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Research Article

High global satisfaction in magnetically controlled elongations in 29 early-onset scoliosis patients versus primary spinal fusion in 20 adolescent idiopathic scoliosis patients

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Abstract

Background and purpose: Early-Onset Scoliosis (EOS) treatment aim to improve natural history and the child's quality of life. Magnetically Controlled Growing-Rods (MCGRs) represented a major evolution in distraction-based management of EOS by eliminating the surgical elongations. The technique can be used until cessation of growth and consequently it overlaps with primary Permanent Deformity Surgery (PDS). Patient reported outcomes of growth instrumentation compared to PDS is an interesting but uninvestigated subject.

Our aim was to investigate the psychological burden, physical burden and global satisfaction in MCGR lengthening procedures in EOS patients and their parents, compared to PDS in adolescent idiopathic scoliosis patients.

Patients and methods: A single-center cross-sectional cohort study: 29 MCGR-treated EOS patients, mean age 11(range, 6-14) years, compared to a PDS control group of 20 AIS patients age 16(12-20) years. Follow up in the MCGR group was 25(SD 14) months and 19(SD 12) months in the PDS group. The parents responded to a 9-item *Satisfaction Questionnaire* with a 0-10 Likert scale [0 none, 10 maximum].

Results: The median (range) physical strain was 0(0-7) for MCGR vs. 7(5-9) in PDS, the psychological strain was 0(0-7) vs. 7(0-10), the procedure related back pain was 0(0-5) vs. 8(0-10), the pain intensity between distractions/follow-up 0(0-8) vs. 2(0-8), the parental concern was 0(0-7) vs. 9(2-10). Overall satisfaction of the treatment concept was 10(6-10) vs. 9(2-10).

Interpretation: Overall satisfaction was uniformly high in both groups. Both the physical and psychological strain and pain in conjunction with MCGR lengthening procedures were low in comparison with primary deformity surgery.

Level of evidence: Level IV, cross-sectional cohort study.

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Introduction

Early-Onset Scoliosis (EOS) treatment seeks to improve the natural history of untreated scoliosis and diminish the severe complications the condition may entail [1]. The main concerns are impaired thoracic and pulmonary development, furthermore the impact on the children's quality of life must not be neglected. Magnetically Controlled Growing-Rod (MCGR) treatment is one of the most popular novel growth-sparing techniques for surgical management of EOS. The MCGR is elongated by means of non-invasive transcutaneous magnetic stimulation without sedation [2]. This eliminates the need for repetitive surgical interventions under general anesthesia which is required in the conventional growing rod method [3]. Therefore, MCGR treatment is on the rise worldwide [4-7]. Despite the findings of recent reports on MCGR-actuator failures [8] and complications similar to those affiliated with conventional growing rods [3,9], MCGR treatment is still considered an evolution in distraction-based growth instrumentation in the surgical management of EOS.

Peers, health care providers and caretakers of the children suffering severe EOS have called for evaluation of patient satisfaction. While the general impression is that both surgeons, MCGR-treated children and their parents are satisfied with the treatment, we are not aware of any scientific studies investigating this claim.

The aims of this study were to estimate the overall satisfaction with MCGR treatment, the stress and discomfort experienced by the patients and their caretakers regarding the MCGR lengthening procedures. In order to provide a reference, results were compared with a control group of primary fused adolescent idiopathic scoliosis patients.

Materials and methods

Study design

A questionnaire-based cross-sectional cohort study in which the parents/caretakers filled in a 9-item satisfaction questionnaire (Table 1, and *Supplementary Appendix 1 and 2*). Clinical information was extracted from patient files.

Patients

The cohort comprised 29 EOS patients (Table 1) undergoing magnetically controlled growing-rod (MAGEC, NuVasive, San Diego, California, USA) interval lengthening procedures at a university hospital. MCGRs were implanted between September 2014 and August 2018 at a single center and subsequently they were scheduled for non-invasive lengthening procedures at 2.5-3-months intervals in an outpatient setup without anesthesia or analgesia until end-of-growth. Elongation of the MCGR was verified with C-arm fluoroscopy at the lengthening procedure. A median of 9(2-16) MCGR procedures per patient were performed before inclusion in the current study. The majority of patients (23 of 29) had a single MCGR in combination with a contralateral passive-gliding rod construct (i.e. CB-MCGR hybrid Figure 1) [10]. Of the remaining patients, 4 patients had dual MCGRs, and 2 patients had a single MCGR combined with osteotomies (Figure 1). An assessment of procedural pain during MCGR lengthening is reported separately. Criteria for selection of patients for MCGR growth instrumentation instead of primary fusion included: growth potential of at least 2 years (Risser sign <2-3), impaired pulmonary function, and inability to manage the curve by bracing or secondary salvage procedures following earlier surgery or congenital deformities.

The fusion control group of normal adolescent idiopathic scoliosis patients receiving primary fusion was identified via a local deformity database within the same study period. The inclusion criteria were primary fusion surgery in AIS patients aged 11-20years with a follow-up time of 3-24 months at time of inclusion via the database, thereby having completed at least a routine 3-month follow-up. 25 patients fit the inclusion criteria. Exclusion criteria were psychosocial factors non-compatible with the study. Thus, two AIS cases were excluded due to foster care placement instability. Leaving 23 eligible for the fusion group of which 20 responded to the questionnaire (87%) (Table 1). The 3 non-responders had

Table 1: Patients.

	MCGR (n=29)	Fusion (n=20)	p-value
Gender, no.	23F, 6M	13F, 7M	0.3*
Etiology, no. Neuromuscular Idiopathic Syndromic Congenital/structural	 14 5 6 4	 0 20 (AIS) 0 0	<0.0001
Age at index operation: years., mean±SD (range)	10.8±2.5(5.6-14.1[b])	16.2±2.3(12.0-20)	<0.01¤
Instrument span: no. levels, mean±SD (range)	13.5±2.4(9-16)	9.8±1.9(4-13)	<0.01¤
Post index follow-up[c], months, mean±SD (range)	25±14(5-48)	19±12(3-34)	0.12¤
Lengthening count, median (IQR)range	9 (3-10)2-16	NA	
Post-op complication count (no. of pts.)	8	2	0.15*
Unplanned surgery (no. of pts.)	6	1	0.22*

Etiology according to the Classification of Early-Onset Scoliosis. NA, not applicable. [a]Few observations, no statistical calculation. [b]Patient aged 14.1 at index operation was very small for age with >5 years delayed skeletal maturity. [c]Follow-up time in months at the time of responding the questionnaire. *Fisher's exact test. ¤Unpaired two sample t-test.

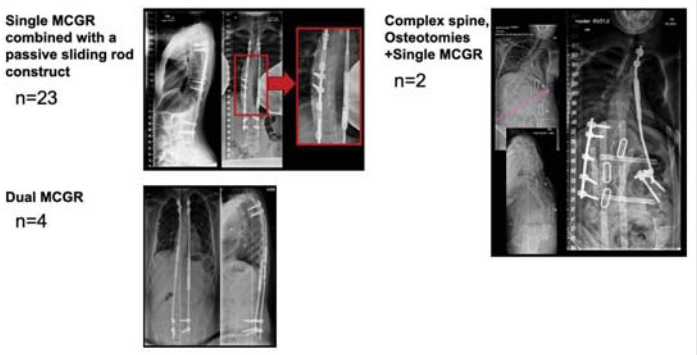

Figure 1: MCGR applications in the study.
The different applications of magnetically controlled growing rods within the MCGR cohort. The majority had a single MCGR for concave distraction combined with a contralateral passive sliding construct (i.e. CB Concept).

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similar characteristics to the responders and they had no re-operations or special remarks recorded at their latest outpatient follow-up.

Questionnaire

The questionnaires focused on the distraction procedures in the MCGR group and the primary surgery in the fusion group. The replies of the domains were scored on a 0-10 Likert scale (Table 2). The questions were slightly rephrased for the control group in order to refer to the similar entity for the primary fusion surgery. The translated questionnaires are available (*Supplementary Appendix 1 and 2*).

Statistical analysis

Data were assessed for normal distribution by Q-Q plots and histograms. Results are presented as mean, Standard Deviation (SD), median value, Inter Quartile Range (IQR) and range. Unpaired tests were applied to test null hypothesis between groups: unpaired two sample t-test for parametric data, Wilcoxon-Mann-Whitney test for nonparametric data, Fisher's exact test for dichotomous data, and Fisher-Freeman-Halton test for unordered categorical data. A p-value <0.05 was considered statistically significant. Missing observations occurred in 3/380(0.8%) domain scores, no imputations were made.

Ethics

Informed consent was obtained from the patient, parents or other legal guardian and all patients were included. All treatment costs of each patient were covered by the national public health care system. None of the participants received reimbursements for study participation and none of the involved medical doctors or staff had any personal financial interests in the study. No external funding was received for this study.

Approval to collect, store and analyze patient data was obtained from the Danish Data Protection Agency (1-16-02-92-14) and the Regional Committee on Biomedical Research Ethics (Ref. 126/2014).

Results

The results of the study for both groups including p-values are presented in Table 3. Overall patient-parent satisfaction with the MCGR treatment was rated to a median 10(6-10) in the MCGR group vs. 9(2-10) in the fusion group [0 very dissatisfied, 10 very satisfied].

The likelihood of requesting MCGR if the MCGR patients were to repeat surgery was a median 10(range 9-10) [0 no preference regarding method, 10 highest preference for MCGR]. Notably, the MCGR method was unanimously considered most gentle by caretakers of children who had experienced open distraction(s) due to for example MCGR conversion, subsequent distraction failure or coronal imbalance correction (n=8).

There were significant differences in outcomes between the two groups (Table 3). The fusion group experienced more pain, more strain, and more parental concern. No difference between the groups was observed regarding non-procedural related leg and back pain (Table 3). However, 3 patients in the fusion group complained about back pain, one of them from protruding hardware, and 2 reporting intermittent pain of moderate intensity which influenced their daily living (not dependent on the post-op follow-up duration). 2 reported that paracetamol was administered prior to the distraction due to minor discomfort and back fatigue during prior MCGR distractions.

Table 2: The MCGR group Satisfaction Questionnaire and Likert rating scale.

Question	Score 0		Score 10
1. How much does the distraction procedure physically affect your child?	not at all		worst imaginable physical strain
2. How much does the distraction procedure psychologically affect your child?	not at all		worst imaginable psychologic strain
3. How much back pain does your child experience in relation to the distraction procedures?	no pain		worst imaginable pain
4. How concerned are you as parent/ legal guardian about the distraction procedures?	not at all		very concerned/anxious
5. How much back pain does your child experience in the period between distraction procedures?	no pain		worst imaginable pain
6. How much leg pain does your child experience in the period between distraction procedures?	no pain		worst imaginable pain
7. How satisfied are you with magnetically controlled growth instrumentation overall?	very dissatisfied		very satisfied
8. If your child required another spinal growth instrumentation, would you prefer a magnetically controlled growth instrumentation if available?	no preference regarding method		highest preference towards magnetically controlled distraction
9. If your child has had both conventional and magnetically controlled distraction procedures, which method was most gentle and best tolerated?	conventional open method	equal /no difference	Magnetic controlled method
10. Other comments?	Free text		

The MCGR Satisfaction Questionnaire and domains. In question 1 to 8 a 0-10 numeric rating scale was applied, in question 9 a categorical scale, and free text in question 10 for other comments.

Table 3: Results.

Domain	MCGR	Fusion	p-value*
Physical strain (Q1)	0 (0-1) 0-7	7 (5-9) 0-10	<0.0001
Psychological stain (Q2)	0 (0-3) 0-7	7 (3-10) 0-10	<0.0001
Back pain related to proc. (0-5d§) (Q3)	0 (0-1) 0-5	8 (5-10) 0-10	<0.0001
Parental concern (Q4)	0 (0-1) 0-7	9 (8-10) 2-10	<0.0001
Back pain between proc. (now¤) (Q5)	0 (0-2) 0-4	2 (1-3) 0-8	0.01
Leg pain between proc (now¤) (Q6)	0 (0-1) 0-8	0 (0-0) 0-7	0.3
Overall satisfaction (Q7)	10 (8-10) 6-10	9 (8-10) 2-10	<0.001
Willingness to repeat MCGR (Q8)	10 (10-10) 0-10	Na	
Best tolerated distr. method (Q9)	8/8 MCGR	Na	

Scores presented as median (IQR) range. Q, question no. Na, not applicable. ¤Control group. *Wilcoxon-Mann-Whitney test.

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There was a single outlier, both in physical, psychological strain and parental concern items. The father of this child reported: that "due to mental deficits my child is always very anxious about situations not being a part of his daily routines, including situations such as preparation for general anesthesia when it has been required for previous surgical interventions". He commented further, that "conventional growing-rod instrumentation with planned interval distractions under general anesthesia would never have been an option for my child". The leg pain score of 8 also represents an outlier which was caused by hip subluxation in a child with spastic cerebral palsy. In the fusion group there was an outlier with score 0 in the physical strain domain. The low number of dual MCGR applications in the present study do not allow for a direct comparison with single MCGR but they appeared to respond similarly.

The overall satisfaction was higher in the MCGR group, 10 vs 9 in the fusion group because a couple of patients in the fusion group only scored 2; one was the before mentioned patient with persisting back pain, which could explain the lower score. The other patient reported high pain intensity immediately after the surgery, while reporting to be pain-free at 2-year follow-up with only a minor notion about cosmesis, there was no obvious reason for the low satisfaction.

Discussion

The current study is the first to report patient/caretaker reported outcomes regarding MCGR treatment in EOS. We found a uniform high overall satisfaction, and 8 out of 8 with experience from open distraction procedure(s) would choose MCGR again if it was an option. The physical- and psychological strain and pain experienced in conjunction with the MCGR distraction procedure were low. Consequently, parents expressed full confidence in the MCGR procedure. Compared to adolescent and young adult controls reporting similar measures about their primary fusion surgery: they report both significantly higher physical strain, psychological strain, procedure related back pain and patient/caretaker procedure related anxiety level.

The reasons for choosing the AIS control group are multifold. There is an overlap in age and selection of fusion levels in the 2 groups and we experience patients who could benefit from both procedures. The typical MCGR treatment involves a higher number of vertebrae (longer span of instrumentation, Table 1). Possible side-effects may not be detected until 10-20 years later. Awareness of distal disc degeneration and curve progression is a classic challenge in AIS surgery. However, there is some evidence that a well-balanced lumbar curve is protected from further degeneration following surgery [11]. In contrast, too short AIS fusion in specific curve types such as Lenke 1A often leads to add on, torsion and distal adjacent level degeneration [12]. The idea of performing multi-segment growth friendly instrumentation may be a viable solution which may be justified until skeletal maturity. Further studies are needed with long-term follow-up. But so far, the MCGR treatment seems to be relatively pain-free and accepted by both patients and their caretakers.

There was a high overall satisfaction in both groups median 10 in the MCGR group vs. 9 in fusion group. It is uncertain whether high satisfaction will remain over time but we anticipate that potential instrumentation and hardware-related complications are going to increase in the MCGR group with longer term follow-up [9]. However, we did a pilot test almost 1.5 year earlier using the same instrument in 19 of the 29 MCGR patients and the conclusion remained unaltered. Considering complications, 8 patients in the MCGR group experienced at least one complication (Table 1) and 6 of them required unplanned re-operation. Surprisingly, it did not impact their overall satisfaction compared to patients without complications. Likewise, there is no correlation between duration of treatment and satisfaction. 13 of the patients had already undergone more than 10 MCGR lengthening's and high parental satisfaction was maintained ranging 8-10 (10 highest satisfaction). The relative novelty of the MCGR treatment might bias the responses. The effect of this is unknown, but the high degree of user satisfaction was confirmed by the pilot test results, which is reassuring and leads us to believe that this effect most likely is negligible. Ultrasound is a viable and feasible alternative without any exposure to radiation, however this technique is not yet fully implemented at our institution [13].

Limitations of the study include: use of a non-validated questionnaire but the uniform responses and the wide range of grading the reply within each domain may outweigh this concern. The obvious difference between the two procedures is another limitation, non-invasive MCGR lengthening versus primary open surgery. However, it answers our concerns of how children respond physical and psychologically to repetitive MCGR lengthening procedures. Due to the nature of EOS and the optimal indications for growth instrumentation in neuromuscular deformity we were not able to have uniform etiologies in the two groups within the study timeframe.

Several of the respondents noted, the avoidance of multiple procedures under general anesthesia to be the main benefit of the MCGR treatment method. Adverse effects which may be attributed to repeated surgeries requiring general anesthesia on psychosocial and cognitive function and general development have been reported [14-16]. Some EOS patients suffer from cognitive impairment rooted in their basic etiologies and in comorbidities; some also undergo multiple procedures under general anesthesia for non-spine related pathologies. Thereby, the total anesthesia exposure is increased.

The long-term cost of MCGR-treatment has been estimated to be lower than in conventional growing-rods based on estimations in various countries and health care systems, e.g. in France [17], the United Kingdom [18], the United States [19] and Hong Kong [20]. Nonetheless, the initial cost of the MCGR implants may seem prohibitively expensive, both in private and public health-care settings. The use of a single MCGR in combination with contralateral passive sliding rods instead of dual MCGRs may further improve cost-benefit. Long-term studies are warranted in order to verify the high satisfaction rate in this study. The use of validated instruments such as the EOSQ-24 in prospective studies may in time be helpful.

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Conclusion

Overall satisfaction was uniformly high in both groups. Both the physical and psychological strain and pain in conjunction with lengthening procedures, and parental concern were low in comparison with the fusion group.

8/8 MCGR patients having experienced open distraction(s) preferred the MCGR lengthening procedure. However, further studies are needed to assess the long-term effect of the extended instrumentation areas used in growth instrumentation. The results do not justify changes in guidelines for surgical intervention in EOS.

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