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Continuous intrathecal baclofen delivery in severely disabling spasticity

Kontinuirana intratekalna primena baklofena kod teškog onesposobljavajućeg spasticiteta

Hakan Simsek, Emre Zorlu, Omer Bakal, Selim Akarsu, Mehmet Güney Senol

Gülhane Military Medical Academy, Haydarpasa Teaching Hospital, Istambul, Turkey

Abstract

Background/Aim. Spasticity is the consequence of several clinical conditions including cerebral palsy, brain injury, spinal cord injury, multiple sclerosis, aneurysm bleeding, and some other neurological disorders. The aim of this study was to determine the efficacy of intrathecal baclofen (ITB) treatment in medically intractable severely disabling spasticity and present the challenges encountered during pump implantation surgery on these patients. **Methods.** The patients who underwent intrathecal baclofen pump implantation surgery between the years 2012 and 2015 with minimum follow-up of six months were recruited from the clinic archives. Twenty two patients with severe spasticity who had Modified Asworth Spasticity Scale (MASS) score of 3 or 4 were enrolled in our series. Eight of twenty-two patients were at pediatric age and they all were non-ambulant before surgery. **Results.** All of the patients underwent programmable intrathecal baclofen pump implantation surgery. Catheters were placed via percutaneous technique into to the subarachnoid space in 18 patients while, we had to perform partial hemi-laminectomy in order to place the catheters in 4 patients. All the patients improved significantly and 5 began using upper extremities and 3 adults became ambulant following physical therapy. Mean of the MASS scores improved from 3.59 to 1.32 ($p < 0.001$). **Conclusion.** The ITB therapy obviously increased quality of life and functional outcome in patients with disabling spasticity. As a result, physical treatment was more useful for these patients. Although some spinal abnormalities due to spasticity may necessitate partial hemilaminectomy to implant the pump, patients with intractable spasticity should be given the chance of intrathecal baclofen treatment at the earliest period of their lifetime disability.

Key words:
baclofen; infusion pumps; anesthesia, spinal; catheters, indwelling; muscle spasticity; brain diseases; spinal cord diseases; prognosis.

Apstrakt

Uvod/Cilj. Spasticitet je posledica nekoliko kliničkih stanja kao što su cerebralna paraliza, povrede mozga, povrede kičmene moždine, multipla skleroza, ruptura neurizme sa krvarenjem, kao i neki drugi neurološki poremećaji. Cilj ove studije bio je da se utvrdi efikasnost primene intratekalnog baklofena (ITB) u lečenju upornog teškog onesposobljavajućeg spasticiteta, kao i izazovi sa kojima se susrećemo tokom hirurške ugradnje pumpe kod ovih bolesnika. **Metode.** Iz kliničkih protokola u periodu 2012–2015. godina izdvojili smo bolesnike kojima je ugrađena baklofenska pumpa intratekalno uz minimlno praćenje od šest meseci. Dvadeset dva bolesnika sa teškim spasticitetom koji su imali modifikovani Asworth skor spasticiteta (MASS) između 3 i 4 bili su uključena u studiju. Osam od 22 bolesnika bila su u dečjem uzrastu i svi su bili nepokretni pre hirurškog zahvata. **Rezultati.** Svi bolesnici bili su podvrgnuti hirurškoj implantaicji programabilne intratekalne baklofenske pumpe. Kateteri su postavljeni perkutano u subarahnoidni prostor kod 18 bolesnika, dok smo parcijalnu hemilaminektomiju primenili za ugradnju katetera kod četiri bolesnika. Kod svih bolesnika javilo se značajno poboljšanje, 5 bolesnika počelo je da koristi gornje ekstremitete, a tri odrasla bolesnika postala su ambulantna tokom fizikalne terapije. Srednji MASS skorovi poboljšali su se od 3.59 do 1.32 ($p < 0.001$). **Zaključak.** ITB terapija je očigledno popravila kvalitet života i funkcionalnu sposobnost bolesnika sa onesposobljavajućim spasticitetom. Zahvaljujući tome fizikalna terapija bila je mnogo korisnija kod ovih bolesnika. Iako neke abnormalnosti zbog spasticiteta mogu zahtevati parcijalnu hemilaminektomiju da bi se ugradila pumpa, bolesnicima sa upornim spasticitetom treba pružiti šansu za primenu ITB lečenja u najranijem periodu njihove doživotne onesposobljenosti.

Ključne reči:
baklofen; infuzione pumpe; anestezija, spinalna; kateteri, trajni; mišići, spastičnost; mozak, bolesti; kičmena moždina, bolesti; prognoza.

Correspondence to: Hakan Simsek, Gülhane Military Medical Academy, Haydarpasa Teaching Hospital, Istambul, Turkey.
E-mail: drhakansimsek@hotmail.com

Introduction

Spasticity is the consequence of several clinical conditions including cerebral palsy (CP), brain injury, spinal cord injury, multiple sclerosis (MS), aneurysm bleeding, and some other neurological disorders [1]. Spasticity can be described as the muscle stiffness and spasm that is accompanied by involuntary jerking and sometimes pain [2]. When the spasticity is generalized and severe, the patient is usually immobilized and has the propensity to very low quality of life and poor care. Grading of the spasticity is achieved by applying the Modified Ashworth Spasticity Scale (MASS) in order to gain a standardized objective determination of the spasticity. It also helps to measure the efficacy of the treatment modalities in the follow-up. Practically, MASS measures resistance during passive soft tissue stretching. It is done in the supine position. Since spasticity is velocity dependent, the joint or the muscle group subject to testing is moved at the speed of gravity. After establishing an accurate diagnosis of spasticity, treatment options are assessed. Therapeutic options for these cases include oral medications, nerve blocks, destructive neurosurgical procedures and intrathecal administration of antispastic agents [3]. Baclofen is used orally to treat spasticity but its systemic side effects limit the dose a patient can take. It is a synthetic analog of gamma aminobutyric acid (GABA) and acts by stimulating the GABA type B receptor subtype in the central nervous system. In 1984 Penn and Kroin [4] introduced intrathecal administration of baclofen to treat spasticity and it was used in patients who had developed resistance to it or could not tolerate orally administered antispasmodic drugs. In the last decade, the use of baclofen delivered intrathecally via an implanted programmable pump became the principal treatment in the management of spasticity [5–7]. Initially, a trial injection of intrathecal baclofen (ITB) is applied and patient's response to the administered dose of the drug is observed. The decision to implant a pump is established on a positive response, that is, at least two-point decrease in Modified MASS and absence of the unwanted adverse effects [8].

We intented to emphasize the difficulties in baclofen pump implantation surgery and share our experience in the management of severe spasticity cases.

Methods

Patients

Patients who attended the Gülhane Military Medical Academy, Haydarpaşa Teaching Hospital and underwent ITP implantation surgery at the Neurosurgery Department between 2012–2015 were recruited from the medical records of the Clinic. The study design was approved by the Ethical Committee of the GATA Haydarpaşa Teaching Hospital and conforms to ethical standards as described in the Declaration of Helsinki. The same team of a neurologist, physiatrist and neurosurgeon obtained the MASS scores for each individual at their follow-up visits (Table 1).

Table 1

Demographical data of the patients enrolled in the study

Patient	Age (years)	Gender	Etiology	Follow up (months)	Final baclofen dose (mcg/dL)	Preop MASS	Postop MASS	Preop VAS	Postop VAS
1	50	M	Aneurysmal subarachnoid hemorrhage	19	62	3	1	8	3
2	38	F	Multiple sclerosis	19	55	3	1	10	5
3	63	F	Cervical spinal cord injury	21	60	3	1	10	5
4	9	M	Cerebral palsy	19	125	3	1	n/a	n/a
5	12	M	Cerebral palsy	18	50	3	1	n/a	n/a
6	47	F	Multiple sclerosis	18	142	4	1	9	4
7	14	M	Cerebral palsy	19	66	4	2	8	3
8	23	M	Cervical spinal cord injury	22	115	3	1	10	6
9	46	M	Transverse myelitis	18	70	3	1	n/a	n/a
10	38	M	Multiple sclerosis	18	60	4	1	9	4
11	7	M	Cerebral palsy	6	140	4	2	n/a	n/a
12	51	M	Cervical spinal cord injury	12	82.5	4	1	10	5
13	10	M	Cerebral palsy	6	65	4	2	8	3
14	44	F	Aneurysmal subarachnoid hemorrhage	6	170	4	2	n/a	n/a
15	34	F	Multiple sclerosis	12	50	4	2	10	4
16	27	M	Multiple sclerosis	13	55	4	1	10	3
17	35	M	Traumatic brain injury	15	70	3	1	n/a	n/a
18	11	M	Cerebral palsy	8	100	4	1	n/a	n/a
19	40	M	Multiple sclerosis	7	70	4	2	9	4
20	9	F	Cerebral palsy	10	55	4	1	n/a	n/a
21	13	M	Cerebral palsy	17	50	4	2	n/a	n/a
22	45	M	Multiple sclerosis	9	70	3	1	10	3
Mean	30.27			14.18	80.95	3.59	1.32	9.3	4

MASS – Modified Ashworth Spasticity Scale; VAS – Visual analog scale; M – male; F – female.

Twenty-two patients met the following criteria for inclusion in the study: ITP placement surgery; non-ambulant patients with severe spasticity (MASS 3–4), impairing function and personal care; at least 3 preoperative assessments free from antispastic drugs; available follow-up visits at the end of the first, third and sixth month postoperatively.

Pump implantation

When an indication of ITP implantation was decided on in case of positive trial response, a pump (SynchroMed II, Medtronic, Minneapolis, USA) was implanted by the first author (HŞ) in the subcutaneous pocket in the lower quadrant of the abdomen on the left side and connected to the intrathecal catheter under general anesthesia (Figures 1 and 2).

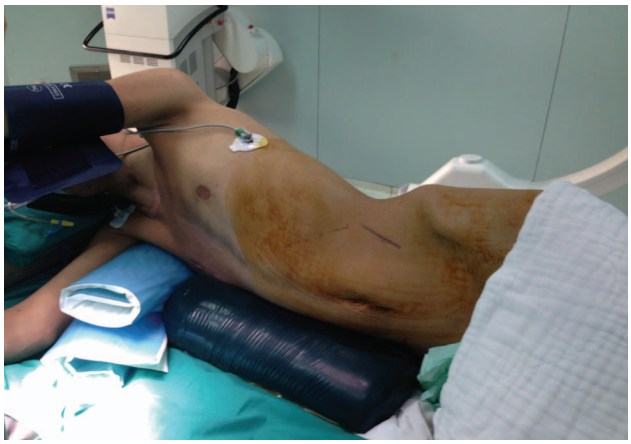

Fig. 1 – All the patients were operated in the lateral decubitus position regardless of the degree of their spasticity or contractures. To obtain the appropriate position and free the hip with possible joint contractures, we fed and supported shoulder and elevated the thorax and lower abdomen with silicon bedding and soft pillows. This allowed us implant the pump in the same position without violating the stiff joints.

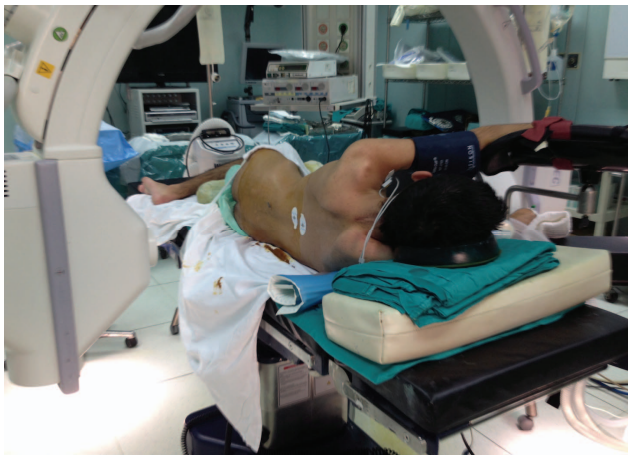

Fig. 2 – We marked dorsal spine with disposable self-adhesive electrocardiographic (ECG) electrodes in order to place the tip of the catheter at the desired level with reduced fluoroscopic shots.

Pumps with 20 mL volume capacity were implanted to the patients in the pediatric group while 40 mL volume capacity pumps were preferred for the adult patients. The level where the tip of the catheter would be left was determined according to the involvement of neck and the upper extremities.

When percutaneous catheter insertion was not successful despite fluoroscopic guidance, this position let us switch to direct catheter placement in the intrathecal space via partial hemi-laminectomy at the same level where percutaneous placement of the catheter was intended. We usually performed partial hemilaminectomy at the lumbar 2–3 interlaminar space. Once the patient was anesthetized and positioned appropriately, we believe that the patient deserved pump implantation in any available way and it was mentioned in the informed consent that was routinely obtained from the patients or their families.

The baclofen start doses are mentioned in Table 1. Starting on the third postoperative day, we began dose adjustments every week till the patient, physiatrist, neurologist and the family were satisfied with the clinical outcome. That usually took 4 to 12 weeks to compromise on an acceptable continuous daily intrathecal constant baclofen dose. We established our outcomes of the ITB therapy on the evaluations that were held in the end of the postoperative first, third and sixth month when available. Once the pump was implanted, depending on the dose-response situation, the patients needed percutaneous refills every 1 to 6 months. The demographic specifications of the patients are also shown in Table 1.

Statistical analysis

Raw data were analyzed using SPSS statistics packet program version 20.0 for Mac. Minimum value, maximum value, mean, and standard deviation (SD) were used to define data. The postoperative MASS scores were compared to that of the preoperative values using the Wilcoxon Signed-Rank test. *P* values less than 0.05 ($p < 0.05$) were considered statistically significant.

Results

Eight of the patients were at pediatric age (mean age 10.6 years, ranged from 7 to 14 years) and they developed spasticity due to CP. They were all non-ambulant and families had great difficulty in caring for the children. Visual analog scale (VAS) scoring could not be applied to 9 patients. Fourteen adult patients (5 females, 9 males) had a mean age of 41.5 years (range: 23–63 years). All of them were not ambulant and were unable to sit in a wheelchair. The cause of spasticity in the series was MS in 7 cases, spinal cord injury in 3, CP in 8, transverse myelitis in 1, aneurysmal subarachnoid hemorrhage in 2, and traumatic brain injury in 1 patient (Table 1). Twenty of the patients were quadriplegic and 2 patients with MS were paraplegic.

All the patients ceased oral medications at least 3 days before the trial day, if applicable, and then underwent a prepump implantation trial of ITB with 50 µg bolus delivered by lumbar puncture and followed by tone assessments over 6 to 8 hours. Records revealed that we had to administer a 50% increased second baclofen dose to only 3 patients during the prepump baclofen benefit trials on the following day. Pediat-

ric group received ITB (25 μg) at the dose that was a half of the dose the adults had received. Reduced mean MASS of at least 2 points was taken as positive response to trial. Again, the patients ceased antispastic oral drugs 3 days before surgery and the same physiatrist and a neurologist/pediatric neurologist evaluated them the day before implantation of the ITP free of oral antispastic medications.

The catheter was placed (between C7-T10 level) through a percutaneous technique into the lumbar subarachnoid space in 18 of the 22 patients. Four of the patients with CP (2 adult and 2 children) had severe spinal rotation and scoliosis, therefore the 16 T gauge Tuohy introducer needle could not be inserted in the intrathecal space and we had to place the catheter after performing a partial hemi-laminectomy in the lateral decubitus position. Positioning the patients was a challenge, but the operation room team got used to manage the condition after several cases. Induction of the anesthesia dissolved spasticity, but muscle contractures remained. Hip motion was usually restricted so in order to give the lateral decubitus position on the right side, we fed the whole body with silicone pads to release the right hip and shoulder and supported the left leg over the right leg with pillows and fixed the body in lateral position. We used anterior and posterior supports for chest and a posterior support at the upper thigh level. Therefore, adductor muscles of the hips with contracture did not encounter violation and extra injury (Figures 1 and 2).

Laminectomy alone was not a reason for a longer hospital stay in any of the patients. The patients did not suffer extra pain because of the laminectomy procedure as they are on analgesic medication for the pump pocket incision site.

Follow-up examinations were arranged at the end of the first, third and sixth month. Mean follow-up time of the overall group was 14.18 months. Owing to the continuous delivery of a constant dose of ITB, all of the patients got a steady relief of spasticity. All the patients enrolled in the study were severely disabled and immobile at the beginning (20 spastic quadriplegic, 2 spastic paraplegic). Mean MASS score of the patients improved from 3.59 to 1.32 (Table 1). P value was lower than 0.001, representing a highly significant difference (Table 2).

Mean VAS score of the available 13 patients was 9.3 in the preoperative assessment and it regressed to 4 at the third month evaluation in the postoperative follow-up. Adult group received an average of 80.8 μg daily baclofen dose, while the pediatric group received 81.4 μg daily baclofen, indicating that there was not a significant difference between the adult and pediatric group regarding the dose they received. The MS patients had remarkable benefit from the baclofen treatment. We recorded at least 2 points of MASS score reduction. Five of seven MS patients were able to walk by the end of three months following appropriate physical training. The patients with CP were able to sit in the wheel chair following the ITB treatment, but they were not able to walk. Since they were not coordinating, they could receive only passive physical training to regain the appropriate range of motion of their joints. Nevertheless, caregivers or families who were attending these patients were satisfied with the ease of care they had after the ITB treatment. Further studies including electrophysiological and mental tests should be performed for these patients to measure any improvement in cognitive functions.

Table 2

Preoperative and postoperative Modified Asworth Spasticity Scores (MASS)

Number of patients	MASS, mean ± SD		z (*p*)
	preoperative	postoperative	
22	3.59 ± 0.50	1.32 ± 0.48	-4,315 (0.001)

Postoperative MASS scores were compared to that of the preoeprative values using the *P*-Wilcoxon Signed-Rank test; values less than 0.05 were considered statistically significant (*p* was found lower than 0.001 in the series).

In the postoperative follow-up period we did not encounter any complications in our series other than in one patient who was referred back to our clinic with fluctuating swellings in the pump area and lumbar incision site. He was a 23-year-old man with cervical spinal cord injury who presented with spastic tetraplegia. ITP implantation surgery was planned, but percutaneous catheter placement was unsuccessful, so we performed partial hemi-laminectomy and transduced the catheter under direct visualization at the lumbar 3rd vertebra level. We revised the pump and found that the pump and the catheter system were intact. CSF was entrapped in the pump pocket and in the lumbar subcutaneous pouch. Lumbar fascia at the laminectomy site was tight but catheter required anchoring, and the tightening sutures were put where it penetrated the fascia. We reimplanted the pump in its pocket and postoperative course was uneventful and he did not experience any other complications (Figure 3).

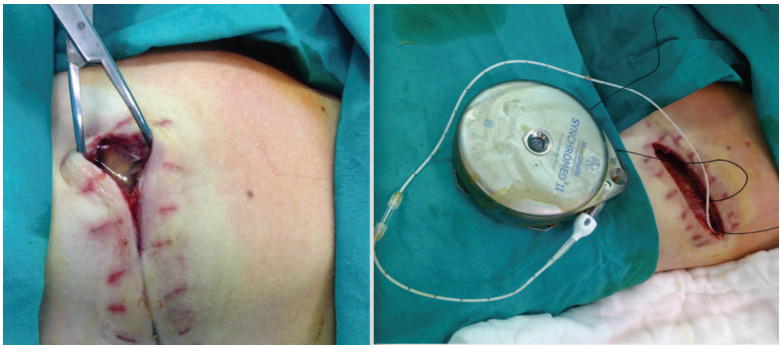

Fig. 3 – One patient experienced cerebrospinal fluid (CSF) collection in the pump pocket and the spinal incision site. We revised the pockets and the pump was reimplanted after ensuring that the system was intact. The fascia that was damaged by the Tuohy needle during our attempts to place the catheter by percutaneous technique was the route of the CSF fistula into the pouch and we repaired it with several stiches and anchored the catheter by a purse-string suture to the fascia.

Discussion

In the case of disabling spasticity, oral medication was the first choice because of easy administration route. Oral baclofen is widely used, however the untoward effects of oral baclofen such as sedation, respiration problems and muscular weakness in higher doses, limit its use. It also modulates pain due to its direct effect on GABA receptors. Though not all patients with spasticity benefit from this treatment, it allows a successful management of the spasticity [7]. Inhibition of spasticity increases mobility and makes the patient more liable to benefit from physical treatment [9, 10]. Overall benefit is increase in quality of life of the patients and caregivers as well [11, 12]. However, as in most of the surgical interventions involving implantation of a catheter and pump as foreign bodies, certain complications including infection, hardware malfunction, displacement of the catheter or the mechanical device, rejection of the system by the host, patient's intolerance to the system, the uncooperative patient profile and alterations in response to medication because of the individual features may be encountered. Inadvertent effects of the medication used via such closed systems are the most challenging of all since the administered drug has pretty narrow therapeutic window. Fluctuations in dose may not be tolerated because both withdrawal and overdose of intrathecally administered baclofen may be potentially life threatening and necessitate intensive care [13]. Although these complications are rare if certain practice guidelines are followed, clinicians should be prepared to recognize and treat them timely. Abrupt withdrawal of ITB can result in high fever, drowsiness and sometimes coma, return of spasticity, muscle rigidity, and in rare cases even death. An acute massive overdose can cause coma, while less severe overdoses can cause drowsiness, lightheadedness, respiratory depression, seizures, hypotonia, and loss of consciousness. The most prominent side effect is hypotonia, and can be addressed in most cases by adjusting the rate of administration [11, 14, 15].

A steady cerebrospinal fluid (CSF) concentration of the drug allows to generate the same effects as those of oral high dose administration of baclofen, except for that untoward side effects including sedation, respiration problems and muscular weakness will be avoided. It takes several weeks to several months to set to the desired effects and dose relation.

In our series, following a series of incremental adjustments, dosage remained stable after three months. That is ideal to find out how the patient would feel like when the drug reached therapeutic concentration, because some patients require doses above or below the designated range and even some patients experience drug toxicity within the therapeutic range.

Actually, during classical trial injections to the patient, incremented dosage was administered and takes 3 days to the longest, and did not need hospitalization unless the patient had a special condition that necessitated so. In the severely disabled group of patients, we did not have to readminister a second or third incremented baclofen dose to observe the benefit of the patients, because they all had significant relief following the initial trial dose. The next step for these patients remained dose adjustments following the implantation of the pump. Overall, continuous intrathecal administration of the baclofen to evaluate its systemic and functional effects could be considered as a helpful method as mentioned by some authors [16], but we believe it would put extra burden, both on the patient and the hospital by hospitalizing and using another trial pump for several days. After coming to a consensus on the implantation of the baclofen pump, all the patients were operated and a catheter was placed in the intrathecal space either via percutaneous route or via partial hemi-laminectomy in the right decubitus position usually at the 2–3 or 3–4 interlaminar spaces. In the severely disabled patients, usually the spinal column is anatomically deformed and intervertebral space does not allow the Tuohy needle to pass through. Since the patient had general anesthesia, we did not give up the implantation procedure in any of the patients and performed the laminectomy to place the catheter in the subarachnoid space. Sometimes the dural compression and arachnoid synechias due to the interrupted CSF turnover do not let CSF to flow through the Tuohy needle although you might be in the thecal sac. After transducing the catheter into the subarachnoid space and placing the tip in the way to reach a desired level, CSF flow is observed. After experiencing a CSF collection in the subcutaneous pouch, we began passing the catheter through the fascia by penetrating it at the intact site to prevent CSF fistula.

In order to measure the goal achievements after implantation, the patients (when available), caregivers, and the family were asked to rate in their terms whether the goals were achieved satisfactorily, or not. Better seating, feeding, improved sleep patterns, mood, eased provision of care, decreased pain were expressions of satisfaction and they were set as a simple statement implying overall benefit from the procedure [17]. Our results were also consistent with the current literature. Current data indicate that the ITB therapy effectively and significantly reduces severe spasticity in non-ambulatory patients caused by various reasons [7, 18]. This striking success of intrathecal baclofen use might be attributed to several factors including appropriate patient selection, education about realistic expectations and careful dose titration in time. To the benefit of the patients, physiatrists were also involved in the decision-making and postoperative assessment period, so early involvement of rehabilitation therapists in the procedure contributes to maximize clinical outcome.

Caregivers report muscle relaxation alone, as a positive benefit of the therapy but further physical treatment is needed. While the patients are under the effect of baclofen, determining the range of motion of each joint and the muscles with intractable contracture, which are candidates for surgical release, is another important issue to deal with. After reaching the physiological limits of the functioning muscles, additional treatment modalities might be considered. After all, when the patients are anesthetized and myorelaxant agents are administered, you can evaluate the limits of physiological motion and contractures at the extremities of these patients. The main goal is gaining the largest span of independent active, and passive movement of the extremities and

the trunk. Since all of the patients in our series were dependent on others in terms of hygiene, feeding, positioning, and ambulation, this also brought ease of care for the caregivers. After the ITB treatment, the MASS scores of the patients improved significantly. As the restriction of the disabling spasticity is decreased gradually, 5 patients began using their hands for grasping and 3 patients began ambulating in the house with an assistive device following intensive physiotherapy. As reported previously, another benefit of the ITB therapy was improvement in nutritional status, particularly in the pediatric patient group [19]. They began putting on weight in the end of the second month firstly because they could swallow easier as mentioned by the parents or caregivers and secondly because their health conditions improved and they had less infectious problems due to decreased pulmonary aspiration. In accordance with the improvement of the MASS scores, we found out pain relief in 13 patients and it was quantified with the VAS assessments (Table 1). Four patients in the pediatric group had improved mood and decreased yelling and crying episodes as noted by their parents. Pediatric neurologist ceased to apply sedative medications to these patients.

Some authors reported impairment in the spinal column alignment and worsening of the scoliosis in some of the patients who received the ITB treatment after a certain period of time [20, 21]. Our overall impression from our study is that the ITB therapy does not interfere with the underlying natural tendency to develop scoliosis for the most severely disabled children. Likewise, we also observed that the number of the orthopedic surgical interventions did not increase because of the ITB therapy, on contrary, both the orthopedics and the families had tendency to reconsider surgical intervention [22, 23]. Because it is rational that if the patient is found relaxed compared to the prepump assessments, one may cancel the preplanned operation for an individual, while he can identify new potential benefit and onsider orthopedic intervention [18]. The most important question of the issue here is if early onset of the ITB therapy will reduce contractures and yield more definite improvements in terms of ambulation and functionality. Besides ease of access to physiotherapy and insurance coverage, consistency of the patients and their families to a regularly based training sessions and home training takes the first place in the improvement of these patients, thereafter [24].

Conclusion

We retrospectively assessed the patients whom we operated on and implanted ITP in a selected group of non-ambulant patients with severely disabling spasticity. Detailed examination of the records revealed that all had satisfactory outcomes in the minimum 6 months of follow-up. Although spinal structural deformities of the severely disabling spastic patients are a challenge in the placement of the catheter, it does not totally restrict surgical intervention. Determining rationale goals preoperatively is the core issue, and is followed by patient and family consistency to treatment. Therefore, while planning this treatment, realistic balance of likely gains and possible losses should be carefully explained to the families and patients if applicable. We observed that families and physiatrist got excited about involving them in physiotherapy with the hope of further improvement. ITB usually produced many other improvements apart from the programmed aims and beyond the expectations of the families or caregivers. The ITB therapy apparently increases quality of life and increases functional outcome. So, as a surgical treatment modality, selected patients should be given this chance at the earliest period of their lifetime disability.

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