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Yoga and Botulinum Toxin Reduce Adolescent Idiopathic Lumbar Scoliosis – A Control, Randomized Study

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Objective: Determine safety and efficacy of increasing muscular strength symmetry in AIS.

Results: Each group had 10 patients. All completed the three-month study period. Mean self-reported daily side plank time = 155 s. The mean initial lumbar curvatures for groups 1, 2 and 3 were 29.8, (SD 6.6), 37.8 (SD 8.0) and 33.0 (SD 6.31) degrees, respectively. Curves were reduced at 3 months by +1.8 (2.4), -7.8° (7.1) and -12.2°(8.79) respectively, with ($p < 0.001$) improvement in Group 2 vs. Group 1 and Group 3 vs. Group 1. Group 3 showed the greatest improvement. Harms: one patient in Group 2, one in Group 3, with transient shoulder pain that resolved by using the forearm in the pose.

Conclusion: Muscle strength asymmetry appears to be relevant to AIS treatment. Side planks performed with the convex side downward alone and side planks combined with incobotulinum injections on the concave side appeared more effective in reversing lumbar AIS than placebo exercises. Incobotulinum injections with yoga appeared to be the most effective.

Keywords: adolescent idiopathic scoliosis, botulinum toxin, yoga.

This study was conducted in accordance with the Declaration of Helsinki and approved by the institutional Review Board CIRBI, now Advarra on December 2, 2020.

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It was registered at ClinicalTrials.org at NCT04922983 on 17 July 2021.

Neither Dr. Fishman nor Dr. Rosner have conflicts of interest regarding this paper.

The data for this study can be found on Figshare.

I. Introduction

Scoliosis is a three-dimensional spinal curve with side-to-side curve(s) and spinal rotation. It affects 2 - 3% of the world's population.[1] Of Earth's approximately 8 billion people, 160 – 240 million people suffer from scoliosis. Effective antibiotics for tuberculosis and vaccines for polio have made adolescent idiopathic scoliosis (AIS) nearly 90% of all scoliosis[2] Females are more likely than males to acquire the condition, the ratio changing from 1.4:1 in curves of 10–20 degrees to 7.2:1 in curves above 40 degrees.[2] Although asymmetric sports such as tennis and baseball have no bearing on scoliosis, dancing significantly raises the risk.[3] It is uncertain whether this is due to ligamentous and bone changes or to the greater flexibility of dancers, enabling asymmetric forces to curve the spine more readily.

When a curve's Cobb angle exceeds 25 degrees, braces are often implemented to deter progression, since this is the level at which most studies report the highest rates of progression.[4-7] However, several other systems make their own determinations: The Rigo–Cheneau classification stipulates its own guidelines for implementation, and designs and crafts braces in ways that may depart somewhat from the 25-degree demarcation.[8] It coordinates brace design with fabrication, using its own principles of correction, and thus has control over the relationship between when to prescribe and what is furnished. The soft Spine-Cor brace has its own system as well, with its own parameters of internal consistency.[9]

Generally, braces are not expected to diminish curvature but rather reduce curve progression.[10] Nevertheless, the Spine-Cor and Lyons braces have been reported to have corrective capacities.[11,12] When the goals of bracing were polled among authorities in the field, aesthetics, quality of life, disability, back pain and psychological well-being were found to be the most important goals in that order.[13] These goals are promoted naturally through curve correction as well. The same group judged the evidence in favor of bracing to be stronger than the evidence for any other conservative modality, with scoliosis-specific exercises second.[14] Nevertheless, discomfort, embarrassment at school, lowered self-esteem, body image[14] and consequent issues of compliance are relevant, and questions have

been raised about whether core stabilization, scoliosis-specific exercises, and even the use of a second orthotic or insoles improve braces' efficacy.[13,15]

Other conservative methods, such as the Schroth, and chiropractic systems, such as Pettibone and Clear, have mixed reports regarding efficacy, and physical therapeutic exercise programs are also currently being tested.[16-19] Greater clarity on ancillary treatments with braces is desirable, especially concerning the underlying principles that can guide therapeutic decisions.

Typically, surgical intervention is considered only when curves exceed 45 degrees. Surgery has rightfully dominated the field of scoliosis since it has been the most reliable and effective remediation for many years. The natural history of AIS suggests 0.4 to 2.2 degrees of annual progression, depending upon age, Risser number and curve type, although teenagers' spines are capable of much greater change.[4-6] When visiting their surgeons, young patients have an X-ray taken, and they and their families often are told of the 45-degree threshold for surgery. With or without braces, parents and their children with AIS are relegated to the passive role of "watchful waiting" unless and until curves reach 45 degrees.

Although genetic, anatomical and neuroanatomical correlates of AIS have been discovered[20-23] promising physiotherapeutic work to effectively stabilize and reverse scoliosis awaits high-quality studies that confirm it.[24] A reliable, innocuous method would be particularly valuable since, unlike major surgery, it could be instituted in patients with much smaller curves, when treatment would commence earlier and likely would not be as disruptive nor last as long.

Previous work suggests electrophysiological and hormonal muscular asymmetries are at work in AIS,[25,26] supporting the possibility that muscular imbalance may be a relevant factor in its pathogenesis. We tested this hypothesis by utilizing botulinum toxin type A, incobotulinum, a medication that temporarily weakens muscles, on the concave side of lumbar curves, and an asymmetrical yoga pose, the side plank, to strengthen the convex side. Incobotulinum has few other effects after intramuscular injection.

The hypothesis that muscular imbalance is important in AIS is also supported by a study finding that the Schroth method, a muscle-oriented treatment, significantly improved curves.[19] Further, this single yoga pose, the side plank, performed with the convex side of lumbar curves held inferiorly, was found to be helpful in lumbar AIS in multiple studies.[27-29] A randomized, controlled repeat of this method found it ineffective,[30] but close reading of that study reveals that unfortunately, the randomization of the intervention group was such that not a single patient with a lumbar curve was included in it.[31] In the current study, we used the side plank to strengthen the weaker (convex) side and added incobotulinum injections of the contralateral (concave) paraspinal, quadratus lumborum and psoas muscles to temporarily weaken the stronger side. Bracing of patients was not permitted during the test period to avoid a confounding factor. Testing the validity of the muscular imbalance hypothesis, the primary and secondary objectives of this study were to assess the benefits and the harms[32] of combining incobotulinum injections with yoga to reverse lumbar and thoracolumbar AIS.[28-30]

The current study has been approved by the Chesapeake IRB (now Advarra) and the FDA, since this use of botulinum toxin is virtually new in the United States. One other institution is studying it in a similar context.[33] The current study was made public on Clinical Trials.org NCT04922983 on 17 July 2021 and was accessed on that day. Recruitment began 17 July 2021.

II. Methods

This is a randomized, controlled study, with two non-botulinum groups: Group 1 received a placebo yoga pose only, while Group 2 received the intervention yoga pose and preservative-free normal saline (placebo) injections. The full intervention group, Group 3 received both the interventional yoga pose and botulinum injections.

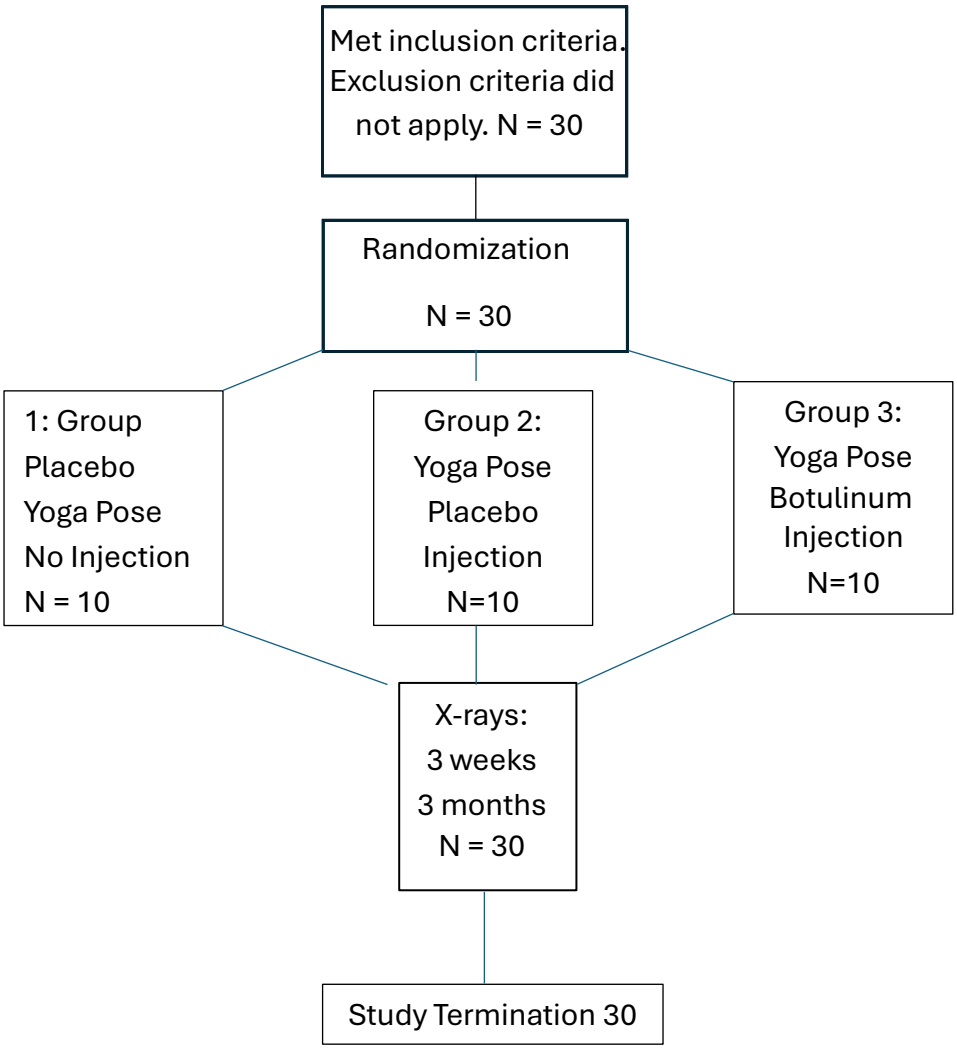

Figure 1: Flow Chart

a) Eligibility

i. *Inclusion Criteria*

- Age 12–20 years.
- Lumbar or thoracolumbar curve of 25°- 45°.
- Willingness to perform one yoga pose for as long as possible three times daily for three months.
- Parental or guardian agreement.

ii. *Exclusion Criteria*

- Neuromuscular or musculoskeletal disease, e.g., cerebral palsy, Guillain–Barre syndrome, Marfan's syndrome.
- Current use of brace.
- Previous spinal surgery.
- Previous exposure to botulinum toxin type A.
- Positive pregnancy test.

iii. *Particulars of the Study*

The study was conducted in private offices in Manhattan, New York, USA.

The study accepted non-pregnant applicants who had 25°-45° lumbar or thoracolumbar curves on Cobb X-rays completed less than 6 months before their visits. Group 1 patients were given a regular yoga pose, the plank, that consists of a symmetrical two-handed suspension of the upper body with extended elbows and lower body suspended on dorsiflexed feet. Group 2 patients were given the side-plank (*Vasisthasana)* in which the body is supported by one extended arm with the torso's coronal plane perpendicular to the floor and the lower body weight supported by the posterolateral foot of the convex side of the curve, and placebo injection of 0.33 cc normal saline injected into each muscle: the lumbar paraspinals opposite the apex of the curve, the quadratus lumborum opposite L3, and the psoas with needle entry approximately 7 cm. lateral to the L4 spinous process. Group 3 patients were given the side plank and injections of 33 IU incobotulinum into these same muscles. All injections were given on the curves' concave sides. Paraspinal and quadratus lumborum injections were performed with 1.5 inch inoject needles; the psoas injection was performed with

a 7 inch inoject needle; all injections were conducted under EMG guidance. Instructions to both placebo and interventional participants were that poses were to be performed three times daily for as long as possible each time. Patients' vital signs and weight were tested before the injections and again (except for weight) 15 min after the injections. Patients repeated their scoliosis X-rays at 3 weeks and 3 months. EOS technology was used whenever possible to minimize exposure to radiation. Checks on participants' compliance with the three-times-daily full plank or side plank regimen were made by telephone and email.

Power calculations based on previous papers[23-25] yielded 10 subjects in the control group and ten subjects in the study group, where alpha = 0.05 and (1 – beta) = 80%, (10 subjects per group). Statistical measures included regression analyses, both crude and adjusted for age, weight, Risser score, and sex. Randomization was conducted through random.org as patients qualified for the study presented in the office. There was no blocking.

Each patient or the parents of patients under 18 read and signed the Informed Consent Form. A medical assistant enrolled the patients; the office manager generated the randomized treatment group. The medical assistant prepared the syringe with preservative-free normal saline or lyophilized incobotulinum plus 1 cc of preservative-free normal saline, both colorless liquids. The participants, care providers and radiologists performing the initial and subsequent scoliosis X-rays and measuring Cobb angles were all blinded regarding group assignment. Apart from Group 1, which performed the two-handed 'placebo' yoga pose, and which of necessity was different in appearance from the intervention yoga pose, and the fact that this group had no injection, all procedures were indistinguishable to participants, care givers and radiologists. Mixed effects regression analyses were used to test the hypotheses, since differences between three groups was sought.

This study was conducted in accordance with the Declaration of Helsinki and approved by the institutional Review Board CIRBI of Advarra on December 2, 2020.

It was registered at ClinicalTrials.org at NCT04922983on 17 July 2021.

III. Results

Groups 1 and 2 made up control groups of 10 patients each, with 3 males in each group. Group 3 had 10 patients with one male. (See figure 1.) Mean age of controls and intervention patients: Group 1: 16.2 (S.D. 2.5); Group 2: 16.8 (2.8); Group 3: 15.8 (2.0). Mean weight of controls and intervention groups: Group 1: 119.3 lb. (10.7); Group 2: 117.5 lb. (20.2); Group 3: 126.7 lb. (13.0). Risser numbers: Group 1: 3.96 (.9) Group 2: 3.6 (1.4) Group 3: 3.7 (.7)

Table 1: Demographics

Group	Age	Male	Wt	Side	Size	Type	R#	FHx
Group 1	16.22	3	119.33	6 Rt	29.8	4S,2L,4TL	3.96	**50%**
SD	2.49		10.7		6.89		0.93	
Group 2	16.8	3	117.5	3 Rt	38.1	5S,2L,3TL	3.6	60%
SD	2.80		20.17		7.97		1.4	
Group 3	15.8	1	120.1	2 Rt	33	3S,3L,4TL	3.8	50%
SD	2.00		20.17		6.31		0.73	
Mean	15.1		119.0	3.7 Rt	33.63	2.6S,4.3 L,4TL	3.7	53%

Wt = weight.
Side = curve side.
Size =Cobb angle of lumbar or thoracolumbar curve.
Type =Curve type: S = "S" or "Inverted S" curve, L = lumbar, TL = thoracolumbar.
R# = Risser number.
FHx = Positive family history

Group 1 had 1 dropout, with two dropouts in both Groups 2 and 3 that were non-compliant at second or third X-rays. Three prospective patients experienced injection anxiety after randomization but before any treatment was initiated and therefore were not treated or included in the study. There were no reported injuries from the yoga pose in any group beyond a few days of sore shoulder and forearm muscles: one patient in Group 2 and one in Group 3 had transient complaints of this nature. These two patients continued the side planks on their forearms, but they did not otherwise alter their yoga routines. There were no changes in vital signs or later side-effects after administration of incobotulinum or placebo.

With rarely missed days, all patients reported performing the side plank or full plank at least twice daily beginning at a mean 30 s per side plank, with a mean initial cumulative reported dose of 80 s daily and ending at a mean 73 s per side plank after 3 months, with a mean cumulative dose of 160 s daily, during the three-

month period. Most participants performed the multiple side planks successively in the morning.

Mean lumbar scoliosis at study onset: Group1:29.8° (S.D. 6.68), range:25°-45°;Group 2: 38.1° (S.D. 6.52), range: 25°-45°; Group 3: 33.2° (S. D. 6.7), range: 25°-45°. Mean 3-week Cobb measurements were Group 1: 30.15°(S.D. 6.73.); Group 2: 29.4° (S.D. 9.19); Group 3: 24.0° (S.D. 8.3). The three groups were roughly equivalent at study onset. (See table 2.) Cobb measurements at 3 months were Group 1: 31.6° (S.D. 7.08); Group 2: 30.35° (S.D. 11.52) and Group 3: 21.0(S.D. 8.3).

Significant differences appeared between Groups 1 and 3 at three weeks ($p < 0.001$) and at 3 months ($p < 0.001$); between Groups 1 and 2 at 3 weeks ($p < 0.001$) and 3 months ($p < 0.001$). Group 3 was clinically significantly improved vs. Group 2 at 3 months (p = .056). (See tables 2 and 3 and figures2, 3 and 4.)

Table 2: Study Results

	Group					
	1		2		3	
	(N = 10)		(N = 10)		(N = 10)	
Variable	mean	sd	mean	sd	mean	sd
Age (yrs)	16.0	2.4	16.8	2.8	15.8	2.0
Weight (lbs)	119.3	13.7	117.5	20.2	126.7	13.0
Risser	3.9	0.9	3.6	1.3	3.7	0.7
Male sex (%)	0.30		0.30		0.10	
Score_T1	29.8	6.6	37.5	8.0	33.2	6.7
Score_T2	30.2	6.2	28.8	10.2	24.0	8.3
Score_T3	31.6	6.4	29.8	12.7	21.0	9.2
Change Score T2 minus T1	0.4	1.6	-9.1	5.8	-9.2	5.8
Change Score T3 minus T1	1.8	2.5	-7.8	7.3	-12.2	5.2

Table 2: sd = Standard deviation.
T1 = Cobb angle at study onset.
T2 = Cobb angle 3 weeks after study onset.
T3 = Cobb angle 3 months after study onset.

Table 3: Regression Results

Time Points		Comparison of Group 2 vs. Group 1			Comparison of Group 3 vs. Group 1			Comparison of Group 3 vs. Group 2		
		Beta	se	p-value	Beta	se	p-value	Beta	se	p-value
T2 minus T1	Crude	-9.1	2.2	< 0.001	-9.6	2.2	< 0.001	-0.4	2.0	0.85
	Adjusted[a]	-0.3	2.5	0.001	-9.9	2.5	< 0.001	-0.6	2.7	0.83
T3 minus T1	Crude	-9.6	2.4	< 0.001	-14.0	2.4	< 0.001	-4.5	2.4	0.076
	Adjusted[a]	-9.4	2.7	0.002	-15.1	2.6	< 0.001	-5.7	2.8	0.056

[a] *Adjusted for age, weight, Risser score, and sex.*
Table 3: se = Standard error.
T1 = Cobb angle at study onset.
T2 = Cobb angle 3 weeks after study onset.
T3 = Cobb angle 3 months after study onset.

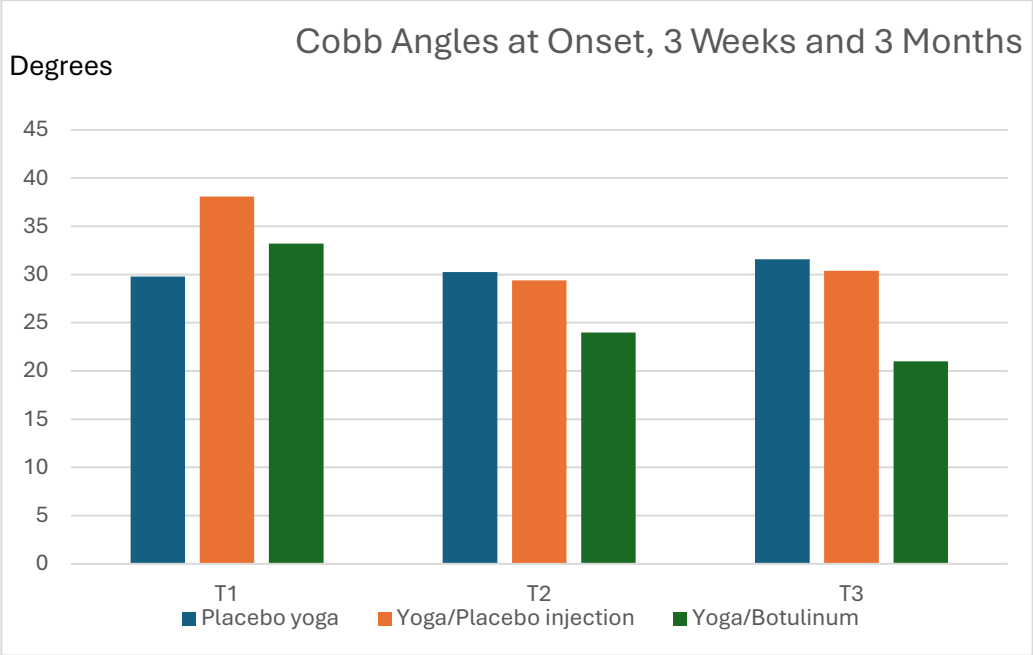

Figure 2: Greatest Reductions with Yoga and Botulinum

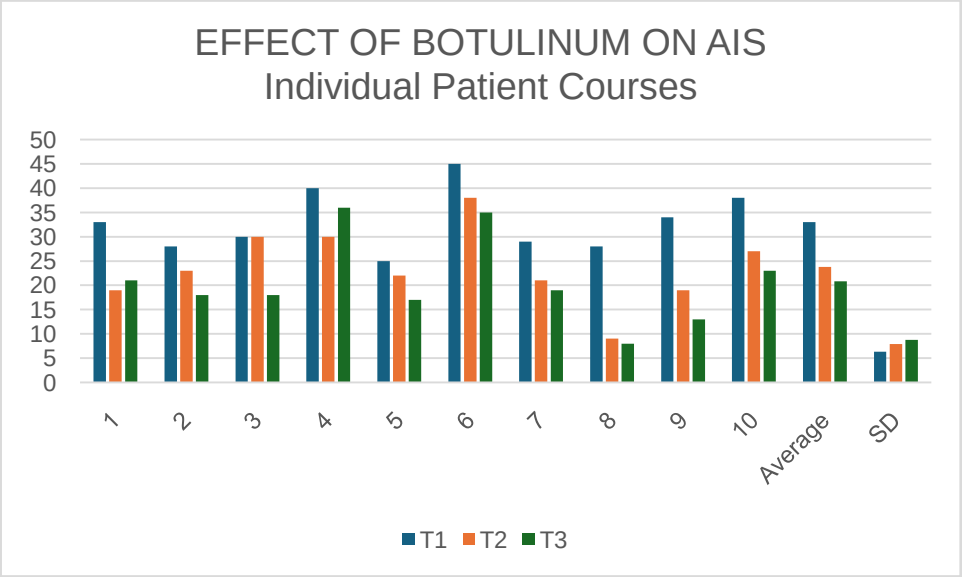

Figure 3: T1 = Study onset T2 = 3 weeks later. T3 = 3 months later. The magnitude of individual curve improvement: Group 1 (left-most columns) placebo yoga, Group 2 (middle column) true yoga pose and placebo injection, and Group 3 (right-most columns) true yoga pose and botulinum injection into the concave side's paraspinal musculature, the quadratus lumborum and the psoas muscles

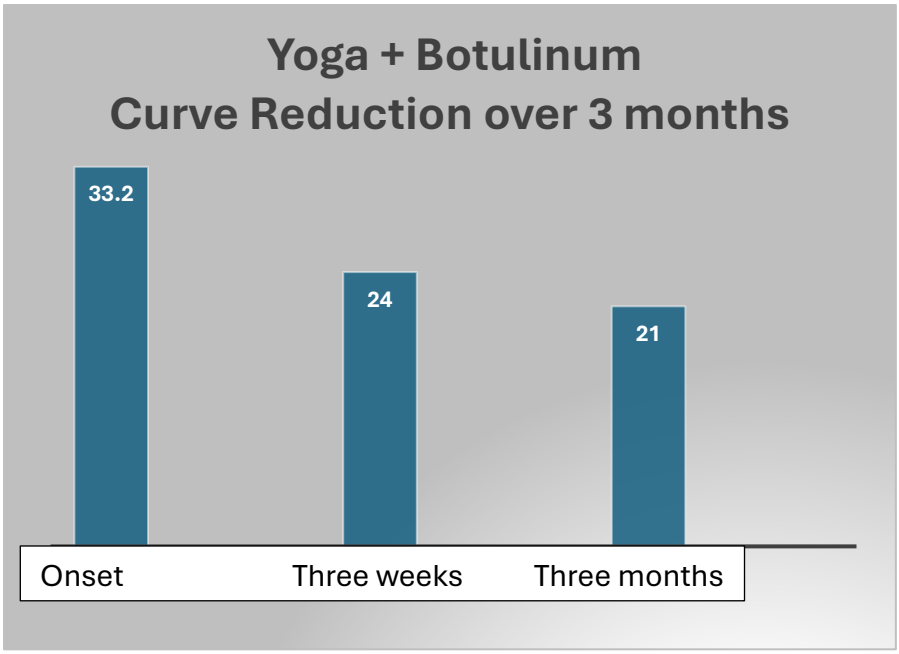

Figure 4: Mean curve reduction in Group 3 over 3 months = 36.75%

Apart from the transiently sore shoulders and forearms mentioned above, no harms were seen in any participants, although they were rigorously sought along SOSORT guidelines.[13]

IV. Discussion

The data, results and implications of this small study must be regarded with caution.[32] We view the spine as a tensegrity structure, a concept of the architect Buckminister Fuller which embraces configurations known for their strength and dynamic response to load,[34] like the human spine. Tensegrity structures are not held together by nails or rivets but by tension between their parts. Tent poles, Roman arches and radio antennae with their supporting cables are examples. The solar system, and the Bohr atom are somewhat extended examples, with gravity and centrifugal force, and electrical charges force providing the invisible tethers that generate tension and retain the structures' integrity. The spine may be seen as such a structure, but unlike the static edifices of architecture, the spine is held together by the quite variable tensions of the muscles that surround it. A spine-like tower by Frei Otto, *Vertebras Tensadas,* which curves in response to pressure from its cables is an architectural example of this. Seen this way, pervasive muscular asymmetry could be a major aspect of scoliosis.

Throughout the phylum *Chordata*, the spinal cord and the notochord are composed of many segments or metameres. These elementary units are interrelated in their control and in their movements and comprise a basic defining characteristic of the phylum. The spinal cord and its attendant ligaments, and, critically, its muscular attachments, always allow for movement and changes in leverage in all three planes, although this differs greatly from, e.g., thoracic to lumbar spine. In the turtle, it is the ribs that have coalesced to form the shell; inside it is a segmented creature with a flexible spine. To the authors' knowledge, in no case does a single bone form the spine the way the femur forms the sole support in the thigh. Throughout the phylum, from reptiles to humankind, the spine is always firm, but flexible in its multiple vertebrae,giving support, balance and leverage to our various bending, twisting, liftings and inclinations. However, many of the prominent surgeries of our day fuse the spine, rendering portions of it inelastic in a way nature has never allowed. An alternative therapy that repairs the spine without fixing it in a set conformation would be advantageous.

Significant improvement in Cobb angles at three weeks post-botulinum-injection in Groups 2 and 3 vs. Group 1 supports the hypothesis that some AIS is due at least in part to muscular imbalance, and that efforts to strengthen the convex muscles and temporarily weaken the concave muscles reverse the scoliosis significantly. Previous work with children with cerebral palsy had been ineffective and possibly dangerous,[25] but EMG work with children having AIS reveals that botulinum toxin alters side-to-side muscle recruitment ratios.[36] The simultaneous use of yoga and incobotulinum seems to have several advantages even after the two-month period of the medicine's activity:

1) Although inactive after two months, longer-term reduction in muscle tension is seen in botulinum toxin's cosmetic and dental uses.[37-41]

2) The botulinum weakens the strong (concave) side of the lumbar curve, enabling the actin and myosin fibers of the weak (convex) side to slide further together, increasing the number of cross bridges, and proportionately increasing their power to contract.[42]
3) Three-times-daily practice of the side plank yoga pose alone, held for as long as possible once daily, has been shown[27-29] to reverse lumbar curves due to AIS, through its strengthening effect on muscles of the convex side of the lumbar curve during the three-month period. The "head start" given by the incobotulinummay raise patients' enthusiasm, a critical ingredient in maximal compliance.

The adolescent idiopathic scoliotic spine is vulnerable to severe deepening of its curve. This is evidenced in the dramatic increase in Cobb angles seen in some patients. This may suggest that the actual advantage of the incobotulinum-plus-side-plank program may be even greater than those seen in this study of adolescents. This tendency of AIS to worsen dramatically in the teen years may to some extent obscure the actual benefit that intervention group patients received regarding the corrective influence of the yoga plus botulinum injections.

If the efficacy of this method is borne out in larger studies, it is sufficiently innocuous, low-cost and readily available to enable young people and their parents to embark on treatment of lumbar and thoracolumbar AIS as it develops, and before it reaches anatomically and socially significant levels.

V. Limitations of the Study

1) Although it reached statistical significance, this randomized controlled study is based on a small sample. Larger, randomized controlled trials are clearly necessary to demonstrate the efficacy of the botulinum-plus-yoga treatment more reliably.
2) A single blinded radiological opinion was utilized throughout this study. A second and even a third blinded radiologist (for non-unanimous assessments) would improve the objectivity in these studies.
3) The opposite limitation is also present: the ranges of the patients' Risser numbers, ages and curve sizes are too large. Some researchers find that a combination of bracing and exercise is differentially effective in AIS at different Risser numbers and this type of variability may apply to the current study's treatment as well[4-6] and should be investigated.
4) Studies have found that bracing plus exercise substantially improve curves in AIS.[43] Studies using bracing and exercise, including the side plank and botulinum toxin injections, might further advance and enhance conservative treatment.
5) Further study design can also raise the level of objectivity regarding harms, e.g., by measuring activities of daily living.[44] More specific considerations mentioned by leaders in the field may also be relevant, including aesthetics, quality of life, disability, back pain, psychological well-being, self-esteem, body image and embarrassment in high school.[13,14]
6) Longer follow-up is also necessary to demonstrate the value of the treatment. Two- or three-year follow-up or more would be desirable.
7) This study injected the minimal effective doses of botulinum. Dosages up to six times greater are patently safe.[45] It is possible that a proportionately greater effect would be seen with larger doses of incobotulinum. This study does not answer that important question.
8) One may additionally question whether the most relevant muscles have been treated. The iliocostalis, longissimus, semispinalis and spinalis muscles, as well as the external and internal intercostals and obliques, the superior and inferior serratus posterior, the subcostal, the quadratus lumborum, the latissimus dorsi and trapezius, the transversus abdominis, the rectus abdominis and the diaphragm itself might all function to laterally flex and/or rotate the spine. These muscles should be studied, both with EMG and possibly musculoskeletal ultrasound in different exercises and other types of exertion vis à vis strengthening them, and for appropriate dosages of botulinum toxin to weaken their contralateral counterparts.

VI. Conclusions

Muscular imbalance appears to play a part in the pathogenesis and longevity of adolescent idiopathic lumbar scoliosis. The side plank and botulinum toxin type A injections may be more effective in reversing lumbar AIS than a placebo yoga pose.

Funding

This study was funded by Merz Pharmaceuticals and registered with ClinicalTrials.org at NCT04922983 on 17 July 2021. Travel to and from our office was partially subsidized by the Childrens Scoliosis Foundation of California.

Institutional Review Board Statement

This study was conducted in accordance with the Declaration of Helsinki and approved by the institutional Review Board CIRBI, currently Advarra on December 2, 2020, approval number "The IRB approved the above referenced protocol and the site with the modifications listed below on 28 May 2021: Modifications to the Adult/Parent/Subjects turning Age of Majority (AOM) Informed Consent Form".

Informed Consent Statement

Written informed consent was obtained from all subjects involved in this study. In the case of minors, written informed consent was obtained from their parents or guardians.

Data Availability Statement

The data for this study can be found at Figshare.

Conflicts of Interest

The authors affirms that they have no conflicts of interest with the subject-matter or any part of the paper given above.

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