Retrospective Review

Real-Time Ultrasound-Guided Intrathecal Delivery of Nusinersen in Adult Patients With Spinal Muscular Atrophy and Complex Spinal Anatomy

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Background: Spinal muscular atrophy (SMA) is a rare genetic neuromuscular disorder characterized by progressive muscle atrophy and weakness. Nusinersen, the only US Food and Drug Administration-approved antisense oligonucleotide specifically for SMA management, is administered intrathecally. However, a substantial proportion of adult patients with SMA develop severe scoliosis, posing significant technical challenges for traditional lumbar puncture procedures. Real-time ultrasound guidance offers a potential solution for intrathecal nusinersen administration in these challenging cases.

Objectives: We sought to evaluate the technical feasibility and safety profile of real-time, ultrasound-guided intrathecal delivery of nusinersen in adult patients with SMA and complex spinal anatomy, including those with scoliosis or vertebral hardware.

Study Design: Retrospective chart review.

Setting: This study was conducted at a single medical center.

Methods: The data were retrospectively collected from the medical records Of 26 adult patients with SMA who had challenging intrathecal access (scoliosis or vertebral hardware) and who underwent real-time ultrasound-guided intrathecal nusinersen administration. Real-time ultrasound-guided lumbar puncture was performed using either the paramedian sagittal oblique view translaminar approach or the coronal view transforaminal approach. Procedure time, technical success, and adverse events were noted.

Results: A total of 151 real-time, ultrasound-guided lumbar punctures were performed. All procedures were technically successful and well-tolerated. The mean procedure time for the paramedian sagittal oblique view translaminar approach was 10.5 ± 1.7 minutes for moderate scoliosis and 20.7 ± 9.3 minutes for severe scoliosis. The mean procedure time for the transforaminal approach, used when the paramedian sagittal oblique view translaminar approach was not feasible, was 22.5 ± 6.1 minutes. No severe adverse events were observed.

Limitations: This was a retrospective, single-center study with a relatively small sample size. Generalizability may be limited.

Conclusions: Real-time ultrasound-guided intrathecal administration of nusinersen is feasible and appears safe in adult patients with SMA and complex spinal anatomies. Further prospective, multi-center clinical trials are warranted to validate these findings and evaluate long-term safety and efficacy in a larger patient cohort.

Key words: Spinal muscular atrophy, interventional ultrasonography, intrathecal injections, scoliosis, nusinersen, ultrasound-guided procedure, lumbar puncture, complex spinal anatomy

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Spinal muscular atrophy (SMA) is a rare genetic disorder characterized by progressive muscle atrophy and weakness. It is caused by mutations in the SMN1 gene, leading to a deficiency of the survival motor neuron protein, which is essential for the survival and proper function of motor neurons (1) .

Nusinersen is the only US Food and Drug Administration-approved antisense oligonucleotide specifically designed and administered intrathecally for treating SMA. By increasing the production of functional survival motor neuron protein, nusinersen can slow disease progression and potentially improve motor function and quality of life, particularly in patients with severe forms of SMA (2). The drug is typically given once every 4 months in order to directly target motor neurons in the spinal cord (3).

As SMA progresses, many patients develop severe scoliosis or undergo spinal surgeries; this significantly complicates the lumbar puncture and intrathecal injection procedures (Fig. 1). These anatomical alterations significantly increase procedural complications risks, such as spinal cord or nerve root injuries. Therefore, an individualized, multidisciplinary approach is essential to minimize these risks and promote the safety and efficacy of therapeutic interventions.

Previous studies have employed laminectomy to establish a surgical access route for intrathecal nusinersen injections in patients with severe SMA (4,5). Other studies have suggested that computed tomography (CT) or x-ray guidance can be useful for intrathecal injections. Shin, et al (6) reported that 87% of their patients with SMA received nusinersen via CT guidance. While CT-guided procedures can be effective, they expose patients to ionizing radiation. The cumulative radiation dose from repeated, long-term exposure to ionizing radiation poses a major concern (7).

Therefore, a safer and more efficient method of delivering intrathecal medications to patients with SMA and complex spinal anatomies is needed. Ultrasound-guided neuraxial intervention has become increasingly popular in clinical anesthesia and pain management practice. In a previous study, Zhang, et al (8) reported their experience of using ultrasound guidance for intrathecal nusinersen administration in 3 patients with SMA and severe scoliosis. Our group has developed expertise in ultrasound-guided neuraxial techniques. As a result, we established a multidisciplinary team comprising anesthesiologists, neurologists, and surgeons to use ultrasound when administering nusinersen to patients with severe SMA and complex spinal anatomies.

Our retrospective study aimed to summarize our experience and evaluate the feasibility and safety of real-time, ultrasound-guided intrathecal injections in this patient population at our medical center.

Methods

We conducted a retrospective single-center study to evaluate the technical success rate, safety profile, and feasibility of real-time ultrasound-guided intrathecal nusinersen administration in adult patients with SMA and complex spinal anatomy.

This study was approved by the Ethics Committee of Tongji Hospital (TJ-IRB20230874) and registered with the Chinese Clinical Trial Registry (No.: ChiCTR2300075122; Date: August 25, 2023) . Informed consent for this study was obtained from all patients or their legal guardians.

Patient Selection

The study included all adult patients with SMA and moderate or severe scoliosis who received nusinersen treatment via ultrasound-guided lumbar puncture at our hospital from January 2022 through December 2023, while excluding patients with who were under 18 years of age, those with cognitive dysfunction, or those who received nusinersen treatment through traditional or CT/x-ray-guided lumbar puncture techniques.

Procedures

Real-time Ultrasound-guided Paramedian Sagittal Oblique View Translaminar Approach

The paramedian sagittal oblique (PMSO) view is currently the most popular approach for central neuraxial blocks. We applied the PMSO technique for real-time, ultrasound-guided lumbar puncture as described by Karmakar and Sivakumar (9,10).

Before each puncture, we reviewed the patient's lumbar CT images to plan the puncture trajectory. The patient was placed in a lateral decubitus position with the lumbar spine flexed and secured. A low-frequency ultrasound probe (Edge II, FUJIFILM SonoSite, Inc.) was placed 1-2 cm lateral to the posterior midline of the lower back.

To obtain the PMSO view, the transducer was tilted slightly medially. The sacrum, a flat hyperechoic structure with a large acoustic shadow, was first identified. Moving cranially, the L5 lamina, a hyperechoic short slope with an acoustic shadow below, was visualized. The L5-S1 interlaminar gap, the space between the sacrum

and L5 lamina, was then identified. Subsequently, the L4-L5 and L3-L4 interlaminar spaces were determined cranially. The interlaminar space serves as the "acoustic window" through which neuraxial structures within the spinal canal can be visualized. The ligamentum flavum, a hyperechoic band, spans across adjacent laminae.

Next, the posterior dura, a linear hyperechoic structure, was identified. Below the posterior dura, the anechoic subarachnoid space containing cerebrospinal fluid was seen. Deeper visualization revealed the anterior dura and posterior longitudinal ligament, together forming a hyperechoic structure. The "double track

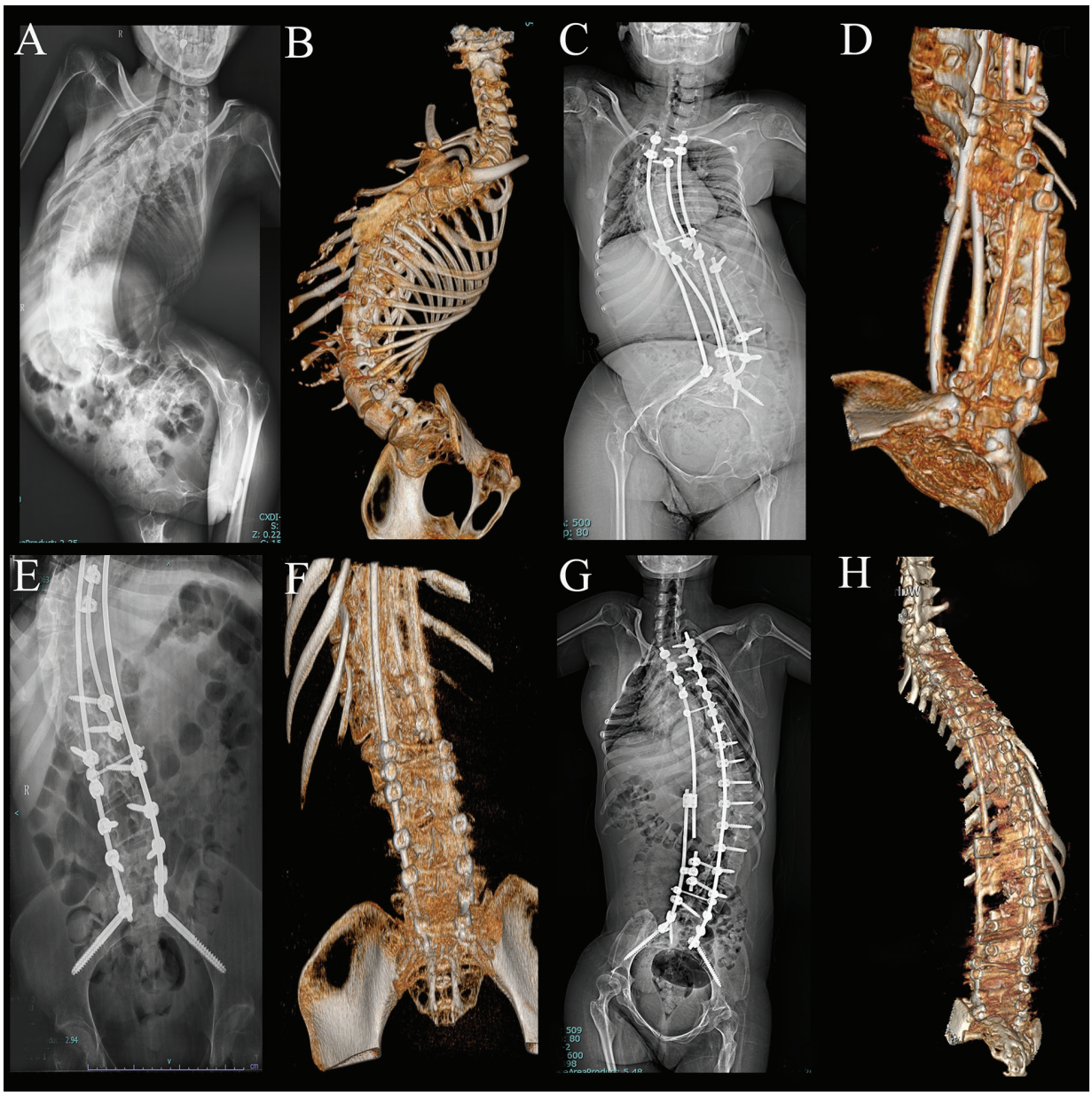

Fig. 1. *Spine x-ray and 3D CT reconstructions of adult patients with spinal muscular atrophy (A, B). X-ray and the corresponding 3D CT of spine images of one patient show severe scoliosis (C-H). X-ray and corresponding 3D CT of spine images of additional 3 patients demonstrate severe scoliosis together with spinal hardware following corrective surgery. These complex spinal anatomies significantly hinder traditional lumbar puncture techniques.*

sign," which is characterized by the dorsal dura mater, the anechoic subarachnoid space, and the ventral dura mater, is an important landmark for the procedure.

In patients who have undergone lumbar spine surgery, the morphology of the lamina may be altered and may no longer exhibit the typical short-slope appearance. However, the "double track sign," even when observed through atypical interlaminar spaces, can still serve as a reliable target for puncture (Fig. 2).

After skin preparation, 5 mL of 1% lidocaine was injected locally at the puncture site. A 21G × 3.8 cm guiding needle was then inserted in-plane, lateral to the ultrasound probe, and angled toward the dorsal dura mater. Subsequently, a 25G × 10 cm spinal needle was advanced through the guiding needle. Under real-time ultrasound guidance, the spinal needle was slowly inserted until it penetrated the dorsal dura mater and entered the subarachnoid space. A loss of resistance was felt upon dura puncture. Successful needle placement was confirmed by the aspiration of clear cerebrospinal fluid; 5 mL (12 mg) of nusinersen was then administered.

Real-time, Ultrasound-guided Coronal View, Transforaminal Approach

When the PMSO approach was not feasible, the coronal view, transforaminal approach was utilized, as previously described by our group (11).

Before the procedure, patients underwent lumbar spine CT and magnetic resonance imaging (MRI) scans. The MRI was used to identify the level of conus medullaris termination. The intervertebral foramen on the protruding side was carefully assessed on both 2D and 3D CT reconstructions. The largest and most superficial foramen below the conus medullaris was selected as the puncture target.

The patient was placed in a lateral decubitus position with the protruding side upward. A low-frequency ultrasound probe was placed above the selected intervertebral foramen to obtain a coronal view (Fig. 3). The pedicles of adjacent vertebrae appeared as hyperechoic lines with acoustic shadows underneath. The intervertebral foramen was identified between the 2 pedicles. Within the foramen, the bilateral dura mater appeared as hyperechogenic lines, and the anechoic subarachnoid space was visualized. The "double-track sign" was also observed, consisting of the bilateral dura mater and the subarachnoid space (Fig. 3). After local anesthesia, and under ultrasound guidance, a 21G x 3.8 cm guiding needle was inserted in-plane toward the lateral dura mater. A 25G x 10 cm spinal needle was then advanced through the guiding needle and into the inferior one-third of the lateral dura mater. A loss of resistance can be felt upon dura puncture. Clear cerebrospinal fluid was aspirated, and 5 mL (12 mg) of nusinersen was administered intrathecally. Patients were kept awake during the entire procedure in order to report any discomfort, particularly radiating pain in the lower extremities. If such symptoms occurred, needle advancement was immediately halted and the insertion angle was adjusted before proceeding again. This cautious approach helped to prevent potential nerve root injury.

Data Collection

We reviewed the medical records of all adult patients with SMA who were treated at Tongji Hospital from January 2022 through December 2023. The data collected included demographics (gender, age at first injection, body weight, and height), medical history (gene diagnosis report, disease classification, scoliosis severity, spine correction surgeries, and comorbidities), imaging studies (spine x-ray, lumbar CT, and lumbar MRI), nusinersen administration details (lumbar puncture level, approaches, and time duration of puncture), and any relevant adverse events.

The primary outcome was the technical success rate, defined as the presence of cerebrospinal fluid flow and subsequent successful nusinersen administration. Safety was assessed by records of adverse events such as post dural puncture headache, back pain, nerve root injury, meningitis, epidural hematoma, or subarachnoid hemorrhage over a 4-month postadministration follow-up period.

Demographics

The clinical characteristics of the 26 patients included in this study are shown in Table 1. Based on the age of onset, symptoms, and motor function, 12 patients were classified as SMA type II, 9 as SMA type III, and 5 as SMA type IV. Ten patients (38.5%) exhibited severe scoliosis, as determined by Cobb's angle measurements; 3 of these 10 patients underwent spinal correction surgeries.

Analyses

Our primary analysis evaluated the technical success rate of real-time, ultrasound-guided intrathecal nusinersen administration, defined as successful lumbar puncture and drug delivery. The secondary analysis

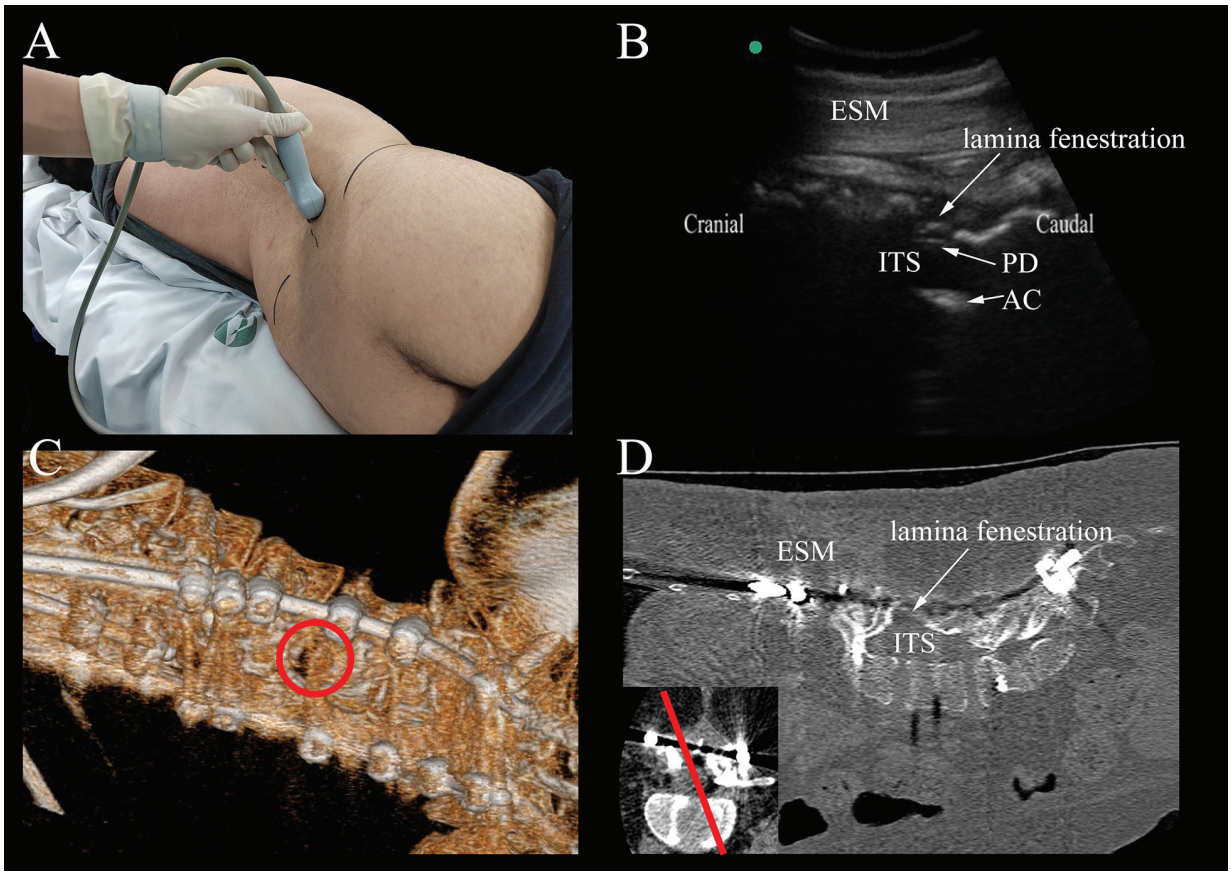

Fig. 2. *Paramedian sagittal oblique (PMSO) ultrasound view of one patient with spinal muscular atrophy and spine instrumentation*
(A) Patient positioning for the PMSO approach. The patient is positioned in a lateral decubitus position and the ultrasound probe is placed obliquely next to the posterior midline. (B) Ultrasound image of the PMSO view of her lumbar spine to show the lamina fenestration, which was created at the L3-L4 level to facilitate intrathecal access. The image demonstrates visualization of the erector spinae muscle, posterior dura mater, subarachnoid space, and anterior complex. (C, D) 3D and 2D CT reconstructions of the lumbar spine, respectively, showing the complex spinal anatomy with hardware and the lamina fenestration at the L3-L4 level (marked with a red circle). Abbreviations: ES: epidural space, PD: posterior dura mater, ITS: intrathecal space, AC: anterior complex, ESM: erector spinae muscle.

examined procedure times and clinical outcomes stratified by scoliosis severity (moderate: Cobb angle 25°–40°; severe: Cobb angle > 40°) and approach type—either the PMSO approach or the transforaminal approach. Demographic and clinical characteristics, including SMA type (II, III, or IV), age at first treatment, body mass index, and presence of instrumentation were descriptively summarized. Procedure-specific data, including durations and puncture levels for the PMSO and TF approaches, along with adverse events such as back pain, nerve root irritation, and severe events (e.g., meningitis or hematoma) over a 4-month follow-up period before the next administration, were documented descriptively. Data were collected from medical records using case report forms, entered into an Excel spreadsheet (Office 2016, Microsoft Corporation), and analyzed using descriptive statistics to summarize procedure times, success rates, and adverse events.

Results

All 26 patients received the prescribed 4 nusinersen loading doses followed by maintenance doses in accordance with the recommended dosing regimen. A total of 151 lumbar punctures were performed. All procedures were technically successful, with the full prescribed dose of nusinersen administered intrathecally in each case. The average procedure time for the translaminar approach was 10.5 ± 1.7 minutes for

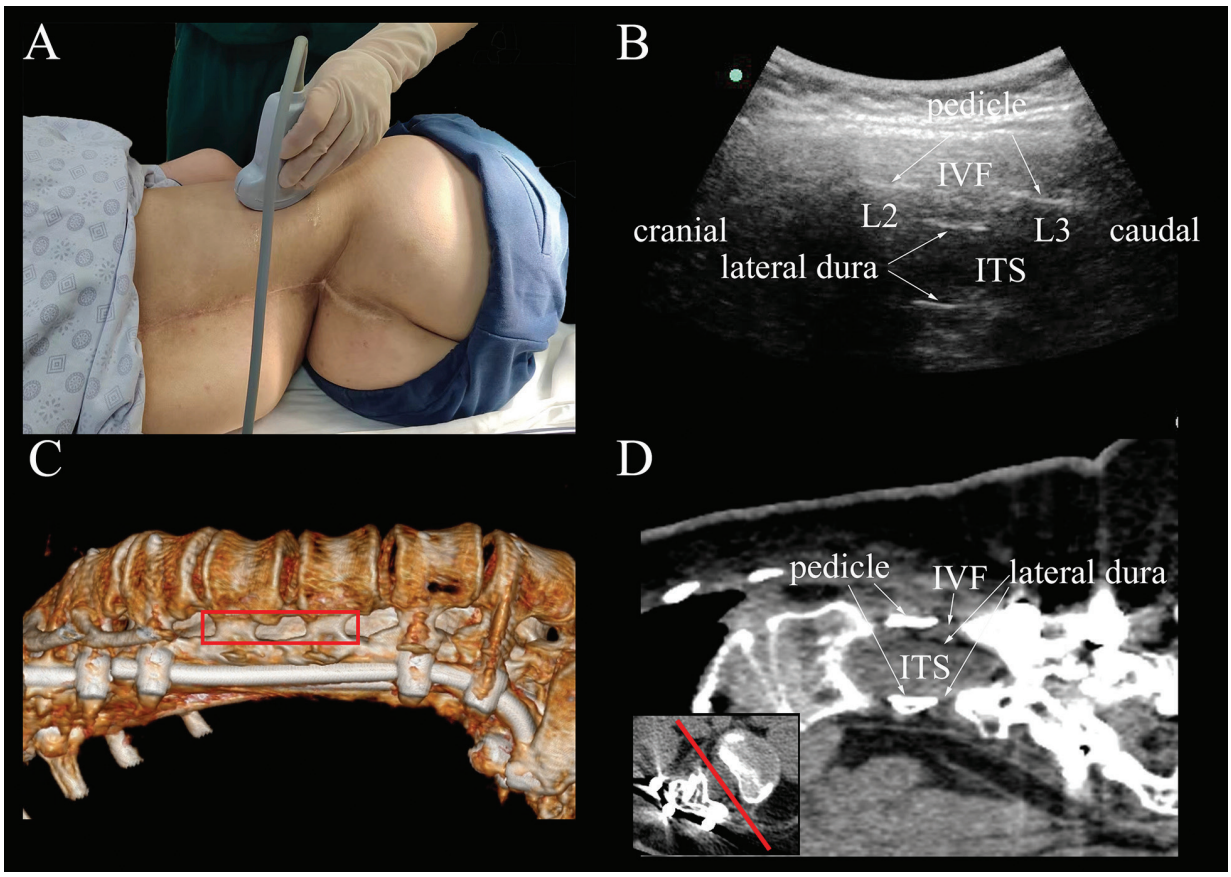

Fig. 3. *Transforaminal coronal view of one patient with spinal muscular atrophy and severe scoliosis and lumbar instrumentation.*
(A) Patient positioning for the transforaminal approach. The patient is positioned in a lateral decubitus position, and the ultrasound probe is placed coronally above the lumbar intervertebral foramen. (B) Ultrasound image of a coronal view of the lumbar intervertebral foramen. The patient had severe scoliosis that made the lumbar intervertebral foramen more superficial than normal. The bilateral dura mater can be clearly seen through the intervertebral foramen between 2 adjacent pedicles. (C) 3D reconstruction of the lumbar computed tomography image. The image shows severe scoliosis and twisting deformity. The wide and superficial opening of the intervertebral foramen are visible. The L2 and L3 pedicles and the intervertebral foramen are marked within a red frame, corresponding to the ultrasound image of (B). (D) 2D reconstruction of the coronal plane of the lumbar spine computed tomography image showing the pedicles, intervertebral foramen, and the bilateral dura mater. Abbreviations: ITS: intrathecal space, IVF: intervertebral foramen.

those with moderate scoliosis, and 20.7 ± 9.3 minutes for those with severe scoliosis (Table 2). The average procedure duration for the transforaminal approach in those with severe scoliosis was 22.5 ± 6.1 minutes.

All patients tolerated the puncture procedures well, with no severe complications reported. There were no instances of post dural puncture headache or puncture-related infections. Five instances of transient nerve root irritation occurred during transforaminal procedures, which resolved after needle repositioning. Additionally, 5 patients experienced mild back pain following lumbar puncture, which resolved spontaneously within 72 hours without the need for specific treatment.

Discussion

Our study cohort included 26 patients who were genetically diagnosed with SMA; many of whom had severe scoliosis or had undergone complex spinal corrective surgeries. These anatomical challenges make traditional lumbar puncture techniques difficult, highlighting the need for a safe and reliable method for intrathecal delivery of nusinersen in this patient population.

Table 1. *Demographic and clinical characteristics of adult patients with spinal muscular atrophy (SMA).*

Demographics	SMA Type II	SMA Type III	SMA Type IV	Total
Number of patients (n)	12	9	5	26
Men/women	5/7	7/2	4/1	16/10
Age at first treatment (y)	18~51	18~40	22~50	
BMI (kg/m^2), mean ± SD	22.9 ± 7	21.8 ± 3.5	23.1 ± 4.3	
Clinical Data				
Moderate/severe scoliosis (n)	2/10	9/0	5/0	16/10
Instrumentation (n)	3	0	0	3

BMI = body mass index; SD = standard deviation
*Moderate scoliosis: Cobb angle between 25° and 40°
Severe scoliosis: Cobb angle > 40°

Table 2. *Clinical characteristics, procedural outcomes, and adverse events of ultrasound-guided intrathecal nusinersen delivery in Adult patients with spinal muscular atrophy and scoliosis.*

Scoliosis	Moderate	Severe
Cobb angle	< 40°	> 40°
Number of patients	16	10
Instrumentation	0	3
Ventilation support	0	1
Puncture Level		
L2/3	0	5
L3/4	16	5
Translaminar Approach		
Patients/procedures	16/85	6/42
Duration (min)	10.5 ± 1.7	20.7 ± 9.3
Transforaminal approach		
Patients/procedures	0	4/24
Duration (min)	—	22.5 ± 6.1
Adverse events		
Post dural puncture headache	0	0
Back pain	3	2
Nerve root irritation	0	5
Severe adverse events*	0	0

*Severe adverse events include infection leading to meningitis, bleeding resulting in hematoma formation, nerve damage causing neurological symptoms, seizures, and allergic reactions to anesthetics or disinfectants used during the procedure.

Previous studies have explored alternative approaches to intrathecal nusinersen administration in patients with SMA who have difficult lumbar access. There are reports of using CT-guided approaches for intrathecal injections in such patients (7,12-16). Fluoroscopy-guided techniques have also been utilized with high success rates (15,17). However, using ionizing radiation in these procedures is a concern, particularly with the need for multiple injections over a patient's lifetime. One study involving 20 patients with SMA undergoing 108 cone-beam CT-guided procedures reported an average radiation dose of 10 mSv (13). Given these concerns, our group employed a radiation-free, ultrasound-guided technique, which has steadily gained popularity in our practice (11).

The results of our study demonstrate that real-time ultrasound-guided intrathecal nusinersen administration is both technically feasible and well-tolerated in adult patients with SMA and complex spinal anatomies. All 151 ultrasound-guided lumbar punctures were technically successful and there were no severe adverse events recorded. Notably, no patients reported post dural puncture headache, a common complication of lumbar punctures. Using a 25G pencil-point spinal needle likely minimized cerebrospinal fluid leakage and, consequently, the incidence of post dural puncture headache. Mild back pain was reported in 3.3% (5/151) of procedures but resolved spontaneously within 72 hours. Additionally, 20.8% of the patients undergoing transforaminal puncture experienced transient electric shock-like sensations; no lasting nerve damage occurred. This suggests that ultrasound-guided transforaminal lumbar puncture is a safe and effective technique when performed carefully.

Previous reports have reported using ultrasound for lumbar punctures to administer local anesthetics or therapeutic medications (9,18). Some studies have advocated for using ultrasound for prepuncture localization (19), while others have utilized real-time ultrasound guidance for needle insertion (20). Wei, et al (21) used a real-time ultrasound-guided translaminar approach for intrathecal nusinersen administration with a success rate of 95% using an 18G needle and puncture frame. Zhang, et al (8) reported 15 successful ultrasound-guided intrathecal nusinersen procedures in 3 patients with SMA and severe scoliosis, using the PMSO approach and a 22G echogenic needle. In comparison, our study achieved a 100% success rate using a 25G spinal needle, which also can be clearly visualized on ultrasound images. The smaller diameter of this needle minimizes tissue and dura trauma and the likelihood of post dural puncture headache, which may be

particularly beneficial for patients requiring repeated punctures.

Moreover, we introduced a novel ultrasound-guided coronal-view transforaminal approach for patients with extremely complex spinal anatomies, in whom the PMSO approach was not feasible. The 100% technical success rate achieved in our study should be interpreted with caution, given the small sample size. While this outcome reflects the precision and feasibility of the ultrasound-guided approach in our hands, it is possible that with a larger sample size, the technical success rate may vary. Additionally, the small sample size may have introduced bias, potentially overestimating the true success rate of the procedure. Therefore, future studies with larger cohorts are needed to validate these findings and provide a more comprehensive assessment of the technical success rate.

Notably, the transforaminal approach, while effective, carries a potential risk of nerve root injury or radicular artery injury, and should be considered only when the translaminar approach is not feasible. Literature concerning transforaminal intrathecal injection is scarce. One study using CT guidance reported 4 adverse events in 27 procedures, including a serious case of subarachnoid hemorrhage (22). Snoj, et al (23) achieved a 60% success rate using ultrasound-guided transforaminal delivery of nusinersen in patients with SMA; they did not provide specific technical details. In our study, we used a 25G spinal needle for the transforaminal approach, and achieved a 100% success rate, although the procedure took slightly longer than the translaminar approach.

Once the translaminar approach is not feasible, the transforaminal approach should then be considered, especially in patients with laterally displaced vertebral foramina. This anatomical alteration facilitates ultrasound-guided interventions within the intervertebral foramen. However, safety is of the utmost importance when considering this technique, and actions must be taken to avoid complications. Kambin's triangle, located at the lower third of the intervertebral foramen, an anatomical corridor utilized in transforaminal endoscopic procedures (24), can guide safe needle placement, avoiding critical vascular and neural structures. In addition, patient vigilance during the procedure is crucial. patients must remain awake to promptly report any discomfort, particularly shooting or electric shock-like sensations, to minimize the risk of nerve injury.

The successful use of ultrasound-guided techniques in our study opens avenues for broader clinical applications, including spinal anesthesia or pain management for patients with severe scoliosis. Further research is needed to explore the potential of ultrasound guidance in other clinical scenarios, such as epidural analgesia and other interventional procedures.

Limitations

Our study suggests the feasibility and safety of real-time ultrasound-guided intrathecal nusinersen delivery in adult patients with SMA and complex spinal anatomy. However, several limitations need to be acknowledged. The retrospective nature and small sample size, due to the rarity of this patient population, may limit the generalizability of our findings. The lack of a control group further restricts our ability to draw definitive conclusions about the comparative effectiveness of this technique. Additionally, the single-center design and the highly specialized skills required for this approach may limit its broader application. Furthermore, the 100% technical success rate reported in our study, while reflecting the precision of the ultrasound-guided approach in our hands, warrants cautious interpretation and necessitates validation through long-term clinical outcome data. Finally, the inherent risks associated with the transforaminal approach, particularly concerning potential nerve root injury or spinal vascular injury, necessitate meticulous attention to detail and adherence to safety protocols.

Despite these limitations, our study addresses a critical clinical need by developing a novel technique to resolve challenges encountered in real-world practice. The successful implementation of ultrasound-guided intrathecal nusinersen delivery in adult patients with SMA and complex spinal anatomies highlights the potential of this approach to improve patient care and outcomes. We believe that our findings contribute to the existing body of knowledge and may help inform clinical practice in this area. Further research is needed to address the identified limitations and validate the long-term efficacy and safety of this technique.

Conclusion

Real-time ultrasound-guided intrathecal administration of nusinersen is feasible and appears safe in adult patients with SMA and complex spinal anatomies. Further prospective, multicenter clinical trials are warranted to validate these findings and evaluate long-term safety and efficacy in a larger patient cohort.

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