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Preliminary Results of Chronic Intrathecal Therapy in the Treatment of Spastic Syndromes of Various Etiologies

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Objective. The method of chronic intrathecal infusion of lioresal (baclofen) and opioid analgesics can be effectively used in severe spastic parapareses and tetrapareses that are resistant to conservative treatment and treatment with botulinum toxin. The objective of this study is to evaluate the efficacy of chronic intrathecal therapy in the treatment of generalized spastic syndromes of various etiologies. **Material and methods.** We operated on 15 patients with generalized spastic syndrome resistant to botulinum toxin, including 8 patients with cerebral palsy, 5 patients with the sequelae of spinal cord injury, 1 patient with the sequelae of traumatic brain injury, and 1 patient with the sequelae of purulent epiduritis. The efficacy of surgical treatment was assessed on spasticity (Ashworth) scale and locomotion status (GMFM-88 and Arens) scales and subjected to statistical analysis. **Results.** In most cases, significant decrease in spastic syndrome was observed from 4.26±0.7 before the surgery to 1.8±0.67 after the surgery ($p<0.004$). Along with regression of spasticity, statistically significant positive dynamics of locomotor function was observed in 8 cases. Conclusion. Chronic intrathecal therapy results in statistically significant regression of spastic syndrome, increase in the range of active and passive motions, and improvement of the locomotor function.

Keywords: *spasticity, chronic intrathecal therapy, baclofen pump.*

Spasticity syndrome occurs in a number of severe neurological diseases, such as cerebral palsy (CP), multiple sclerosis, the sequelae of an acute cerebrovascular accident (CVA), and traumatic brain and spinal cord injuries. Spasticity leads to the limitation of the range of active and passive motions and complicates rehabilitation treatment [1—4].

In most cases, the capabilities of conservative treatment of spastic syndromes are limited. The use of neuromuscular blockade with botulinum toxin in patients with diffuse increase in muscle tone is ineffective in many muscle groups. Reduced sensitivity to drugs and occurrence of adverse effects of anti-spasmodic therapies necessitate more radical methods of treatment of spastic syndrome [1, 2].

Since the mid-twentieth century, destructive neurosurgical operations on the spinal cord and peripheral nerves, such as rhizotomy, neurotomy, and DREZ-operations, are widely used. However, despite the high efficacy, these interventions resulted in a number of complications, such as uncontrolled muscle weakness, dysfunction of pelvic organs, and pain syndrome. Destructive operations do not allow dosing and adjusting the level of muscle tone, causing additional difficulties in rehabilitation treatment [5—7]. Since the 1970s, the method of chronic electrical stimulation of the spinal cord was implemented to clinical practice. It was effectively used in patients with mild spastic paresis [8]. Reversible and manageable effect of action, which allows avoiding uncontrolled muscle weakness, is an important advantage of this method compared to destructive surgeries. However, experience has shown that chronic electrical stimulation of the spinal cord was not sufficiently effective in patients with high level of spasticity (4—5) [9].

Further development of neurosurgery and neuromodulation in the early 1980s led to development of new effective method of treatment of spastic syndrome, chronic intrathecal baclofen therapy (ITB) using implantable pumps. In 1984, R. Penn and J. Kroin first reported the successful treatment of spasticity using ITB [10]. Later on, a number of studies showing the efficacy of ITB in patients with multiple sclerosis and the sequelae of spinal cord injury have been published. In 1991, the report on the efficacy of administration of baclofen in CP patient was published, and as early as in 1993, the effectiveness of administration of ITB in treatment of spastic CP was confirmed [8, 11].

Currently, ITB is widely used to treat spastic syndromes of various etiologies.

Material and methods

The study group consisted of 15 patients, including 9 (60%) males and 6 (40%) females; mean age was 31.33±10.75 years in both groups (**Table 1, 2**). Spasticity was the result of CP in 8 (53%) patients, spinal cord injury in 5 (33%) patients; traumatic brain injury in 1 (7%) patient, and purulent epiduritis in 1 (7%) patient. Five (33%) patients had lower spastic paraparesis, and 10 (66%) patients had spastic tetraparesis. Three CP patients also had a hyperkinetic syndrome, 9 patients had pathological scissor legs with underlying spasticity in the hip adductor muscles, 8 patients had equinus foot with underlying spasticity in the lower leg triceps. In 7 cases, spasticity prevailed in the biceps and brachial muscle,

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causing flexion contracture of the elbow. In one case, spasticity occurred in the triceps muscle of arm, which manifested as pathological extension contracture of the elbow. One patient had nocturnal motoric automatisms in the lower limbs with underlying lower spastic paraparesis.

Before the surgery, all patients received conservative medical treatment with centrally-acting muscle relaxants (baclofen, tizanidine). In all cases, the effect of the therapy was insufficient.

Nine patients underwent one to three courses of therapy with botulinum toxin before the surgery. In 3 cases, it had no effect; in 6 cases, good clinical effect was observed at the beginning of therapy, however, repeated blockades were noneffective. Six patients with tetraparesis were not treated with botulinum toxin in connection with diffuse spastic syndrome.

All patients were included in the study from 2008 to 2013. Follow-up period ranged 0.5 to 5 years. The following inclusion criteria were used:

1) high level of spasticity — 3 points and more;
2) resistance to conservative drug therapy;
3) resistance to physiotherapy and rehabilitation therapy;
4) incapability of orthopedic correction of contractures in the context of spastic syndrome;
5) positive results of baclofen screening test;

Exclusion criteria included:

1) severe deformities of the musculoskeletal system;
2) general contraindications to surgery and general anesthesia;
3) negative results of baclofen screening test;
4) pharmacoresistant convulsive disorders;
5) impossibility of regular refills of the pump for some reason or other (residence of a patient in outlying areas, economic problems).

The patients were preoperatively examined by a neurosurgeon, neurologist, physiotherapist, and orthopedist. In all muscle groups, the level of muscle tone was graded on the Ashworth scale between 1 and 5 points. The range of active and passive motions was also assessed, including video recording of standard motor tests. Locomotor status was assessed according to the normalized GMFM-88 scale in CP patients, and on the Arens scale in other patients. The same survey was conducted 6, 12, and 24 months after the surgery. Preoperative and postoperative values of the level of muscle tone and locomotion status were subjected to statistical analysis using Wilcoxon test; the value lower than 0.05 was considered statistically significant.

Positive baclofen screening test was of key importance for inclusion of patients in the study. Patients were hospitalized for 3—4 days to conduct the test. The test was carried out at the intensive care unit with obligatory insertion of peripheral venous catheter and monitoring of the heart rate, blood pressure, and oxygen saturation, as well as the capability of artificial lung ventilation, if necessary. All patients underwent lumbar puncture at L3—L4 under local anesthesia. The starting dose of lioresal (baclofen, Novartis Pharma) was 50 μg in all cases. Lioresal was diluted with liquor in the ratio of 1:1 and then injected intrathecally (slowly) during 1 minute. The screening test was considered to be positive, if decrease in muscle tone by one or more points on the Ashworth scale was observed within 12 hours after

Table 1. **The results of surgical treatment of CP patients before and after surgery**

Patient	GMFM, %		Tone		Age, years	Follow up
	before	after	before	after		
M.	60	67	4	2	34	5 years
P.	33	35	5	3	38	21 months
Sh.	35	38	3	1	20	19 months
G.	30	40	4	2	32	16 months
K.	35	35	4	2	24	16 months
L.			4	2	9	pump was removed
M.	35	40	5	2	25	11 months
U.	10	10	5	3	25	9 months

Table 2. **The results of surgical treatment of patients with spinal spasticity before and after surgery**

Name	Arens		Tone		Age, years	Follow up, months
	before	after	before	after		
Sh.	1	2	4	2	28	18
Ya.	0	0	5	1	47	18
K.	3	4	3 + automatisms in legs	1; suppression of automatisms	51	17
K.	1	2	5	2	26	12
B.	0	0	4	1	35	10
O.	4	4	4	2	42	6
L.	1	1	5	1	34	1

injection. When there was no convincing muscle tone dynamics, the test was repeated with 75 μg of lioresal on the next day. The maximum test dose was 100 μg. The patients were discharged on the following day after the test. In the case of a positive result, implantation of baclofen pump was recommended; in the case of a negative result, patients were advised to use alternative methods of surgical correction of spastic syndrome.

We implanted Codman Med-stream pump (Codman, USA) in 4 cases and Medtronic Synchromed 2 pump (Medtronic, USA) in 11 cases. The operation was carried out under endotracheal anesthesia in the right lateral decubitus position. Skin incised at the projection of L3—L4 spinous processes to implant the catheter. Puncture of the subarachnoid space was performed from an oblique paramedian approach to avoid inflection and compression of the catheter between the spinous processes **(Fig. 1)**. Movement of the catheter was controlled radiographically using electron-optical converter (EOC). In patients with lower spastic paraparesis, catheter was moved to T7—T8 level, and in patients with spastic tetraparesis it was moved to C7—T1 level. Purse string suture was applied around the catheter at the exit from aponeurosis to prevent liquorrhea through the channel, and the catheter was fixed to the aponeurosis using special anchor. The pump was implanted into a pocket formed in the left hypochondrium **(Fig. 2)**. In patients with thick layer of subcutaneous adipose tissue (11 cases), the pump was implanted subdermally, while in patients with thin layer of adipose tissue (4 cases) it was implanted subgaleally.

In all cases, the pump was fixed to the aponeurosis using sutures.

The initial concentration of lioresal was 500 pg/ml in all cases. In patients with high speed of intrathecal infusion, the concentration of the drug was then increased (from 1000 to 2000 pg/ml). The starting rate of intrathecal infusion depended upon the effective dose of lioresal in the screening test and amounted to 50 or 75 mg/day. Later on, the rate was daily increased by 15—20% of the total dose until a clinical effect was achieved. Initial lioresal titration time was 7—10 days.

All patients underwent postoperatively puncture of the pump pocket to prevent the formation of seroma, because the pocket could accumulate tissue fluid due to its relatively large size. Patients were discharged on the 10—14th day after the operation. They were informed of the date of the next refill, which was automatically calculates by the pump. The average frequency of refills ranges 3 to 5 per year. Disposable pump refill kit (US) that includes needles, tubing, and bacterial filter was used for refill in all cases. Refill procedure was carried out at the dressing room. First, the pump was scanned and the residual volume of the container was fixed. Further, filling port was punctured and the remaining lioresal (1—2 ml) was evacuated. The pump container was than refilled with a new dose (20 ml or 40 ml). Usually, lioresal with a concentration of 500 μg/ml was initially used, and only starting with 2—3th refill, we used more concentrated formulation, 1000 and 2000 μg/ml, respectively.

Results

In most cases, significant postoperative decrease in spasticity according to the Ashworth scale was observed, from 4.26±0.7 before the surgery to 1.8±0.67 after the surgery (p<0.004) **(Fig. 3)**.

In 6 cases, complete recovery of joint range of motions was observed during chronic intrathecal infusion after implantation of the baclofen pump. In the remaining 9 cases, there was only partial recovery of the range of motions due to fixed contractures in these patients. In most cases, we used intrathecal infusion in a simple continuous mode, providing a constant lioresal flow rate. The average intrathecal infusion rate was 214±90.6 μg/day. In one case, a flexible infusion mode was used (flex) that enabled changing the rate of intrathecal infusion during the day. Before the operation, this patient suffered from nocturnal motor automatism, which started at 23.00—23.30 and continued until 3.00—3.30 and was accompanied by painful muscle spasms, due to moderate spastic syndrome in the legs. They were the main reason

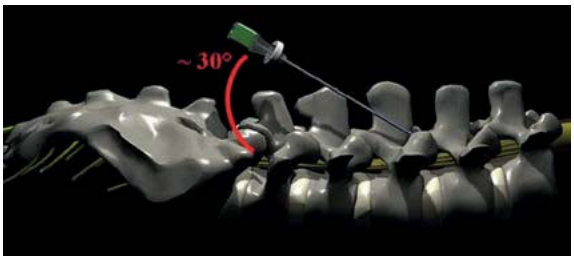


Fig. 1. **Oblique paramedian approach.**

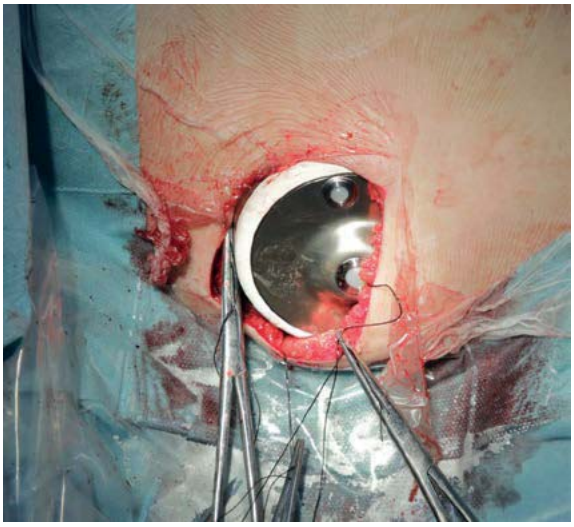


Fig. 2. **Implantation of pump body.**

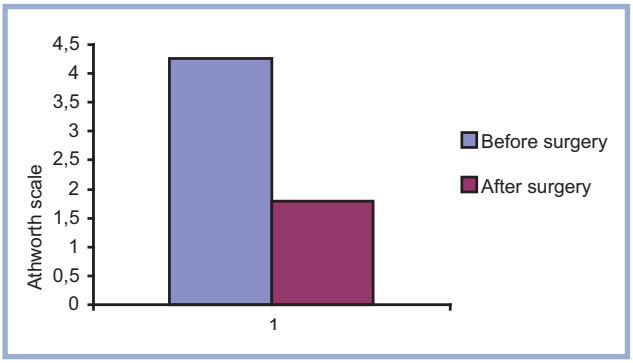


Fig. 3. **The dynamics of spastic syndrome during ITB.**

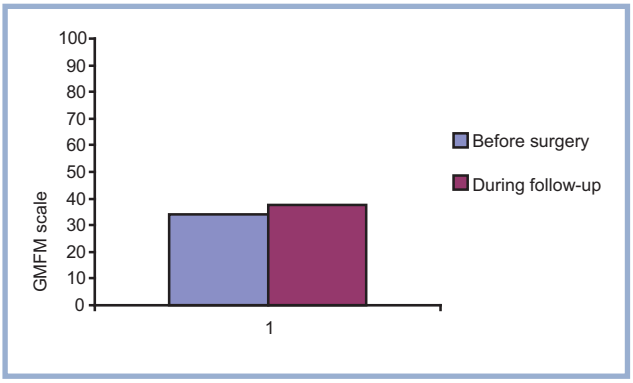


Fig. 4. **The dynamics of locomotor status during ITB according to the GMFM scale.**

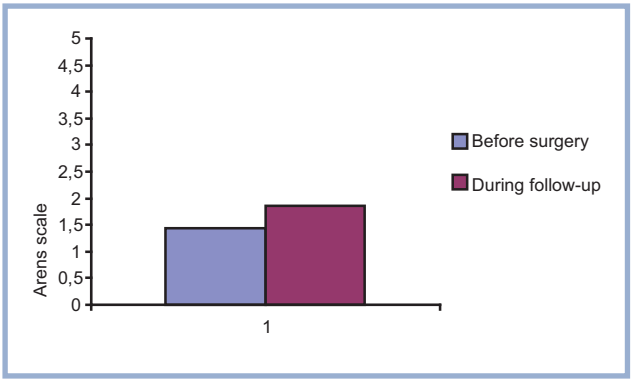


Fig. 5. **The dynamics of locomotor status during ITB according to the Arens scale.**

for complaints. In the daytime, the patient only suffered from equinus foot when walking. In this connection, the patient received intrathecal infusion at a low rate (12 μg/h) for the most part of the day, while between 22.00 and 24.00 (i.e., during the initiation of the automated movements) lioresal was administered at a maximum rate (35 μg/h). The dose was then gradually reduced to 30 μg/h between 24.00 and 3.00, and to 20 μg/h between 3.00 and 6.00. This intrathecal infusion mode prevented from automatic movements of the legs and painful muscle spasms, while gradual decrease in the rate of injection of the drug in the second half of the night prevented from the muscle weakness in the legs in the morning.

In one case, the pump was removed in a 7-year-old patient with the spastic CP. The rate of intrathecal infusion was 100 μg/day within 3 days after baclofen pump implantation. As a result, a good clinical effect was observed, including the reduced muscle tone from 4 to 2 points, and increased range of active and passive motions of the upper and lower extremities. On the 4th day after surgery, the patient's temperature rose to 38°C, and seroma occurred in the pump pocket. In this regard, the regimen of antibiotic therapy was adjusted, and seroma content was sampled for plating. Inoculated medium remained sterile within 7 days. Because of the continued fever response, meningitis was suspected. CSF samples were collected through the catheter port and through the lumbar puncture. Inoculated medium was sterile and cytosis level (within 90/3) did not allowed verifying the diagnosis of meningitis. The pump was removed in 2 weeks due to persistent fever response and seroma relapses. Fever response completely regressed on the 2nd day after pump removal. Inoculation of catheter fragments and pump lavage did not result in flora growth. For this reason, this case is regarded as an allergic reaction to the implant.

Seroma in the pump pocket was observed in 3 patients. All of them resolved within 2 weeks after surgery against the background of punctures.

We assessed the dynamics of locomotor functions 6, 12, and 24 months after surgery. The positive dynamics of locomotor status was observed: from 34±14.56% (before surgery) to 37.85±16.58% (after surgery; $p<0.008$) on the GMFM-88 scale in 5 (62%) patients with cerebral spasticity **(Fig. 4)**; from 1.43±1.5 (before surgery) to 1.85±1.67 (after surgery, $p<0.007$) on the Arens scale in 3 (43%) patients with spinal spasticity **(Fig. 5)**. In the remaining 7 cases, no dynamics of locomotor status was observed despite the regress of spastic syndrome.

Discussion

Numerous studies proved high efficacy of ITB [12, 13], and it may be the treatment of choice in patients with spastic syndrome resistant to conservative treatment. At the same time, ITB presents some risk because of possible disorders of the system, resulting in either excessive or insufficient flow of the drug. The most common causes of insufficient drug flow are the problem with a catheter (twisting, bending, or migration), which can limit or completely stop the flow of lioresal to the cerebrospinal fluid. This leads to spastic syndrome relapse, and, in more severe cases, to multiple organ failure and even death [13—15].

Programming errors, as well as fluctuations in ambient pressure and temperature are the most common cause of drug overdose. Excessive injection of lioresal causes diffuse muscle weakness, somnolence, and

depression of consciousness. Respiratory arrest can also occur [16].

In any case, the patient with complications should be promptly delivered to one of the support centers for system diagnostics and elimination of its disorders. Therefore, patients who reside far from such centers can not be considered as candidates for pump implantation. ITB also can not be used in patients with negative results of baclofen screening test and pharmacoresistant episyndrome. Other methods of neurosurgical treatment of spastic syndrome should be recommended to these patients.

In some studies [17], an increased risk of scoliosis during ITB was also observed. Therefore, in patients with spinal deformities, this technique should be selected with care or abandoned in favor of alternative ones.

A significant factor limiting widespread use of ITB in clinical practice in the Russian Federation is the need for continued support of patients with implanted pumps. In particular, this applies to refills. As practice shows, an average of 3 to 5 refills per year per patient are required. Consumables include lioresal (1 to 8 vials per one refill) and charging set. Currently, there is no unified program of medical support of these patients in Russia. For this reason, in most cases, patients have to buy their supplies at their own expense. One refill costs 50 thousand rubles and more. Thus, the high cost of refills is a significant deterrent to widespread use of ITB method. It is also limited because of the high cost of operation. The amount of quotas allocated for these operations is small and can scarcely meet the demand. Annually, up to 6 thousand new cases of cerebral palsy, up to 10 thousand new cases of spinal cord injury, and more than 50 thousand cases of cerebral and spinal stroke occur. At least 10% of patients are refractory to conservative therapy and require neurosurgical treatment. Thus, the minimum annual need for ITB reaches 6—7 thousand pumps.

Given the need to support patients with implanted pumps, as well as the implantation of new ones, it can be expected that the need for lioresal will grow exponentially. Therefore, lioresal should be included to the GMFM list.

In addition, it is necessary to organize ITB support centers and deploy them both in Moscow and in regions. It is desirable that in the case of complications of ITB, the patient could be delivered within few hours. Given the area of our country, there should be at least 50 such centers.

The main objective of treatment of patients with spastic syndrome is to improve their motor function. However, the reduction of spasticity does not always lead to functional improvement. According to the literature [18, 19], ITB leads to improvement of locomotor function in approximately 50% of patients, which correlates with our results: improved functions was observed in 62% of patients with cerebral spasticity and in 43% patients with spinal spasticity.

Of course, the functional outcome depends on the initial severity of the disease. In patients who belong to level 5 on GMFM scale and 0—1 on the Arens scale, the main objective of the treatment is to facilitate nursing process, while in patients with GMFM level 3—4 and Arens level 2—3, the objective is to improve the functional result.

Y. Lazorthes et al. [20] mentioned high variability of effective therapeutic daily dose of lioresal, which was explained by the etiology of the disease, as well as individual differences in the metabolism of baclofen.

In our series of observations, we used relatively small daily doses of lioresal (214±90.6 μg/day). This is due to the fact that spastic syndrome was the dominating clinical manifestation in all patients, while the secondary dystonia and hyperkinetic syndrome require significantly higher doses [21].

In 15—20% of cases [20], "flexible" mode of lioresal infusion is indicated to patients, when the medication is injected at different rates throughout the day. This mode is mainly used in cases when spasticity increases:

1) at night, which causes sleep disorders;

2) during motor activity and physical exertion [22].

In our series of observations, there was a patient who had dynamic manifestations of spastic syndrome in the form of automated movements that occurred at night. Spastic syndrome was effectively arrested using sharp increase in the rate of intrathecal infusion in the evening and night hours.

In a number of studies [23], the development of detrusor-sphincter dyssynergia was observed during administration of ITB, which caused dysuria in the form of delayed urination. However, no cased of urinary dysfunction were observed in our studies.

Conclusion

Chronic intrathecal therapy can be used in patients with generalized spastic syndromes in case of failure of conservative therapy and treatment with botulinum toxin. ITB results in statistically significant regression of spastic syndrome, increase in the range of active and passive motions, and improvement of locomotor functions.

A large organizational work is required to implement ITB method in clinical practice, including

1) increase in the number of ITB quotas;

2) listing baclofen in the Additional pharmacological support list;

3) expanding the network of ITB support centers;

4) training of specialists.

This requires cooperative action of the Ministry of Health of the Russian Federation and clinics that use ITB method.

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Commentary

Locomotor impairment with underlying spastic syndrome leads to limitation of the range of active and passive motions, causes arrested development of locomotor function, and complicates formation of motor skills. Because of persistent muscle spasticity, myogenic and then fixed contractures occur, which significantly hampers rehabilitation. In patients with generalized spastic syndromes, covering many muscle groups, neurosurgical intervention is considered to be the best treatment. In patients with spastic tetraparesis, implantation of baclofen pump is the most appropriate type of neurosurgical treatment, since this technique enables affecting the pathological muscle tone in the upper and lower extremities.

In this article, the authors present the results of chronic intrathecal therapy of 15 patients with spastic syndromes of various etiologies. The technique of preoperative selection of patients is discussed in detail, including such an important step as baclofen screening test, as well as the technique of pump implantation. Postoperative programming of patients is covered.

The article discusses the important issue of supporting patients with implanted pumps. The need for periodic refill of pumps and correction of intrathecal infusion parameters imposes additional duties on surgeons and requires establishing support centers for patients with implanted systems similar to those in the US and Europe. Intrathecal lioresal is not included in the list of free drugs, which results in substantial coast load on patients. It is necessary to include lioresal in the Additional pharmacological support list on the analogy of the botulinum toxin to achieve the widespread practical use of chronic intrathecal therapy.

Treatment of chronic neurogenic pain syndromes is another important problem of the chronic intrathecal therapy. There is a large group of patients who need chronic intrathecal morphine as the only actually effective method to relieve severe drug-resistant pain syndrome. The problem of supporting patients who receive chronic intrathecal infusion of morphine is even more acute than in patients with spasticity due to the fact that morphine is a controlled narcotic drug, which creates additional difficulties in filling.

In my opinion, it would be appropriate to compare the author's own results with the literature data. It would also be good to analyze the main advantages and disadvantages, indications and contraindications for chronic intrathecal therapy in more detail on the basis of the literature. In order to improve the comprehensibility of the material, the authors should add the annexure to the article with scales and classifications used in the work (in particular, the description of Ashworth and GMFM scales), and provide the corresponding reference in the bibliography.

In conclusion, it should be noted that the article covers the problem of surgical treatment of patients with spastic syndrome resistant to botulinum toxin. For the moment, the study is highly relevant and it is of undoubted interest for neurosurgeons, neurologists, pediatricians, and rehabilitation specialists.

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