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Management of post spinal cord injury lower limbs spasticity: Comparative study between intrathecal baclofen infusion pump versus selective rhizotomy

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Abstract

Background

Lower limb spasticity is a common and disabling consequence of spinal cord injury (SCI), affecting more than 80% of patients and frequently causing pain, impaired mobility, and reduced quality of life. Intrathecal baclofen (ITB) infusion and selective rhizotomy (SR) are established surgical options for medically refractory spasticity; however, comparative data remain limited.

Methods

This prospective cohort study included 40 adults with chronic (> 12 months) SCI-related lower limb spasticity refractory to medical therapy and rehabilitation. Twenty patients underwent ITB implantation and 20 underwent SR. Outcomes were assessed preoperatively and at 3, 6, and 12 months using the Modified Ashworth Scale (MAS), Visual Analog Scale (VAS), and Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET). Complications and treatment costs were also evaluated.

Results

Both ITB and SR produced significant improvements in muscle tone, pain, and quality of life throughout follow-up (all $p < 0.001$). No significant differences were observed between groups regarding MAS, VAS, or SCI-SET scores at any postoperative assessment (all $p > 0.05$). Complication rates were low and comparable between groups, with no significant differences in cerebrospinal fluid leakage, wound infection, or sensory impairment..

Conclusions

ITB and SR provide comparable improvements in spasticity, pain, and quality of life in patients with chronic SCI. While ITB offers adjustable and reversible neuromodulation, SR provides durable symptom control without long-term device maintenance and may represent a more cost-effective option, particularly in low- and middle-income countries.

INTRODUCTION

Spasticity of lower limbs is one feature of the upper motor neuron lesion syndrome and major cause of disability in patients with spinal cord injury (SCI). More than 80% of SCI patients develop spasticity.[1]Spasticity can affect the quality and it is usually painful.[2] In general, there are several mechanisms that can explain the occurrence of spasticity in upper motor neuron lesion patients, but the mechanism differs according to the level of injury whether at the level of brain pyramidal and

extrapyramidal tracts or at the spinal level.[2]Management is usually directed to interfere with the pathways that develop spasticity starting from spinal cord down to muscles.[3,4] There are several methods for management of spasticity ranging from medical to surgical.The medical treatment usually includes oral muscle relaxants or Bolutinium toxin injections. Surgical management includes many types of operations categorized into neuroablative surgeries as selective peripheral neurotomy, selective rhizotomy and neuromodulation surgeries either chemical with drug delivery system or electrophysiological stimulating devices.[5]

In addition to its valuable effect against spasticity, baclofen was found to have an analgesic effect; reports have showed its effectiveness in some cases suffering from neuropathic pain and its use in augmenting spinal cord stimulation in early 1990s.[6] In 1888, selective rhizotomy was introduced for the first time to the world for treatment of ascending neuritis and sciatica. Later, the idea became more adapted for management of spasticity of lower limbs because of its direct tone lowering effect. Selective rhizotomy offers partial restoration of the physiological neurological pathways. Based on that it provides a large magnitude of improvement in tone, range of motion and gross motor function. [7] Since its introduction as a muscle tone lowering surgery, rhizotomy underwent many modifications regarding the quality and quantity of resection, the application of electrophysiology monitoring and the type of roots underwent resection either dorsal roots alone or combined anterior and posterior roots resection.[8,9] Although both intrathecal baclofen therapy and selective rhizotomy have demonstrated efficacy in reducing severe spasticity, direct comparison between these treatment modalities in patients with spinal cord injury remain scarce. Therefore, comparative studies are required to guide treatment selection in this challenging patient population.

METHODOLOGY

This prospective cohort study was conducted at Ain Shams University hospitals in Cairo at the time period from Jan. 2020 till 31st Dec. 2023. Adult patients (≥18 years) with chronic lower limb spasticity secondary to SCI were screened for eligibility.

Inclusion criteria :patients with lower limb spasticity post spinal cord injury of at least 12 months duration from onset of injury with failure of conventional medical, physical and rehabilitation methods, age not less than 18 years old, patients without previous surgical intervention for spasticity, patients subjected to regular physical rehabilitation program for at least 6 months (3 sessions/wk,2hr per session with proper splinting) prior to intervention and will be committed to post operative rehabilitation program.

Exclusion Criteria included patients who are unfit for general anaesthesia, age less than 18 years old, patients with dominant upper limbs spasticity than lower limbs, pressure sores at the site planned for surgical intervention, patients with severe spine deformity, patients with severely fixed lower limbs joints deformity, eligible patients who refused to sign informed medical consent, patients who are not willing to preform intensive physiotherapy and rehabilitation program postoperatively.

Patients were assigned to either operation on the basis of intrathecal baclofen pump availability and feasibility otherwise assigned to selective rhizotomy. Randomization was not applicable because insufficient financial resources to provide ITBs at some intervals throughout the study's time. All patients' assessment had been done preoperative, postoperatively after 3 months, after 6 months and after one year using the following scoring scales; Modified Ashworth Scale (MAS), Visual Analogue Score (VAS), Spinal Cord Injury Spasticity Evaluation Tool.

Surgical Procedure

A-Intrathecal Baclofen Pump

All patients underwent an intrathecal baclofen screening test with ascending doses of 50,75,and 100 μadministered at 24 hour intervals to assess the clinical response in spasticity, strength, sensation, and adverse events. The response is assessed over 8 hours. Patients with positive response proceeded with pump implantation .Under general anesthesia a SynchroMed Pump (Medtronic) was implanted in the left abdominal subcutaneous pocket and connected to an Ascenda intrathecal catheter inserted via a lumbar puncture (L3-L4/L4-L5) under fluoroscopic guidance Fig 1 . The cather tip positioned around the T8 vertebral level for lower limib spasticity.

B- Selective rhizotomy

The procedure was performed under total intravenous anesthesia without muscle relaxant for intraoperative electrophysiological monitoring.EMG needle electrodes were placed .

Roots exposure can be done anterolateral to conus medullaris or at lower lumbar region at the level of exit foramina from L1-L5 via laminoplasty Fig 2. Park criteria [10] was used for rootlets sectioning .Inclusion of anterior root for resection in cases of mixed spasticity and dystonia. Dura was closed water tight by continuous running silk sutures, followed by routine post-operative monitoring, wound care , and physiotherapy

Ethical Approval

This study was conducted in accordance with the Declaration of Helsinki and approved by the Research Ethics Committee of the Faculty of Medicine, Ain Shams University (FMASU 545/2020) Written informed consent was obtained from all participants prior to enrollment.

Statistical analysis

Data were analysed using SPSS version 27. The quantitative data were presented as mean, standard deviations and ranges when parametric and median, inter-quartile range (IQR) when data found non-parametric. Normality of continuous variables was assessed using the Shapiro Wilk test before selecting the appropriate statistical tests. Also, qualitative variables were presented as number and percentages. A p-value < 0.05was considered significant.

Results

A total of 40 patients with post spinal cord injury lower limb spasticity were included in this study, comprising 20 patients who underwent intrathecal baclofen (ITB) and 20 patients who underwent SR procedures. The mean age in the ITB group was 43.5 ± 14.95 years compared with 36.4 ± 12.8 yearsin the rhizotomy group. The ITB group included 17 males (85%) and 3 females (15%), whereas the rhizotomy group included 14 males (70%) and 6 females (30%).Regarding the neurological level of injury, patients in the SR group had a level of injury ranging from C5,6 to D10 with C5,6 being the most common level of injury (15%), while in the ITB group and level of injury ranged from C5,6 to D11,12 with C7 representing the most common level of injury (20%).Table 1

Table 1. Baseline demographic and clinical characteristics of patients undergoing intrathecal baclofen (ITB) therapy and selective rhizotomy.

	Selective Rhizotomy (n = 20)	ITB (n = 20)	P-value
Age (years), mean ± SD	36.35 ± 12.82	43.50 ± 14.95	0.113
Age range (years)	18–63	20–68	
Male sex, n (%)	14 (70.0)	17 (85.0)	0.451*
Female sex, n (%)	6 (30.0)	3 (15.0)	
Cervical level injury, n (%)	10 (50.0)	12 (60.0)	0.525*
Thoracic level injury, n (%)	10 (50.0)	8 (40.0)	

Fisher's exact test.
† Independent-samples t-test.

Spasticity and pain outcomes

Both intrathecal baclofen (ITB) therapy and selective rhizotomy resulted in significant improvements in lower limb spasticity during the follow up period. In the ITB group, the median MAS decreased from 3 preoperatively to 1.5 at 3 months and further improved to 1 at both 6 months and 1 year postoperatively ($p < 0.001$). Similarly, in the SR group, the median MAS score decreased from 3 preoperatively to 1.5 at 3 months and reached 1 at both 6 months and 1 year postoperatively ($p < 0.001$).

Pain severity also improved significantly in both groups. In the ITB group, the median VAS score decreased from 8 preoperatively to 3 at 6 months, and 1 at 1 year postoperatively ($p < 0.001$). Likewise, patients undergoing SR demonstrated a reduction in median VAS score from 8 preoperatively to 3 at 6 months, and 1 at 1 year postoperatively ($p < 0.001$).The greatest reduction in both MAS and VAS scores occurred during the first 6 postoperative months.

Quality of Life Analysis

Quality of life, as assessed by the Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET), improved significantly following both surgical interventions (Table 2).In the ITB group, the median SCI-SET score increased from −2.78 preoperatively to 2.13 at 6 months, and 2.63 at 12 months. The improvement over time was highly significant ($p < 0.001$).Similarly, in the SR group, the median SCI-SET score improved from −2.76 preoperatively to 2.12 at 6 months, and 2.70 at 12 months. This improvement was also highly significant ($p < 0.001$).

Table 2 : Comparison of Clinical Outcomes between ITB and SR groups

Outcome	Time point	ITB (n = 20) Median (IQR)	SR (n = 20) Median (IQR)	Between-group P value
MAS	Preoperative	3 (3–3)	3 (3–3)	0.159
	3 months	1.5 (1–2)	1.5 (1–2)	1.000
	6 months	1 (1–1)	1 (1–1)	0.194
	12 months	1 (1–1)	1 (1–1)	0.165
Within-group P value		**<0.001**	**<0.001**	
VAS	Preoperative	8 (8–8)	8 (8–9)	0.133
	3 months	5 (4–5)	5 (4–6.5)	0.279
	6 months	3 (2–3)	3 (2–3)	0.616
	12 months	1 (1–1)	1 (1–2)	0.309
Within-group P value		**<0.001**	**<0.001**	
SCI-SET	Preoperative	−2.78 (−2.82 to −2.72)	−2.76 (−2.86 to −2.70)	0.828
	3 months	−0.32 (−0.79 to −0.22)	−0.46 (−0.64 to −0.07)	0.829
	6 months	2.13 (1.80–2.25)	2.12 (2.00–2.20)	0.606
	12 months	2.63 (2.56–2.68)	2.70 (2.59–2.72)	0.066
Within-group P value		**<0.001**	**<0.001**	

MAS: Modified Ashworth Scale; VAS: Visual Analog Scale; SCI-SET: Spinal Cord Injury Spasticity Evaluation Tool.

Complications

Overall, complications occurred in 5 patients (25.0%) in the ITB group and 3 patients (15.0%) in the SR group, with no significant difference between the two groups (p = 0.429). Cerebrospinal fluid (CSF) leakage was observed in two patients (10.0%) in the ITB group and one patient (5.0%) in the SR group (p = 0.549). Surgical site infection occurred in one patient (5.0%) in each group , while transient sensory impairment was reported in one patient (5.0%) in the SR group and in none of the ITB patients (p = 0.311).Procedure specific complications were observed only in the ITB group, including one patient (5.0%) who developed a catheter granuloma requiring revision surgery and one patient (5.0%) who experienced acute baclofen withdrawal necessitating intensive care unit admission. All complications were managed successfully without permanent neurological sequelae.(Table 3)

Table 3 : Complications

Complication	SR (n = 20)	ITB (n = 20)	P value
Patients with ≥1 complication	3 (15.0%)	5 (25.0%)	0.429
CSF leak	1 (5.0%)	2 (10.0%)	0.549
Surgical site infection	1 (5.0%)	1 (5.0%)	1.000
Transient neurological deficit*	1 (5.0%)	0	0.311
Device-related complications†	0	2 (10.0%)	

* Transient sensory impairment. † Catheter granuloma and acute baclofen withdrawal requiring ICU admission.

Cost Analysis

The mean operative cost was significantly higher in the SR group than in the ITB group (92,700 ± 15,911.27 vs. 62,550 ± 9,338.52 EGP, respectively; p < 0.001) . However, after inclusion of the cost of the Medtronic SynchroMed II® pump, the mean total cost of ITB treatment increased to 662,550 ± 9,338.52 EGP. Furthermore, when the average annual cost of three pump refills was included, the estimated mean first-year cost of ITB therapy increased to 797,550 ± 9,338.52 EGP at time of study.

Discussion

Muscle Tone management and electrophysiological changes

Few studies compared the effect of intrathecal baclofen (ITB) versus and selective rhizotomy (SR) while reduction of lower limb spasticity was the primary objective in our study.

Both ITB and SR produced marked and sustained reductions in muscle tone throughout the 12 month follow up. Patients in the ITB group demonstrated a significant improvement in Modified Ashworth Scale (MAS) scores from 3 (IQR, 3–3) preoperatively to 1 (IQR, 1–1) at 1 year postoperatively (p < 0.001).

Similarly, the SR group showed a significant reduction in MAS scores from 3 (IQR, 3–3) preoperatively to 1 (IQR, 1–1) at 1 year postoperatively ($p < 0.001$). These findings confirm that both treatment modalities provide effective long term control of lower limb spasticity in patients with chronic spinal cord injury.

The effectiveness of ITB observed in our cohort is consistent with previous reports demonstrating substantial reductions in muscle tone. Loubser et al.[11] reported a decrease in mean Ashworth score from 3.79 to 2.00 after pump implantation in patients with refractory spinal spasticity. Likewise, Penn et al.[12] demonstrated a reduction from 4.0 to 1.2 with sustained improvement during long term follow up, while Coffey et al.[13] reported a decrease from 3.9 to 1.7 in a large cohort of patients with intractable spasticity. Similar improvements have also been described by Meythaler et al.[14], Abel et al.[15], Nance et al. [16], Azouvi et al.[17], and Burns et al.[18], despite differences in patient populations and follow up duration.

Furthermore, a systematic review by McIntyre et al.[19] concluded that continuous ITB provides consistent and clinically meaningful reductions in spasticity in patients with chronic spinal cord injury, with mean Ashworth scores improving from 3.1– 4.5 at baseline to 1.0 – 2.0 during follow up.

The favorable outcomes in our ITB cohort likely reflect the principal advantage of intrathecal drug delivery: direct administration of baclofen into the cerebrospinal fluid, allowing greater therapeutic efficacy with substantially lower doses than oral therapy while minimizing systemic adverse effects. In addition, programmable pump systems permit individualized dose adjustment according to changes in neurological status, making ITB particularly suitable for patients with fluctuating or progressive spasticity.

Consistent with previous practice, all candidates underwent a preoperative intrathecal baclofen screening test to predict therapeutic response before permanent pump implantation. Although most patients responded favorably, two patients were excluded because of serious adverse events during test dosing, including seizures in one patient and respiratory compromise in another. Similar exclusions after screening have been reported by Loubser et al.[11] and Coffey et al.[13], emphasizing the importance of preoperative testing for patient selection and safety.

Compared with ITB, evidence supporting SR for adult spinal cord injury remains relatively limited. Nevertheless, the available literature consistently demonstrates significant reductions in muscle tone following root sectioning. Gump et al.[20] reported significant improvements in both spasticity and gait after selective dorsal rhizotomy, whereas Kurze et al.[21] and Oraee-Yazdani et al.[22] demonstrated sustained reductions in lower limb spasticity without neurological deterioration. Similarly, Kakodkar[23] , in a systematic review, reported that SDR reduced spasticity in more than 75% of treated adult patients, although the majority of available evidence originated from cerebral palsy cohorts.

Importantly, five patients with mixed spastic-dystonic hypertonia underwent combined anterior and posterior root rhizotomy (CAPR) rather than conventional SDR alone. We believe this strategy is clinically important because dystonia may become clinically apparent once the spastic component is eliminated.

Addressing both anterior and posterior root contributions in carefully selected patients may therefore provide more durable control of mixed hypertonia than SDR alone. This concept is supported by the techniques previously described by Abdel Ghany et al.[8] and Albright et al.[9]

While ITB offers the advantage of adjustable and reversible therapy, SR provides durable tone reduction without lifelong device maintenance. Our findings also expand the limited evidence supporting SR in adults with spinal cord injury and suggest that CAPR may represent an effective surgical option for patients with mixed spastic-dystonic hypertonia.

Pain and Life Style Control

The effective management of spasticity should alleviate pain and improve functional independence. In the our study, both ITB and SR produced substantial reductions in pain intensity together with significant improvements in quality of life over the 12 month follow up. Patients treated with ITB demonstrated a significant reduction in VAS scores from 8.05 ± 0.76 preoperatively to 0.90 ± 0.55 at one year ($p < 0.001$), whereas patients undergoing SR improved from 8.50 ± 1.00 to 1.15 ± 0.81 ($p < 0.001$). Similarly, SCI-SET scores increased significantly in both groups, indicating marked improvements in functional independence and health related quality of life.

Our findings are consistent with previous reports demonstrating that ITB provides benefits beyond muscle tone reduction. Penn et al. [12] observed marked reductions in painful muscle spasms with sustained improvement in sleep quality following ITB implantation. Likewise, Loubser et al.[11] reported improvements in functional independence in most treated patients, while Meythaler et al. [14] demonstrated enhanced balance, endurance, and walking ability among patients with preserved voluntary motor function. Similar improvements in activities of daily living, particularly transfers, dressing, and personal care, were also reported by Azouvi et al.[17] Collectively, these studies suggest that the reduction in spasticity achieved with ITB reflects into meaningful functional gains and improved quality of life rather than merely improving neurological examination scores.

Evidence regarding quality of life outcomes following selective rhizotomy in adults with spinal cord injury remains limited but supports similar functional benefits. Gump et al.[20] reported improvements in gait and overall quality of life after SDR, with transient relief of deafferentation pain in the spinal cord injury subgroup. Likewise, Kakodkar [23]found that approximately 70% of patients with spinal cord injury experienced reductions in musculoskeletal pain together with improvements in activities of daily living following SDR.

The observed improvement in quality of life in both treatment groups is likely multifactorial. Reduction of spasticity decreases painful muscle spasms, facilitates joint mobility and positioning, improves ease of caregiving and rehabilitation, and enhances performance of daily activities.

Complications

Both ITB and SR demonstrated acceptable safety profiles in the present study, with relatively few complications and no permanent neurological morbidity. Importantly, all complications were successfully managed using conservative treatment or surgical revision when indicated, without compromising the overall clinical outcome. In the ITB group, five patients experienced procedure or device related complications, including one episode of acute baclofen withdrawal requiring intensive care admission and pump refilling, one surgical site infection successfully treated with debridement and culture guided antibiotic therapy without device removal, one catheter granuloma requiring surgical revision, and two cases of cerebrospinal fluid (CSF) leakage, one of which resolved with conservative management while the other required dural repair.All patients recovered without permanent sequelae.

ITB is generally safe but remains susceptible to device related complications. Pump malfunction, catheter failure, CSF leakage, infection, baclofen overdose or withdrawal, and the need for revision surgery have all been described following long term ITB therapy [11–15]. These complications are largely attributable to the implanted hardware rather than the pharmacological effects of baclofen itself and emphasize the importance of meticulous surgical technique, careful postoperative surveillance, and long term pump maintenance.The SR group experienced three postoperative complications, including one CSF leak managed conservatively with lumbar drainage and bed rest, one superficial wound infection successfully treated with debridement and culture directed antibiotics, and one case of transient postoperative dysesthesia that resolved spontaneously.The low complication rate observed following SR is comparable to previous reports. Gump et al.[20] reported only transient bladder dysfunction without permanent adverse effects, whereas Kurze et al. [21]documented a single wound infection with no major neurological complications. Together with our findings, these studies suggest that selective rhizotomy is a safe procedure when performed in appropriately selected patients. Although both procedures demonstrated favorable safety profiles, the nature of their complications differed.

This distinction should be considered during preoperative counseling and shared decision making. Patients selecting ITB should be informed of the lifelong need for pump surveillance, refilling, and potential hardware revision, whereas SR offers durable treatment without implanted hardware but remains an irreversible surgical intervention.

Economic Burden

An important finding of the present study was the marked difference in the long term economic burden between ITB and SR. Although the initial operative cost of SR was significantly higher than that of ITB, the cumulative cost of ITB became substantially greater after accounting for the implanted pump and routine baclofen refills. The implantable pump represented the largest contributor to the overall cost of ITB therapy, while the need for lifelong maintenance further increased the financial burden.These findings have important implications for patient decision making, particularly in low and middle income countries. In resource limited healthcare settings, the high cost of implantable hardware and the requirement for periodic pump refills may limit patient access to ITB despite its well established efficacy. In contrast, SR represents a one time surgical intervention that provides durable spasticity control . The

choice between ITB and SR should therefore not rely solely on clinical efficacy, as both procedures demonstrated comparable outcomes .Economic considerations, device availability, patient preference, and the ability to comply with long term follow up should also be incorporated into treatment planning. Our findings suggest that SR may represent a more cost effective treatment strategy for carefully selected patients with chronic SCI related spasticity, particularly in healthcare systems where access to implantable neuromodulation devices is limited.

Limitations:

This study has several limitations. First, treatment allocation was non randomized and influenced by device availability and financial considerations. Second, the study was conducted at a single center with a relatively small sample size, limiting the generalizability of the findings. Third, the follow up period was limited to 12 months and therefore does not capture long-term durability or late complications.

Conclusion

Both Intrathecal Baclofen (ITB) therapy and selective rhizotomy are effective surgical options for controlling Post-SCI spasticity, reducing pain,and improving daily function.Given the high cost of ITB,selective rhizotomy may represent a more cost effective alternative in low and middle income countries

Declarations

Clinical trial number

not applicable

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Author Contribution

E.A., A.I., A.E.S., S.E.M., A.H.A.R., and W.A.A.G. contributed to the conception and design of the study and the surgical management of patients. N.M. and T.S. contributed to patient assessment, rehabilitation, and clinical outcome evaluation. M.G.M. contributed to the anesthetic management of patients. A.H.A.R. coordinated data collection and drafted the manuscript. All authors contributed to the interpretation of the results, critically revised the manuscript for important intellectual content, and approved the final version for publication. All authors agree to be accountable for all aspects of the work.

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Figures

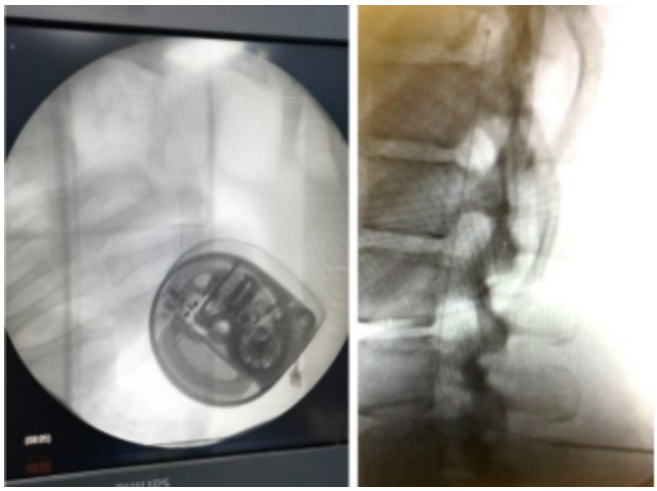

Figure 1

Fluoroscopic imaging of the pump and intrathecal catheter tip route

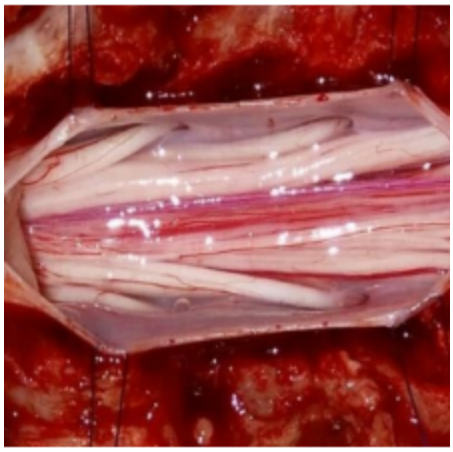

Figure 2

Midline dural opening and roots exposure