CHAPTER

2

Spinal cord stimulation and intrathecal baclofen therapy for patients with severe spasticity after spinal cord injury

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Abstract

Rationale. Spasticity is one of the main complications after the spinal cord injury (SCI). Most commonly, severe cases of spasticity are treated surgically with intrathecal baclofen therapy (ITB). Spinal cord stimulation for chronic pains (SCS) serves as an alternative for ITB. Both methods have their benefits and limitations. This study is aimed at development of a personalized SCS and ITB treatment algorithm for patients with severe cases of spasticity after SCI.

Materials and methods. The paper analyzes the treatment results of 66 patients with severe spasticity after SCI (50 men and 16 women, age ranging from 18 to 62), average age is 36.03 ± 12.29 y.o. Patients who chose surgery as a spasticity treatment option, received experimental stimulation, and after muscle tone reduction to a comfort level they were surgically implanted with a SCS system for chronic pain management. Patients with negative response to experimental stimulation were tested for baclofen and, based on the results, had a baclofen pump implanted. The patients were examined after 1, 3, 6 and 12 months.

Results. Surgical implantation of a SCS system was performed for 18 patients, ITB was used for 15 patients. After first 3 months of observation both groups demonstrated a significant improvement of spasticity index, but the SCS patients had better results. However, 6 months later

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the MAS scores, frequency of spasms and reflexes in both groups were the same. After 12 months of observation the ITB group exhibited a significant improvement of the MAS scores, compared with the control group, and reached the results, similar to the SCS group.

Conclusions. Surgical treatment of patients with severe spasticity after SCI should start with experimental spinal cord stimulation, and, in case of a positive response, be followed by SCS system implantation. Patients with positive response to the experimental stimulation exhibit a significantly prolonged response to treatment, without substantial differences from ITB patients.

Keywords

Spinal cord injury (SCI), Spasticity, Baclofen pump, Intrathecal baclofen therapy (ITB), Spinal cord stimulation (SCS)

1 Introduction

Treatment of patients with a spinal cord injury (SCI) is one of the most challenging issues in medicine. The percentage of SCI incidences in the overall amount of injuries is relatively insignificant and constitutes about 32–65 cases per million. However, these are people of young and productive age, most of whom (16–64%) die, while survivors become incapacitated. The cost of treatment for SCI patients is enormous, and the USA alone spend about 14.5 billion dollars a year on them.

The majority of SCI patients experience severe paresis and paralyzes. Gravity of neurologic deficiency is determined by the extent of the spinal cord damage, and most frequently those are the cases of tetraplegia, severe dysfunction of pelvic organs and total dependency on other people. Spasticity is experienced by 65–78% of patients within a year after the SCI (Adams and Hicks, 2005), limiting their independence in everyday skills, rehabilitation options, as well as resulting in contractures, pressure sores, infections and other complications. 23.4% of patients experience severe spasticity-related problems 2 years after SCI, and 31.2% start having those in a 5-year period (Holtz et al., 2017; Jacinthe et al., 2013).

Spasticity is mostly treated conservatively, using neuromuscular relaxants both as a monotherapy, and in combination with other medication; frequently they complement the complex rehabilitation strategy, involving physical therapy, physiotherapy, acupuncture and biomedical methods. Medication treatment is significantly less efficient in cases of severe spasticity, resulting in worsening of patients' condition.

Baclofen pump implantation with a subsequent surgical intrathecal baclofen therapy (ITB) is the most acknowledged treatment method for severe spasticity (Saulino et al.,2016a,b; Boster et al.,2016a,b). An alternative method of treatment (Barolat et al., 1995; Nagel et al., 2017; Pinter et al., 2000; Dekopov et al., 2015) is a surgically implanted spinal cord stimulation system for chronic pains (SCS).

The choice between these two methods predetermines the effectiveness of rehabilitation and overall results of treating patients with severe spasticity. Multiple aspects of SCS and ITB as independent and efficient methods of spasticity treatment

have been studied (Saulino et al.,2016b; Boster et al., 2016a,b; Barolat et al., 1995; Nagel et al., 2017; Pinter et al., 2000; Dekopov et al., 2015), but there are relatively few papers, comparing their efficiency (Biktimirov et al., 2016), just like there are no algorithms of personalized treatment, based on the method that proves to be more effective for each patient in particular.

The paper is aimed at developing an algorithm for using SCS and ITB in personalized treatment of patients with severe spasticity after SCI.

2 Materials and methods

2.1 Patients

The paper analyzes the treatment results of 66 patients with severe spasticity after SCI (50 men and 16 women, age ranging from 18 to 62), average age is 36.03 ± 2.29 y.o. (Table 1). All were treated at the Medical Center of the Far Eastern Federal University from 2012 to 2018. All patients gave their voluntary and informed consent to be a part of the experiment; the research did not involve patients under 18 years old. An informed consent for publishing the research results was obtained from all patients and their legal representatives. The research was approved by the Ethics Committee of the School of Biomedicine Far Eastern Federal University (FEFU).

2.2 Study design

The patients' eligibility for the trial was based on them having increased muscle tone (Score 3–5 based on the Modified Ashworth Scale), being at least 18 years old, and absence of pregnancy at the beginning of the study. Reasons for exclusion from the trial were presence of fixed contractures, serious physiological disorders, drug addition, purulent-septic complications at the time of selection, grave somatic pathologies, preventing patients from being operated on and further observation. By the time of admission into the Medical Center all patients have undergone at least one round of conservative treatment that resulted in only short-term decrease of muscle tone and did not significantly improve functional abilities of patients. All patients were offered surgery, however, some of them opted for conservative treatment—these patients (33 people) comprised the control group (Fig. 1); subsequently, a number of patients who refused surgery after a year of observation underwent an operation and became a part of the experimental groups.

Patients who chose the surgical treatment of spasticity received experimental stimulation for 3–5 days (SCS-trial group). If their muscle tone decreased to a comfort level as a result of the experimental stimulation, they were surgically implanted with a spinal cord stimulation system and became a part of the SCS group (18 people).

Patients with negative response to the experimental stimulation were tested for baclofen (ITB-trial group) and, based on the results, had a baclofen pump implanted, becoming the ITB group (15 people). The surgically treated patients were examined after 1, 3, 6 and 12 months.

Table 1 Group characteristics.

	Sex		Age			ASIA scale		Level of trauma			
	M	F	Min	Max	Mean, mode	A	Incomplete spinal cord break (B, C, D)	C1–C4	C5–C7	Th1–Th6	Th7–Th12
Control	25	8	18	62	35–36, 35	19	14	3	14	10	6
SCS	15	3	19	62	37–38, 29	14	4	2	7	5	4
ITB	10	5	18	60	33–34, 27	5	10	1	7	5	2

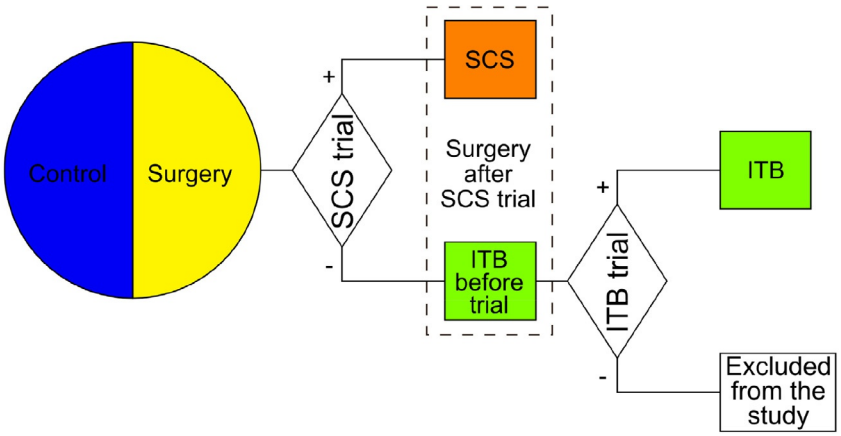

FIG. 1

Study design. Control—non-surgical patient group; SCS trial—spinal cord stimulation trail; SCS—spinal cord stimulation treatment patient group; ITB before trial—negative SCS trial patient group; ITB trial intrathecal baclofen trial—ITB pump.

2.3 Experimental stimulation

Stimulators (Eon C, Eon mini—Abbot, US (Saint Jude)) were implanted, using local anesthesia. Activation of a stimulator and adjustment of its parameters took place on the first day after the surgery. While adjusting the experimental stimulation, we relied on individual responses of the patients to the stimulation, since our review of scientific papers had not provided us with any certain instructions on that matter. Despite a wide range of stimulation parameters, presented in different publications (Nagel et al., 2017), the most effective settings for spasticity management in our trial group were frequency between 60 and 80 Hz, pulse width of 200–400 μs, amplitude was adjusted individually.

2.4 Test for baclofen

Intrathecal baclofen therapy was performed according to the common practice, approved by the international group of experts (Boster et al., 2016a). The test injection contained 50 mcg of baclofen (Novartis, Switzerland), in case of zero response the dosage was increased in stages by 25 mcg each 24 h (50, 70 and 100 mcg regimen). The results were assessed every 1, 2, 4 and 6 h after the injection. Test response was considered to be positive if spasticity level was 1 point lower than the initial score. In case of a positive response a baclofen pump was implanted.

2.5 Implanting baclofen pump

Surgery was performed with general anesthesia. Subdural catheter was placed at the Th4–5 level, the pump was implanted into a subcutaneous pocket in the left section of the abdominal wall. The patients were implanted with either Medstream II (Codman, US) or Synchromed II (Medtronic, US). According to the protocol,

approved by the team of experts (Boster et al., 2016a,b), after the pump implantation all patients received a daily 80 mcg baclofen injection, then each 2–3 days the dosage was increased by 10–20% until the comfort level of muscle tone was reached.

2.6 Clinical status

The severity of a spinal cord injury was assessed with the American Spinal Injury Association scale (ASIA), Modified Ashworth Scale (MAS), Penn Spasm Frequency Scale (PSFS), reflex intensity and motor function scales.

2.7 Statistical analysis of the results

Paired analysis of variance together with a Student's *t*-test was used for statistical processing of the results; cluster analysis with heatmaps and distribution graphs was instrumental in establishing subgroups for further processing of the results. The Mann-Whitney *U*-test was used to compare the ITB subgroup with the control and SCS groups, while the Wilcoxon signed-rank test was used for assessment of change dynamics in the ITB subgroup. The multi-factor analysis of variance with an *F*-test and the Mann-Whitney *U*-test a posteriori with the Bonferroni correction were used for comparing patients' results at 1, 3, 6 and 12-month periods after the surgery.

3 Results

3.1 Effectiveness of experimental stimulation of spinal cord and test for baclofen

The SCS-trial group predominantly had patients with completely damaged cervical and upper thoracic regions of the spinal cord (Table 1), total loss of motor and sensory body functions in the areas below the injury together with central dysfunction of pelvic organs. The clinical status of these patients was similar to the control group (Fig. 2). After the stimulation significant changes in the patients' condition

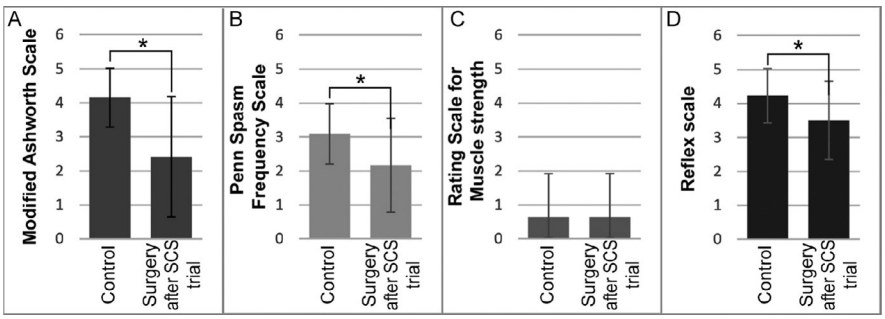

FIG. 2

Comparison of spasticity in the control group and the surgical group after SCS trial. (A, B, D)—$*P < 0.05$ (Student test).

($P < 0.05$) were observed, based on the MAS, spasm and reflex scales, while motor function scales did not indicate substantial changes.

The analysis of data distribution (Fig. 3) showed a significant increase in the variance on the MAS, spasm and reflex scales that allowed to distinguish two subgroups of patients after a subsequent cluster analysis with heatmaps (Fig. 4). The first subgroup included patients with significantly improved clinical status, as compared to the control group, (hereinafter referred to as SCS subgroup), while the second subgroup included patients without significant changes.

The second group of patients was tested for baclofen (Fig. 5). The Wilcoxon signed-rank test showed statistically significant improvements on the MAS, spasm and reflex scales after comparing the clinical status of patients before (ITB-before trial subgroup) and after (ITB subgroup) being tested for baclofen, while there were no changes in motor functions registered (Fig. 5A3–D3).

The ITB group exhibited significant changes in their original clinical status when compared to the control group, the changes were registered on the MAS, spasm and reflex scales (Fig. 5A1–D1), while the comparison of the SCS and ITB groups did not indicate any substantial differences (Fig. 5A2–D2). The Mann-Whitney *U*-test registered the difference on the spam and motor function scales, but, practically speaking, they bear no clinical significance.

3.2 Long-term result of observing the patients

One month later the multi-factor analysis of variance revealed significant differences between the control group and two experimental ones in all the conducted tests, excluding the motor function scale (Fig. 6A1–D1). The SCS group exhibited the best results on the MAS, spasm and reflex scales. No significant differences from the control group on the spasm and reflex scales were discovered for the ITB group.

Three months later the SCS group retained the best results in the clinical status; both the MAS and spasm scales showed significant difference from the control and ITB groups (Fig. 6A2–D2).

Six months later clinical status of the SCS and ITB groups was significantly different from the control group. However, there were no substantial dissimilarities between the experimental groups. The ITB group demonstrated a notable improvement on the motor function scale both compared to the control group and to the one with an SCS (Fig. 6A3–D3). Twelve months later the results proved to have no substantial differences from the previous from the 6-month period (Fig. 6A4–D4).

The analysis of dynamic changes in the compared groups indicated more significant results by the 6th month of observation, that stabilized by the 12th month of observation (Fig. 7). Clinical status of the ITB group was similar to that of the SCS group on the MAS, spasm and reflex scales, while the ITB group also had the best results on the motor function scale (Table 2).

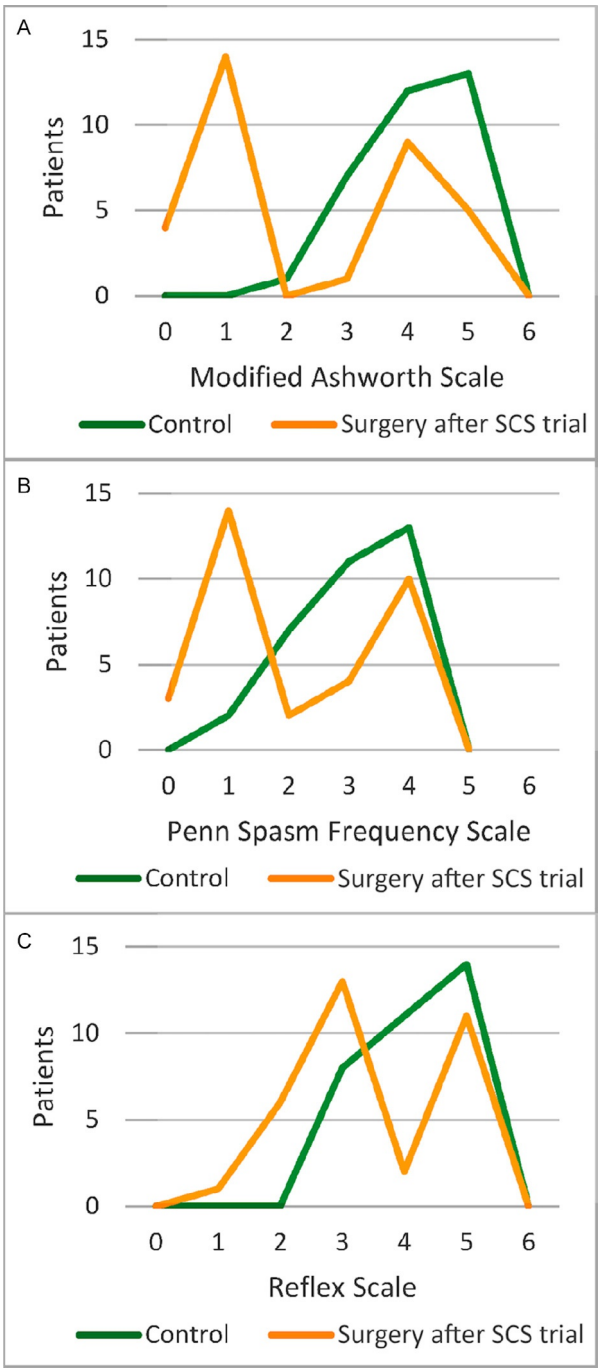

FIG. 3

Change the graph of the statistical distribution of the results of SCS tests.

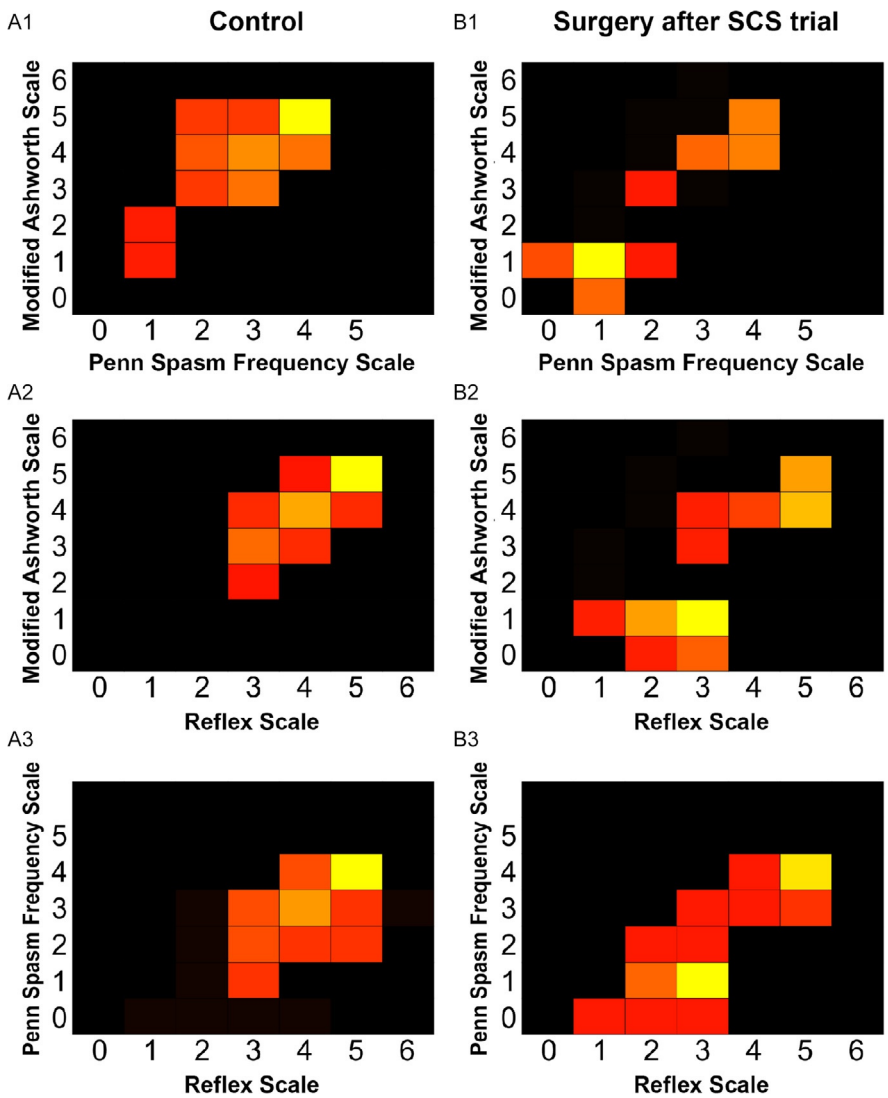

FIG. 4

Heatmap of trail statistics. (A1–A3)—tests of normal distribution of results before the SCS trial; (B1–B3)—are separated into clusters according to the reactions to the SCS trial. On the map shows the division of the patients into two groups of SCS trial reactions.

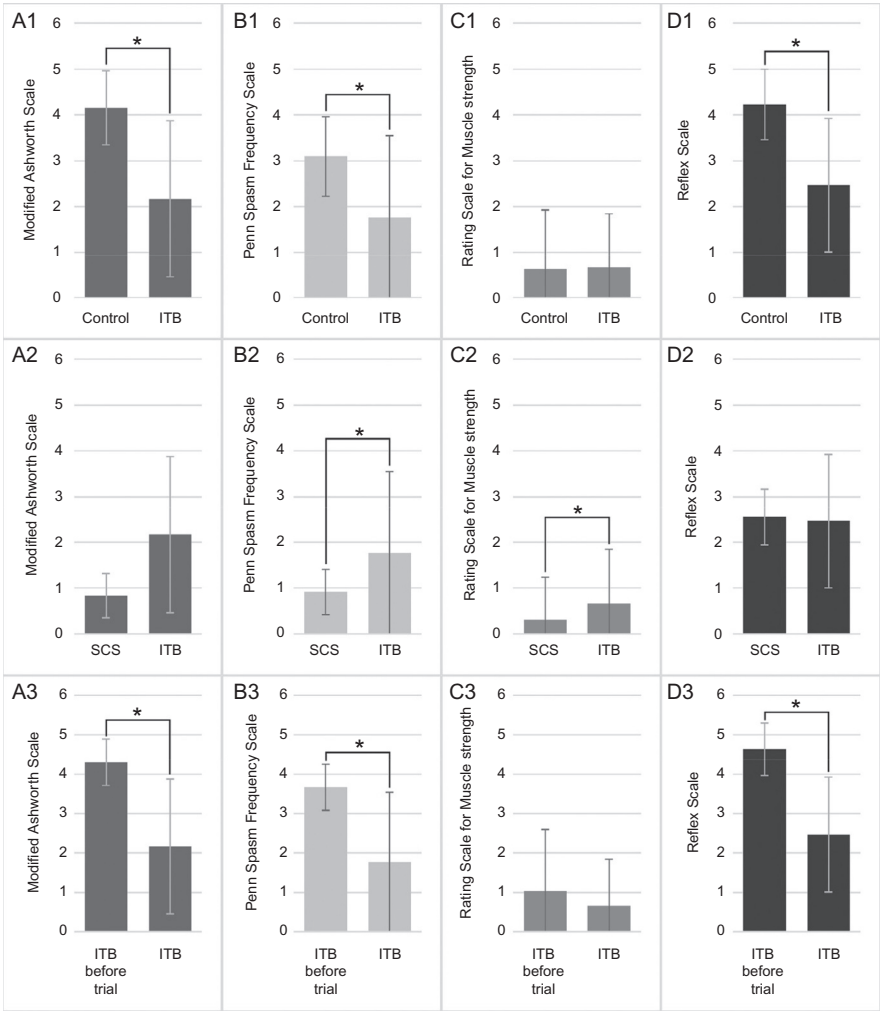

FIG. 5

Comparison of ITB group test results after trial. (A1–D1)—Comparison of patients of the control and group after the baclofen trial. Significant decrease in spasticity was observed on the MAS, PSFS and Reflex scales; (A2–D2)—Comparison of the results of SCS and ITB trials, in the respective groups. The significant difference was observed in the PSFS and Rating Scale for Muscle Strength; (A3–D3)—Comparison of the results of spasticity in the ITB group before the ITB trial and after. The statistically significant decrease was observed in spasticity on the MAC, PSFS and Reflex scales. (A1, B1, D1, B2, C2)—$*U_{Emp} < U_{Crit}$; $\alpha = 0.05$ (Mann-Whitney test). (A3, B3, C3)—$*T_{Emp} < T_{Crit}$; $P < 0.05$ (Wilcoxon rank-sum test).

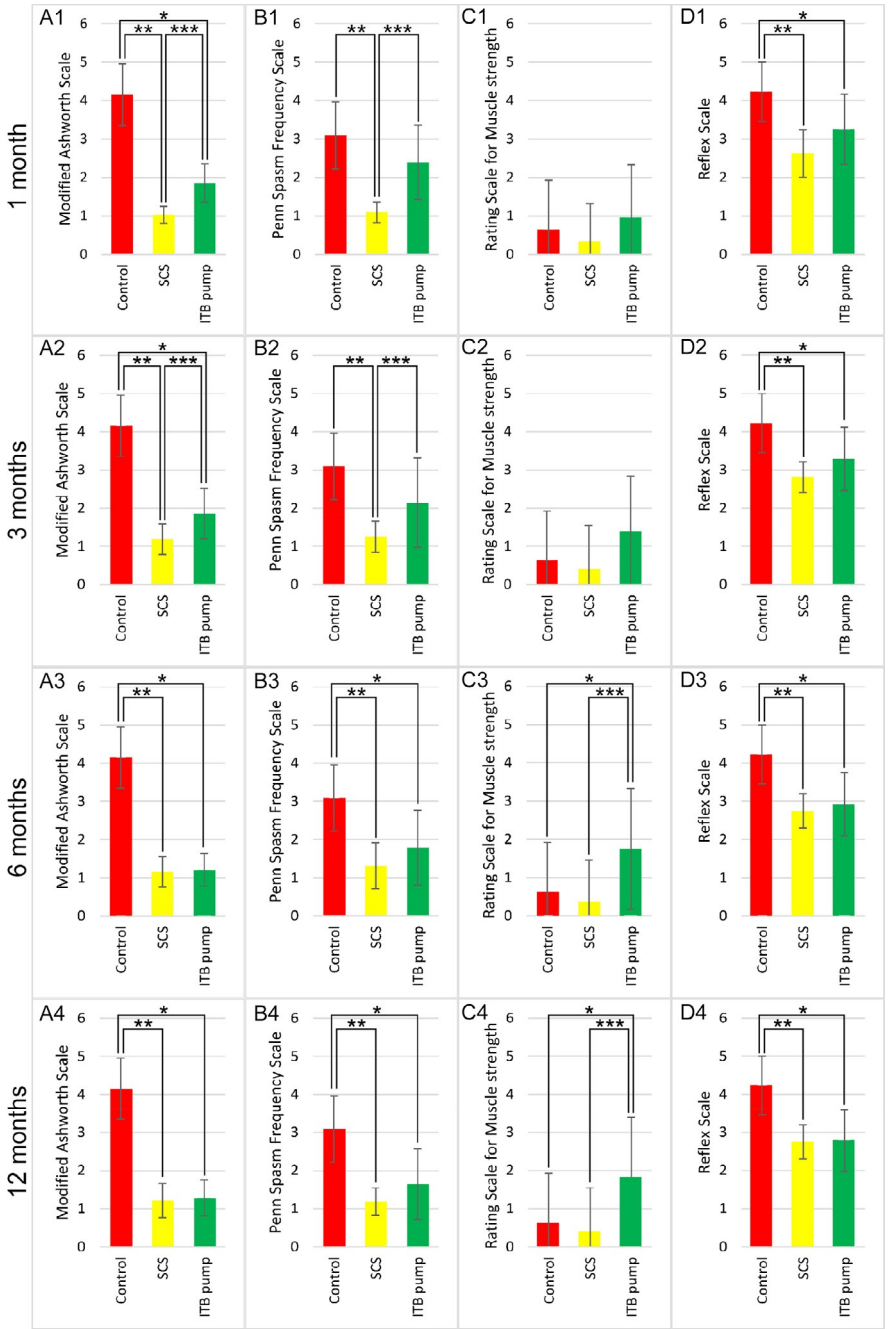

FIG. 6

Dynamics of changes in spasticity indices according to MAS, PSFS, Rating Scale for Muscle Strength and Reflex scales. Control points: 1, 3, 6, 12 months after treatment start. (A1, B1, D1, A2, B2, D2, A3–D3, A4–D4)—*, **, ***$U_{Emp} < U_{Crit}$; $\alpha = 0.05$ (ANOVA, post hoc test: Mann-Whitney test with the Bonferroni correction).

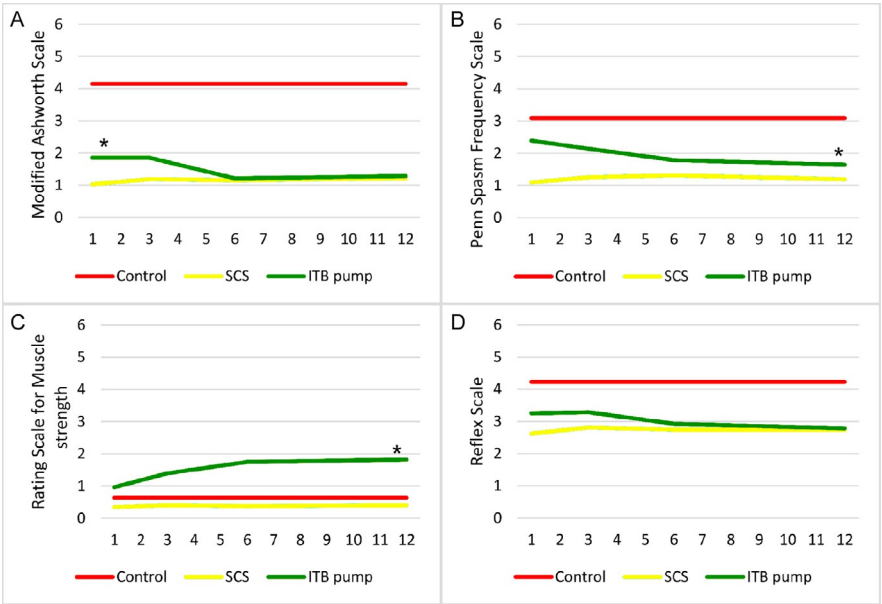

FIG. 7

The dynamics of changes in spasticity during the treatment. Control points: 1, 3, 6, 12 months after treatment start. (A–C)—Significant changes in spasticity of ITB group results was observed in MAS, PSFS and Rating scale for Muscle Strength scales. (A, B, C)—$*T_{Emp} < T_{Crit}$; $P < 0.05$ (Wilcoxon rank-sum test).

4 Discussion

The majority of our patients with SCI experienced severe spasticity and almost complete damage of the spinal cord anatomy. The gravity of their diagnosis provides grounds for considering these patients eligible for a pump implant, according to the expert guidelines for intrathecal baclofen therapy (Saulino et al., 2016b).

Due to the lack of commonplace protocols for selecting patients to receive neuromodulation, we carried out an experimental stimulation of spinal cord at the first stage of patients' selection for a subsequent surgery. Incidentally, the patients who exhibited a positive response to this method of stimulation were people with spinal cord impairment of Grade A according to the ASIA classification, i.e., patients with no sensory or motor function below the injured region.

We noticed that the patients with complete spinal cord injury and predominantly phasic and tonic spasticity, determined by the MAS, had better response to the experimental stimulation, unlike the patients with a high level of external spasticity, reflected in higher scores on the Penn scale. All our observations were proven by the statistical analysis of data that did not indicate a significant difference between the

Table 2 Parameters of spasticity before surgery and 12 months of follow-up after surgery.

	Modified Ashworth Scale (MAS)		Penn Spasm Frequency Scale (PSFS)		Rating Scale for Muscle Strength		Reflex scale	
Group	**Before**	**12 m**	**Before**	**12 m**	**Before**	**12 m**	**Before**	**12 m**
SCS	3.86±0.8	1.22±0.45	2.67±0.75	1.19±0.36	0.31±0.93	0.41±1.14	3.89±0.7	2.75±0.45
ITB	4.5±0.68	1.29±0.47	3.6±0.74	1.64±0.93	1.03±1.56	1.82±1.56	4.63±0.67	2.79±0.80
Control	4.11±0.87	4.15±0.81	3.18±0.86	3.14±0.92	0.64±1.25	0.64±1.12	4.20±0.83	4.23±0.82

SCS and ITB patients' spasticity levels at the pre-surgery stage, both on the MAS and reflex scales, however, there was a clinical and statistical difference on the spasm frequency scales.

Similar observations could be found in the paper of Barolat et al. (1995) who stated that spinal cord stimulation was less effective if a patient experienced intense spasms, and he recommended considering these patients eligible for baclofen pump implantation.

This statement is difficult to prove at present moment, since the existing neurophysiological studies and autopsy materials (Heald et al., 2017; Sangari et al., 2019) show that patients with complete spinal cord injury in 60–70% of case have no neurotmesis and can retain descending control of spinal cord circuitry. Hence, each case requires a thorough multifaceted analysis at different rehabilitation stages and discovery of cause and effect while analyzing different spasticity treatment methods.

For instance, Biering-Sørensen in his 2006 review compared the most widespread scales (such as MAS, AS, spasm scales, pendulum test) and instrumental methods of spasticity analysis (myography, isokinetic dynamometry) and concluded that there was no completely reliable sensitivity test or method, showing a cause-and-effect connection of clinical symptoms of spasticity, the degree of spinal cord injury and scale cores. There is a possibility that in not so distant future artificial intelligence (neural networks) (Kim et al., 2020; Park et al., 2019), robotic systems (Seth et al., 2015), state-of-the-art neuroimaging technologies (functional MRI, DTI, tractography), allowing to visualize the damage of spinal cord parenchyma and ascending and descending tracts of the white matter (Alizadeh et al., 2018; Zhao et al., 2018), will provide a chance to give an accurate assessment of the spinal cord damage extent and design models of treatment results, using various technologies without invasive tests.

In terms of electrode placement and selecting stimulation settings we referred to the paper by Pinter et al. (2000). An electrode with eight cylindrical contacts was implanted at the Th10–L1 level (optimal Th (11)12–L1) along the central line. Stimulation settings: frequency 60–80 Hz, pulse width of 200–400 μs, amplitude was around 3–10 mA and frequently depended on the body position.

We noticed that if at the selection stage a patient experienced a decrease in spasticity in lower extremities that reached a comfort level almost immediately after the beginning of the experimental stimulation, this effect remained for the whole observation period. At the same time, if an electrode was placed precisely along the central line, the positive effect was achieved after activation of any contact. It was registered early in the study that if the electrode with programmed upper contacts (usually 1st–4th) was placed at the Th10–12 level, patients experienced unpleasant sensations in subcostal arch or upper abdomen area. These unpleasant sensations disappeared after reprogramming stimulation via lower contacts. That is why in later stages of our study we implanted the electrode at the lower edge of Th11–L1 level, as shown in the figure.

Interesting results were obtained during the analysis of the motor function scale scores that had neither clinically, nor statistically significant changes in the

experimental stimulation group, when compared to the control group. This phenomenon could be explained by the fact that the SCS group mostly included patients with clinical symptoms of spinal cord neurotmesis.

Another group of patients (subsequently not having participated in neurostimulator implantation) experienced unpleasant sensations in their extremities, and with larger amplitude some patients registered an increase in tonic spasticity, as well as a stronger pain that persisted even after some time. Any attempts at reprogramming the stimulator (changing the frequency, pulse width, stimulation intensity, stimulation time) had no effect on the final result.

At the second stage of selection process the remaining 15 patients were tested for baclofen, resulting in clinically and statistically significant improvement of scores on the MAS, Penn spasm and reflex scales. However, there were no substantial changes on motor function scale, not unlike in groups with the experimental stimulation.

The first stage allowed us to create two experimental groups: a group with implanted spinal cord stimulators (SCS) and a group with implanted baclofen pumps (ITB). Comparing the experimental stimulation and test for baclofen, we obtained the results that had not been described in the reviewed scientific literature. Patients of both groups exhibited clinically and statistically significant decrease of spasticity, when compared with the control group, on all scales, except the motor function scale. Also, there was no substantial difference registered on the Ashworth and reflex scales between the SCS and ITB groups after the conducted tests. However, the spasm and motor function scales revealed significant differences. A better result on the spasm scale was achieved in the experimental stimulation group that could be explained by the fact that patients of this group experienced lower level of spasms, since patients with high level of spasms did not respond to the test stimulation and were randomized to the ITB group. The ITB group had better results on the motor function scale that could be related to the fact that more patients of that group did not have a complete damage of their spinal cord, according to the ASIA classification.

The analysis of the post-surgery observation data showed that at the moment of being discharged from the hospital the patients experienced a notable decrease of spasticity to a comfort level. One month after the surgery a significantly lower muscle tone was registered in both experimental groups (SCS and ITB) when compared to the control group on the MAS, while the level of spasticity was significantly lower in the SCS group than in the one with ITB. It was also discovered that ITB patients had a notable improvement on the spasm frequency and reflex scales, but this improvement was not significantly different from the control group. Another distinctive feature at this stage was no significant change on the motor function scale in both experimental groups, when compared to the control group.

Therefore, observation results after 1-month post-surgery period show that patients with a SCS had statistically better progress than the ITB group, and this fact could be attributed to the latter ones being at the stage of adjusting baclofen dosage, performed according to the protocol suggested by the L. Aaron's international expert team on intrathecal baclofen therapy (2015), while the patients with implanted neurostimulators had a chance to personally adjust the tone level of their lower

extremities depending on their everyday tasks without attending the hospital, and during the scheduled examination we recorded patients' comfort level of spasticity.

Similar statistics was registered at the second examination after 3 months, however, at that time the ITB group showed improvements on the spasm, reflex and motor function scales.

By the 6-month mark both ITB and SCS groups exhibited stabilization and equalization of spasticity levels. Changes in spasticity scores become significant when compared to the control group on the MAS, spasm frequency and reflex scales, and they are not substantially different from each other. ITB patients showed notable improvements on the motor function scale compared to both the SCS group and the control group.

At the 12-month post-surgery mark we registered no statistically relevant changes on all scales, the scores remained stable.

The changes, registered in the second half of a 12-month period after the surgery, especially the ones in ITB group, could be attributed to the fact that most patients had adjusted their dosage by the 6-month mark and, therefore, their spasticity level stabilized. At the same time, better motor function in ITB group could be mostly explained by the fact of the patients in this group having clinically partial damage of the spinal cord. Lower spasticity level allowed them to improve their control over their motor function.

Over 40 years ago Cook and Weinstein (1973) published the first reported case of decreasing spasticity with spinal cord stimulation system for pain management. Until the mid-1980s this method had been actively developed, but Penn and Kroin (1984) announced the effects of intrathecal baclofen therapy for patients with SCI. High efficiency and sensitivity of intrathecal baclofen therapy basically predetermined the preference of this method by medical experts.

There is no doubt that intrathecal baclofen therapy is effective for managing cerebral and spinal spasticity, and our study is a proof of that. However, baclofen therapy should be chosen in case of ineffectiveness of other methods that are not extensively studied, since there is no common algorithm established for their selection in each specific case. As a result of our work, we developed and tested a protocol for personalized treatment of patients with severe spastic syndrome as a result of SCI (Fig. 8), which was described in the materials and methods section.

Nevertheless, the method of intrathecal therapy has a series of disadvantages, the biggest one being a necessity to attend a hospital regularly in order to refill the pump. An average interval between the refills (Chan et al., 2018) is 57 days. This fact was a major contributor to our search for alternative and more effective ways of spasticity treatment, since patients of our hospital live in remote and not very accessible places, so attending the hospital 4–6 times a year for a refill is quite challenging for them. Apart from the necessity of refilling the pump every 2 months, there is at least 30% risk of post-surgery complications for patients with an implanted pump (Borrini et al., 2014; Motta and Antonello, 2014; Paskhin et al., 2017; Pucks-Faes et al., 2018; Winter et al., 2018), and lack of medical attention in case of disruptions of baclofen delivery to a subdural space of spinal cord could result in withdrawal

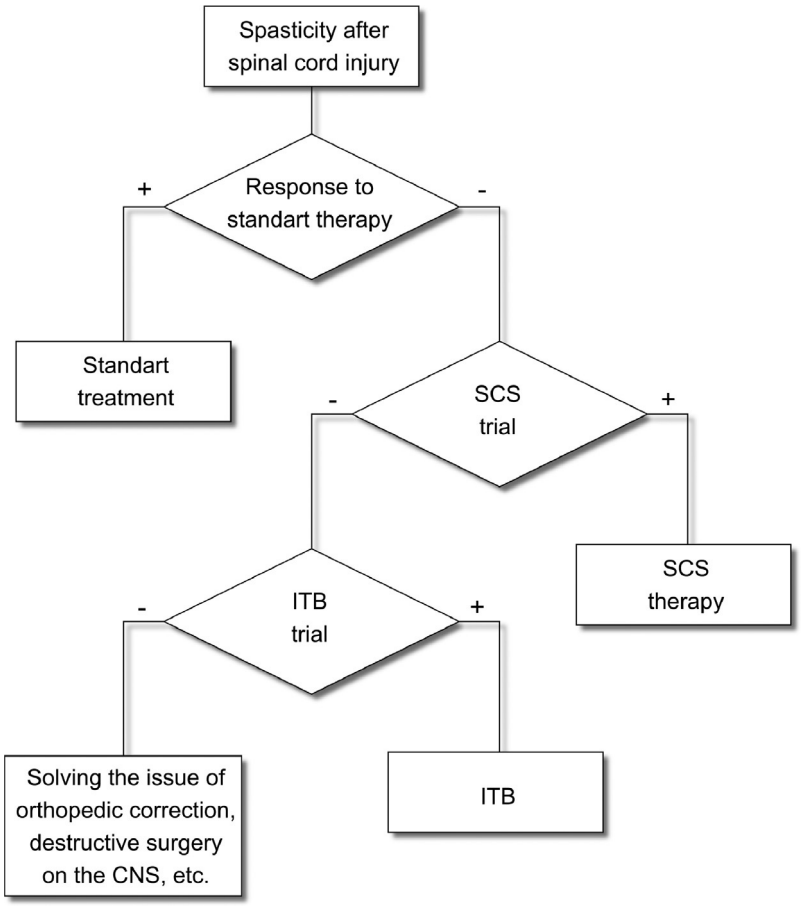

FIG. 8

Effective treatment algorithm based on SCS and ITB testing.

syndrome or overdose that might have serious consequences, even death. Patients with implanted neurostimulators also run the risk of complications (Eldabe et al., 2016), but they are mostly related to electrode migration and could be resolved with a simple stimulator reprogramming, while only 10% of complications require a surgery, and they are not fatal.

Our arguments on the underrated nature of spinal stimulation are supported by one incident during our trial. During the selection process for the surgery one of the patients with a positive response to spinal stimulation requested to be tested for baclofen. We ran the test that gave a positive response, almost identical to the one after the experimental stimulation. Subsequently, the patient was offered to choose between the surgical options. Having considered pros and cons of both methods, she chose spinal stimulation.

One more argument in favor of using spinal cord stimulation is some scientific papers, presenting new rehabilitation options for patients with lower extremities dysfunction after a spinal cord injury (Gill et al., 2018; Harkema et al., 2011). Electrode placement on the lumbar enlargement allows to generate tonic and rhythmic patterns of motor activity in patients with complete loss of motor function and qualitatively improves walking skills of patients with partially damaged spinal cord (Lavrov et al., 2008; Wenger et al., 2016). It is the study of the possible applications of spinal cord stimulation that is our objective for the further research in the area of treating complications after a spinal cord injury.

Another important observation is that the majority of patients with implanted neurostimulators will have to replace them after 6–24 months since the date of implantation due to the intense nature of stimulation with maximum settings; this replacement was provided for our patients who continued their check-ups in our facilities after the trial was completed. That is why we almost completely switched to using rechargeable systems a short while after the study.

5 Conclusions

Surgical treatment of patients with severe spasticity after SCI should start with an experimental stimulation of spinal cord, and, in case of a positive response, continue with SCS system implantation. Patients with positive response to the experimental stimulation retain a significantly prolonged effects of treatment without substantial differences from ITB patients.

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