transient postoperative symptoms occurred in 5 out of 7 (71%) patients. These included transient urinary retention or constipation in two (28%) patients, enhanced spasticity (up to 6 weeks after surgery) in one (14%) patient, and transient lower limb paresthesia documented in one (14%) patient. Wound healing

was excellent in all patients, while no infections or CSF disorders occurred. No permanent morbidity and one (14%) non-SDR-related mortality due to respiratory insufficiency occurred during the follow-up time (Table 2).

Discussion

This study is, to our knowledge, the first to describe the subjective outcome of SDR for CP patients with GMFCS IV–V. Furthermore, the functional outcome after SDR was objectified, evaluated systematically, and compared between age groups. The results of this study underline the importance of PROMs, especially for this mostly very devastating pathology, where outcome and QoL are difficult to measure. The subjective outcome for SDR showed good satisfaction and health-related outcome measures for non-palliative as well as pSDR. PROMs of the early group showed higher satisfaction and QoL, suggesting that CP patients eligible for SDR should be treated at a rather early age. Objective functional outcome

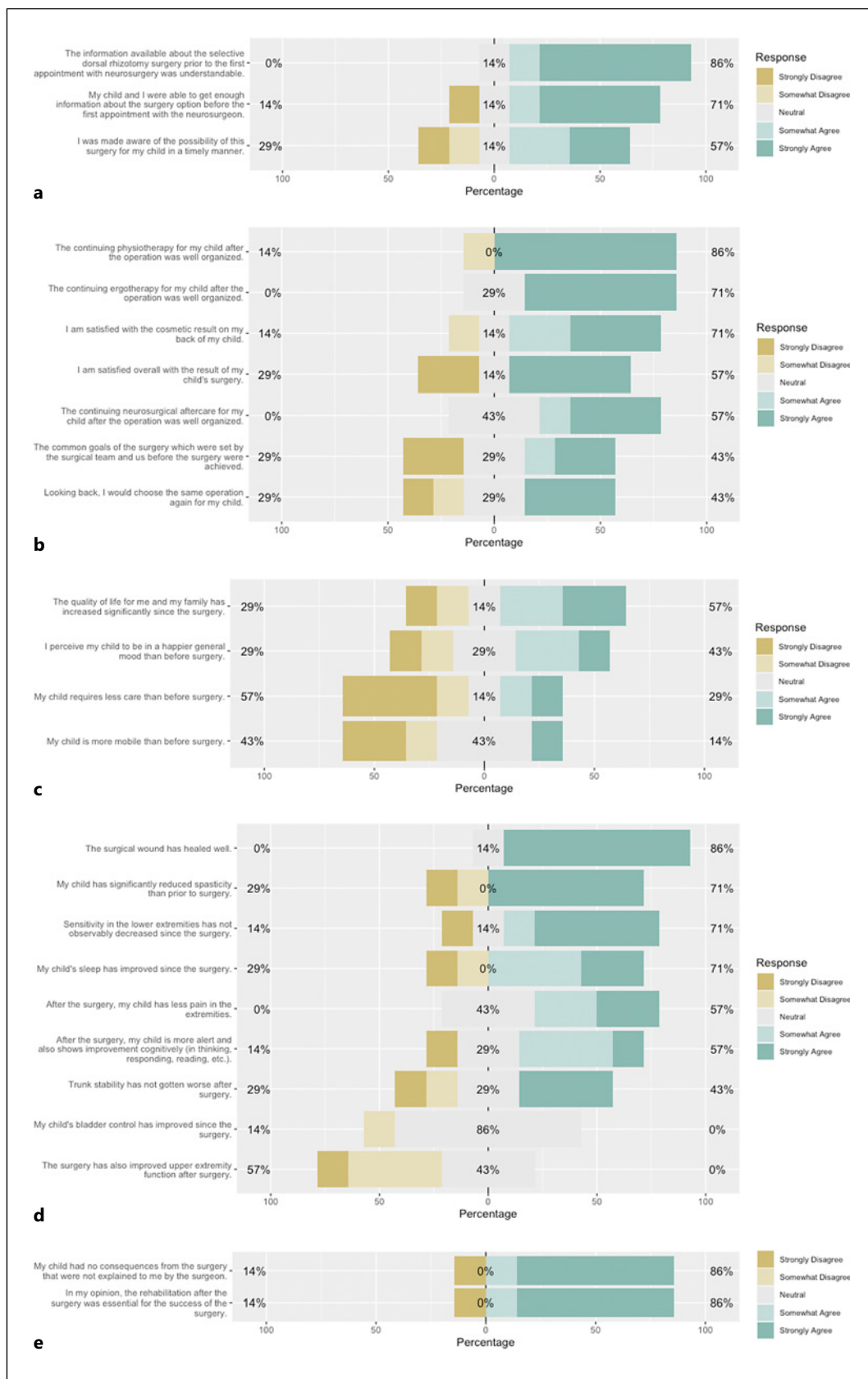


Fig. 1. a “Availability of Information” part of the questionnaire data. 12 percent of the whole questionnaire. **b** “General Satisfaction” part of the questionnaire data. 28 percent of the whole questionnaire. **c** “General Quality of Life” part of the questionnaire data. 16 percent of the whole questionnaire. **d** “Functional Quality of Life” part of the questionnaire data. 36 percent of the whole questionnaire. **e** “Further Aspects” part of the questionnaire data. 8 percent of the whole questionnaire.

Table 4. Summary of ordinary averages of the 25 item Likert scale data for all patients ($n = 7$) and subgroup analysis of the early group ($n = 4$, age ≤ 11) and the late group ($n = 3$, age > 11)

Likert characteristics	Strongly or somewhat disagree (%)		Neutral (%)		Strongly or somewhat agree (%)	
	mean	SD	mean	SD	mean	SD
Availability of Information	14.3	11.7	14.3	0	71.4	11.7
Early group	25		16.7		58.3	
Late group	0		11.1		88.9	
General Satisfaction	16.3	11.9	22.4	12.9	61.2	14.7
Early group	3.6		17.9		78.6	
Late group	33.3		28.6		38.1	
Improved General Quality of Life	39.3	11.8	25	11.8	35.7	16.0
Early group	18.8		31.25		50	
Late group	66.7		16.7		16.7	
Improved Functional Quality of Life	20.6	16.6	28.6	25.2	50.8	29.4
Early group	5.6		30.6		63.9	
Late group	40.7		25.9		33.3	
Further Aspects	14.3	0	0	0	85.7	0
Early group	0		0		100	
Late group	33.3		0		66.6	

SD, standard deviation.

seems to be unrelated to age of treatment. Since this surgery is done in a minimal-invasive fashion, permanent morbidity and mortality seem very low.

Caregiver Report/PROMs

To objectify the outcome of patients with CP after SDR, we created a new questionnaire addressing the specific subjective items for patients and caregivers after SDR. To our knowledge, there is no standardized evaluation tool available. Assessment of important functional outcomes such as pain and cognitive improvements in pSDR patients is essential and clearly underreported. Of the existing SDR outcome studies, only a few include caregiver evaluation [7–9]. Summers et al. [19] assessed prospectively the postsurgical function and QoL 24 months after SDR surgery based on preexisting questionnaires (GMFM-66 and CP-QoL) in children with GMFCS level II or III showing good QoL and functional improvement. Our patient cohort was mainly non-ambulatory with GMFCS levels of IV–V. To our knowledge, no standardized evaluation of QoL and satisfaction measures is available for this group of patients. Our results show that “General Satisfaction” of the patient as well as the caregiver improved after surgery. This is further reinforced with a 57% consensus of overall satisfaction with the surgical result as well as 43% strong agreement and 29% neutral response to the reconsideration for same operation (Fig. 1b). QoL significantly improved after surgery for 57% of the patients and

caregivers. Rehabilitation was noted to be crucial for the success of the surgery by 86% of the responders (Fig. 1e). For “Functional Quality of Life,” parents reported reduced spasticity and improved sleep in 71% of the patients, while pain reduction in the extremities and cognitive improvements were noted in 57% (Fig. 1d). Through conducting PROMs, we could show that functional QoL improved in many aspects of the patient’s life. As our cohort consisted of 5 out of 7 palliative patients, this suggests a potential benefit of pSDR, which should be further explored.

Palliative SDR in the Existing Literature

Davidson et al. [6] 2019 describe ITB historically as the intervention of choice for palliative CP patients (GMFCS IV–V), while SDR as the historical intervention of choice for ambulatory children with a GMFCS I–III. In current studies, more and more authors suggest SDR as an alternative treatment to ITB for non-ambulatory CP patients [6–9]. In our cohort, apart from 1 patient, all had prior treatment using ITB which was eventually removed due to various reasons or baclofen test catheter which showed no benefit (Table 1). Gillespie et al. [20] analyzed 42 children from age 3 to 18 years undergoing SDR and preoperative GMFCS levels I–V suggested that age and GMFCS levels did not correlate with outcome. We observed some age-related differences based on the PROMs. Conversely, short- and long-term follow-up of spasticity and functional outcome was similar in both the

early and the late group. Our preliminary PROMs based data therefore suggests that SDR should be considered as an option alongside ITB and discussed with the parents early, even in patients with GMFCS level IV or V.

Surgical Outcome

For single-level, minimal-invasive laminectomy at the level of the conus medullaris, long-term complications such as scoliosis or lumbar instability are lower than for multilevel SDR [21–24]. None of the included patients suffered a progressive spinal instability or deformity. However, these results might be biased due to the short follow-up of our cohort. Limited data are available addressing the risk of CSF fistula in SDR, while it seems to bear a higher risk for serious complications such as wound infections, neuronal worsening, or meningitis [3, 25]. Greater exposure of dura and greater skin incision have an increased risk for such complications; therefore, our minimal-exposure and meticulous dura closures seem to lead to a low CSF leak rate. This is comparable with the data reported by Park, where they reported a CSF leak rate of 0.1% in their analyzed SDR patient collective [3]. Postoperatively, transient morbidity was seen in 71% of the patients, while no permanent morbidities were apparent. These results are comparable to other studies, where 88% of the transient complications resolve at long-term follow-up [19]. The median hospitalization time was 11 days (IQR 10.5–14.5), and the median rehabilitation time was 89 days (IQR 56–112). The hospitalization time of our cohort is longer than reported in other studies, where patients after SDR are discharged on the fifth postoperative day [7, 8, 10, 26]. In Switzerland, only one stationary pediatric rehabilitation center exists. Therefore, we commence in-house rehabilitation on the fifth postoperative day for all patients, until transfer to the rehabilitation facility is possible. As opposed to other studies where tri-/biweekly ambulatory physiotherapy for 6 months after SDR is reported, all patients within our cohort underwent extensive rehabilitation at a rehabilitation facility for 3 months [7, 8, 10, 26].

Study Limitations

This prospective study with retrospective analysis of medical record data is subject to the limitations inherent of this study design. With a small sample size of 7 patients, association between different effect sizes might be skewed and need to be interpreted cautiously. Although a standardized protocol was used for all survey respondents, the communication between investigator and respondent is always subject to acquiescence bias, selection bias, and information bias. The parents of the

young adult (No. 2) were overall unsatisfied, especially with the rehabilitation due to non-conform possibilities for their 25-year-old son. Thus, their response to all Likert items was mainly “strongly disagree.” This introduced a substantive bias in analysis due to the small number of included patients. Differentiation between SDR operation consequences and the natural CP-related decline is difficult. To further evaluate the outcome, especially the long-term outcome of SDR and pSDR operations, further studies with larger cohorts, control groups, and longer follow-ups are needed.

The strengths of our study lie in standardized SDR surgery performed by the same pediatric neurosurgical team (R.G. and J.S.) and a standardized prospective questionnaire procedure. Through the caregiver evaluation of subjective outcome after SDR, valuable information about patient and caregiver QoL could be gathered. With our study, we strive to improve the evaluation of subjective outcomes, such as pain and cognitive impairment, especially for this disabled and nonverbal patient population. A prospective database of SDR patients with long-term follow-up, based on PROMs, has been established at our center. Further prospective data will help shed light on the subjective outcome of these patients and their caregivers.

Conclusion

SDR seems to improve QoL and leads to high satisfaction among patients and caregivers for both palliative and non-palliative patients, especially when performed at an early age. Further studies with larger cohorts are necessary to underline and confirm our observations.

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Statement of Ethics

This study involved human participants and was reviewed and approved accordingly by the Local Ethics Committee, Ethikkommission Nordwest- und Zentralschweiz EKNZ, Basel, Switzerland, approval number 2021-01131. Written informed consent was obtained from the parents or legal guardian to participate in the study. The research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest that are directly or indirectly related to the work submitted for publication.

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Author Contributions

Abeelan Rasadurai: conceptualization, methodology, investigation, data curation, formal analysis, initial draft preparation, draft

editing, and final review and approval; Nicole Alexandra Frank and Ladina Aurea Greuter: methodology, investigation, formal analysis, draft editing, and final review and approval; Maria Licci: investigation, data curation, formal analysis, resources, and final review and approval; Peter Weber and Stephanie Jünemann: investigation, formal analysis, resources, and final review and approval; Raphael Guzman: investigation, formal analysis, resources, funding acquisition, and final review and approval; and Jehuda Soleman: investigation, formal analysis, resources, funding acquisition, draft editing, supervision, and final review and approval.

Data Availability Statement

All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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