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ORIGINAL RESEARCH

Endoscopic Epidurolysis for the Management of Chronic Spinal Pain: A Delphi-Based Italian Experts Consensus

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ABSTRACT

Introduction: Endoscopic epidurolysis (EE) is a minimally invasive procedure used to manage chronic spinal pain, particularly in cases unresponsive to traditional treatments. Despite its growing recognition, the literature lacks comprehensive guidelines on its optimal use. This study utilized a modified Delphi approach to gather expert consensus on best practices for EE in the Italian pain therapy network.

Methods: The study's scientific board conducted an extensive literature review to define key investigation topics, including clinical indications, preoperative assessments, and technical aspects of EE. A semi-structured questionnaire was developed and administered to a panel of experts. A two-round Delphi process was implemented, with consensus defined as at least 70% agreement on a 7-point Likert scale (agree or strongly agree). Statements that did not reach consensus in the first round were rephrased and resubmitted in the second round.

Results: Twenty-six clinicians participated in the study, with a 100% response rate in both rounds. In the first round, consensus was achieved for 9 out of 19 statements. In the second round, 8 out of 10 rephrased statements reached the consensus threshold. Key areas of agreement included the clinical indications for EE, the importance of preoperative imaging and anesthetic assessments, and the use of specific techniques and tools for EE. However, consensus was not reached on the use of EE for disc herniation with radicular pain and the safety of interlaminar access compared to sacral hiatus access.

Conclusion: The study highlights the need for standardized protocols in EE to ensure consistent and effective treatment of chronic spinal pain. The consensus reached by the expert panel provides a framework for best practices, which can guide clinical decision-making and improve patient outcomes. Further research is necessary to validate these findings and address areas where consensus was not achieved.

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Key Summary Points

Why carry out this study?

Endoscopic epidurolysis (EE) is increasingly recognized for treating chronic spinal pain syndrome, but variability in instrumentation and procedures affects clinical outcomes. Consequently, no definitive guidelines exist.

This Delphi study aimed to gather expert consensus on 19 key areas to identify best practices for EE within the Italian pain therapy network.

What was learned from the study?

Experts agreed on the use of EE for treating lumbar spinal stenosis and failed back surgery syndrome, but not for disc herniation with radicular pain. Key practices include thorough preoperative assessments, preference for sacral access, and accurate documentation of procedure details and fibrosis severity.

The expert panel's consensus offers a comprehensive framework for best practices in EE (Fig. 4) guiding practitioners to enhance patient care and improve outcomes for chronic spinal pain.

INTRODUCTION

Endoscopic epidurolysis (EE), also known as epiduroscopy, spinal endoscopy, epidural myeloscopy, or myeloscopy, is a minimally invasive endoscopic procedure used to treat chronic spinal pain conditions [1]. Its first therapeutic application occurred in 1989, when epidural steroid was administered to 10 patients using a caudal endoscopic approach [2]. More consistent clinical use began in the 1990s, particularly with the introduction of sacral access [3]. Today, it is predominantly used for the treatment of failed back surgery syndrome (FBSS), a chronic pain condition also known as persistent spinal pain syndrome (PSPS) and postsurgical spine syndrome (PSSS) [4, 5]. EE is also used in cases of chronic low back pain (CLBP) refractory to surgical or infiltrative treatments and associated with conditions such as radiculopathies or lumbar spinal stenosis (LSS) [6–9]. Additionally, it can reveal morphological features and pain-triggering mechanisms that are not visible with traditional imaging techniques, providing insights into the structure of the spinal canal and the underlying causes of certain painful conditions [1, 10]. The advancement of EE technology and increasing evidence of its efficacy have led to its recognition as a valuable procedure in pain management by international scientific societies [11]. Despite increasing recognition of EE in pain management, its role and indications, and optimal tools to be used on the basis of the specific pain condition, remain poorly understood and investigated [9]. The procedure lacks standardization in both instrumentation and techniques. Initially, EE involved simple mechanical dissection using the endoscope tip [8, 12, 13]. Over time, advanced surgical tools capable of sectioning/ablating the pathological structures using laser techniques [14] and radiofrequency [15] have been introduced. Notably, Raffaeli et al. [1] developed the Raffaeli-Righetti technique, a novel approach that utilizes a Fogarty-type inflatable balloon and a low-temperature radiofrequency dissector operating at 4 MHz called Resaflex to visualize the anatomical space and effectively isolate pathological areas and then precisely target and ablate fibrotic tissues while preserving surrounding structures. This technique utilizes a new quantum molecular resonance (QMR) device (Resablator) that enables "cold" cutting, as the electrode for surgical lysis (Resaflex) remains below 50 °C. Today, EE techniques include radiofrequency/QMR, laser, and chemical agents for adhesiolysis [16]. After adhesiolysis, corticosteroids or other drugs such as antibiotics can be injected to reduce inflammation [11] or risks of infection [15]. While some practitioners prefer advanced methods like laser [17, 18] or radiofrequency dissectors [19–21],

others continue using traditional approaches involving endoscope tips and pharmacological solutions [6, 22]. Efforts have also focused on enhancing access to the epidural space. Traditionally performed through the sacral approach, some practitioners have adopted the interlaminar approach, which uses a smaller catheter diameter resulting in positive pain reduction outcomes [23]. A transforaminal approach has also been proposed for patients with FBSS at the foraminal level, with positive outcomes at 1-year follow-up [24].

The wide variation in EE techniques complicates the assessment of the procedure's overall effectiveness. Moreover, the lack of definitive evidence from randomized control trials contributes to uncertainty among clinicians regarding best practices in EE. In situations where evidence and guidelines are limited, consensus methods such as the Delphi technique can be highly valuable. The Delphi method involves a multi-round

Table 1 First semi-structured round questionnaire

Statement 1 Central lumbar stenosis is a clinical indication for EE
Statement 2 Failed Back Surgery Syndrome (FBSS)/Persistent spinal pain syndrome (PSPS) is a clinical indication for EE
Statement 3 Disc herniation with radicular pain or radiculopathy is a clinical indication for EE
Statement 4 A lumbosacral spine X-ray is a useful step before planning EE
Statement 5 It is useful to perform a preoperative anesthetic assessment before EE
Statement 6 If it is not possible to reach the epidural space via the sacral hiatus with the endoscope; it is possible to proceed via the interlaminar access
Statement 7 The interlaminar access is as safe as the sacral hiatus access to reach the epidural space with the endoscope
Statement 8 It is necessary to perform an epidurography with epidural contrast medium injection during EE
Statement 9 When performing an EE a saline infusion and a mechanical epidurolysis with specific instruments must be used
Statement 10 Epidural lysis of adhesions with a Racz catheter is a preparatory procedure to EE
Statement 11 Local anesthesia with light sedation is the technique of choice for EE
Statement 12 EE must be performed with an anesthetic plan allowing the detection of alarming symptoms such as neck pain, double vision, or headache
Statement 13 At the end of EE it is a normal practice to inject drugs into the epidural space
Statement 14 Dural tear requires an immediate interruption of the EE
Statement 15 There is a maximum volume of saline infusion during EE and when exceeded you must interrupt the procedure even if no neck pain or headache appears
Statement 16 At the end of the procedure, it is important to report the hyperemia grading and to describe its characteristics (artery or venous ectasia, blood flow interruption while stretching the structure, neoangiogenesis)
Statement 17 At the end of the procedure, it is important to report the severity of epidural fibrosis with the use of a validated scale
Statement 18 At the end of the procedure, it is important to report the presence/absence of allodynia after balloon catheter opening
Statement 19 At the end of the procedure, it is important to accurately describe the technique used for EE

survey process where experts anonymously provide their opinions, which are statistically summarized and refined through subsequent rounds until consensus is achieved [25, 26]. Delphi studies have proven useful in various medical fields, including pain management, for example to establish criteria for patient selection and technical procedures for lumbar facet joint denervation [27] and for spinal cord stimulation [28].

Given the current advancements in EE and the opportunities provided by the Delphi methodology, the ISAL Institute for Research on Pain created a group of Italian experts in EE, the ISAL Research Group, and conducted the present Delphi-based study to gather their opinions to reach a consensus on strategies and recommendations to define the most appropriate clinical practice for EE within the Italian pain therapy network.

METHODS

Study Design

A two-round modified Delphi approach was implemented. The Delphi method involves experts reaching agreement in an area where there is no definitive consensus [29]. The study's advisory board explored and discussed the existing literature to develop and refine topics for an exploratory semi-structured questionnaire. The BRUSO (brief, relevant, unambiguous, specific, and objective) model was used to develop the questionnaire [30]. During an online meeting, the advisory board developed 19 statements for use in a web-based survey to be administered to board members composed of Italian physicians with expertise in EE. These statements were designed to focus on clinical indications and contraindications of EE, preoperative assessment and management, and technical aspects of performing and reporting EE. The first-round semi-structured questionnaire is reported in Table 1.

Study Participants

A panel of experts in EE was invited to participate in the study on the basis of their scientific background or their involvement in EE discussions within scientific societies. The inclusion criteria for participation were as follows:

- Active involvement in EE research: participants must have published papers or conference abstracts related to EE or been actively involved in EE education.
- Experience: participants must have been using EE as a therapeutic tool for at least 5 years.

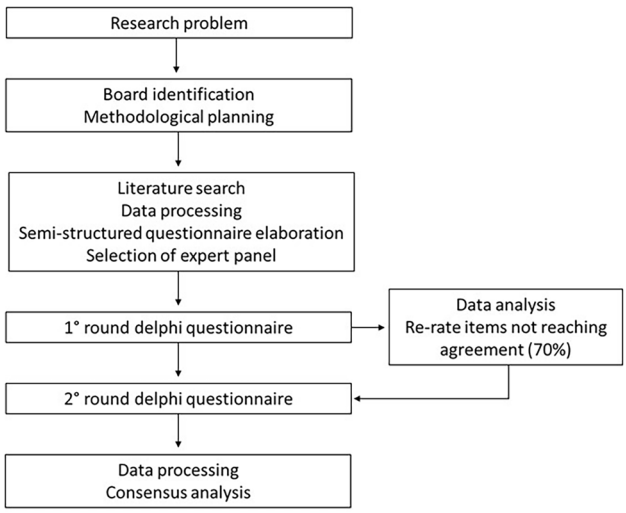

Fig. 1 Study flowchart of the Delphi investigation

- Membership to least one scientific pain society: participants must be members of at least one scientific pain society.

Table 2 Panelists demographics ($N = 26$)

Variable	N (%)
Gender	
Male	21 (81%)
Female	5 (19%)
Age (years)	58 (48–62)
Practice area (Italy)	
North	13 (50%)
Center	9 (35%)
South and Islands	4 (15%)
Specialty	
Anesthesiology and pain management	25 (96%)
Neurosurgery	1 (4%)
Years of experience	
5–10 years	13 (50%)
> 10 years	13 (50%)

On the basis of these inclusion criteria, 26 physicians were selected to participate in the study. An in-person and online meeting between the board and the selected physicians was held in Venice on March 14, 2023, to present the study's aims and methods. Internet tools were used to conduct the Delphi procedure (e-Delphi) [31, 32]. In each round, the panelists received an invitation email with a link to access the questionnaire via Google Forms. A 7-point Likert scale (1, strongly disagree; 2, disagree; 3, somewhat disagree; 4, neither agree nor disagree; 5, somewhat agree; 6, agree; 7, strongly agree) was implemented to assess the level of agreement. For consensus, a minimum of 70% of respondents with a level of agreement at least 6 (agree or strongly agree) was set in advance as the threshold [33]. All statements that met the defined threshold were included in the final recommendations, while those that did not were rephrased and resubmitted for a second Delphi round. In the second round, the same rules as the first round were applied. As previously suggested, the stability of responses was not judged as a stopping criterion [34]. Consequently, two rounds were set as the ending criterion. After the second round, a consensus analysis was implemented, and the research team conducted a final online meeting with all the panelists (Fig. 1).

Ethical review and approval were waived for this Delphi survey, which did not explore

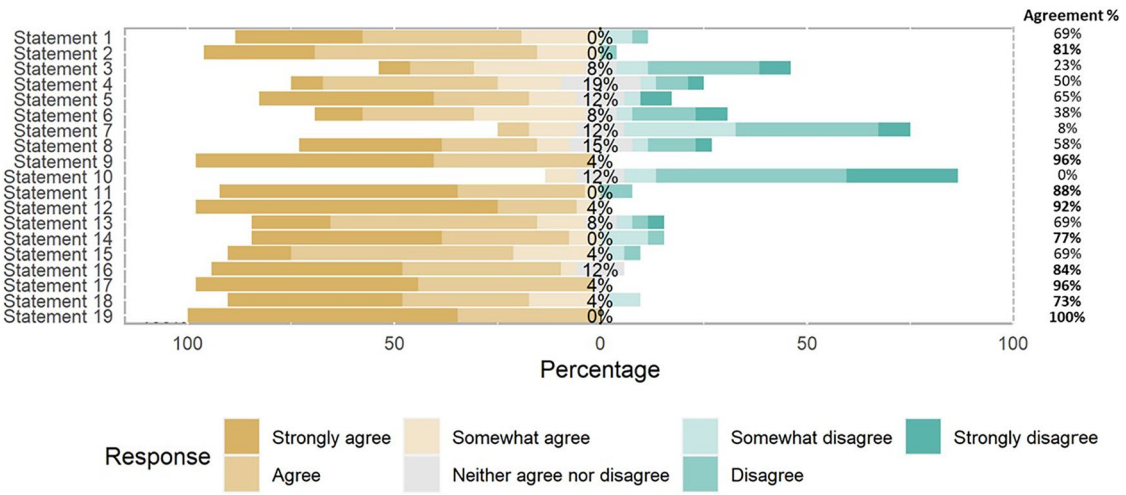

Fig. 2 EE Delphi consensus statements with percentage of agreement (agreement %) at round 1

Table 3 Second round questionnaire

Statement 1 (Rephrased)	Central lumbar stenosis can be a clinical indication for EE
Statement 3 (Rephrased)	Disc herniation with radicular pain or radiculopathy is not a clinical indication for EE
Statement 4 (Rephrased)	A lumbosacral spine X-ray or lumbosacral MRI can be a useful step before planning an EE to rule out the presence of Tarlov cysts and to measure the spinal canal size and the sacral hiatus
Statement 5 (Rephrased)	A preoperative anesthetic assessment can be useful before an EE
Statement 6 (Rephrased)	If it is not possible to reach the epidural space with the endoscope via sacral hiatus, it is possible to consider an interlaminar access
Statement 7 (Rephrased)	The interlaminar access could be less safe than the sacral hiatus access to reach the epidural space with the endoscope
Statement 8 (Rephrased)	It can be useful to perform an epidurography with epidural contrast medium injection during EE
Statement 10 (Rephrased)	Epidural lysis of adhesions with a Racz catheter is not a preparatory procedure for EE
Statement 13 (Rephrased)	In your opinion, it is useful to inject medicine into the epidural space at the end of EE?
Statement 15 (Rephrased)	Do you think there is a maximum volume of saline infusion to use during EE and when you exceeded it, you must interrupt the procedure even if no neck pain or headache appears?

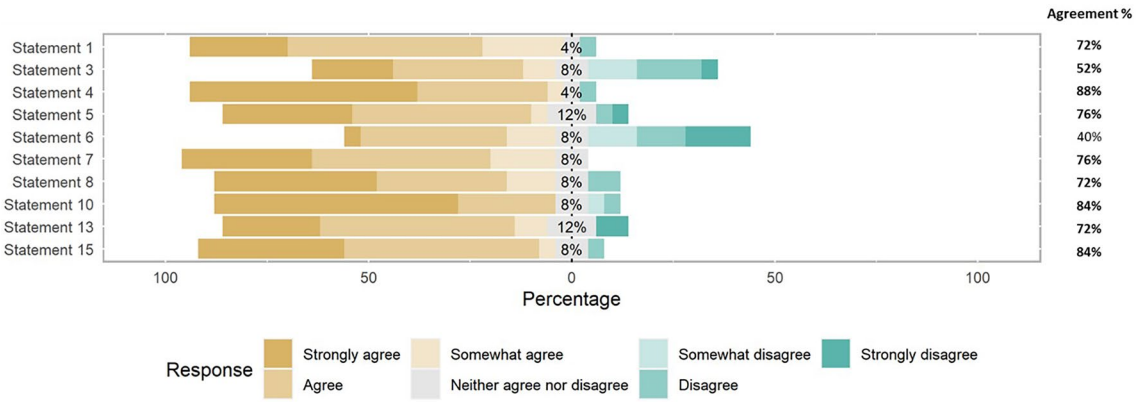

Fig. 3 EE Delphi consensus statements with percentage of agreement (agreement %) at round 2

individual patient therapies or pathologies, nor did it collect sensitive personal or clinical data. According to Italian legislation for non-interventional studies (Ministerial Circular N. 6, 2 September 2002), ethics committee approval is only required if the study addresses issues related to prescribed medicinal products, where patient inclusion in therapeutic strategies is determined by normal clinical practice rather than the trial protocol.

RESULTS

The first and second Delphi rounds were conducted on June 22 and December 6, 2023,

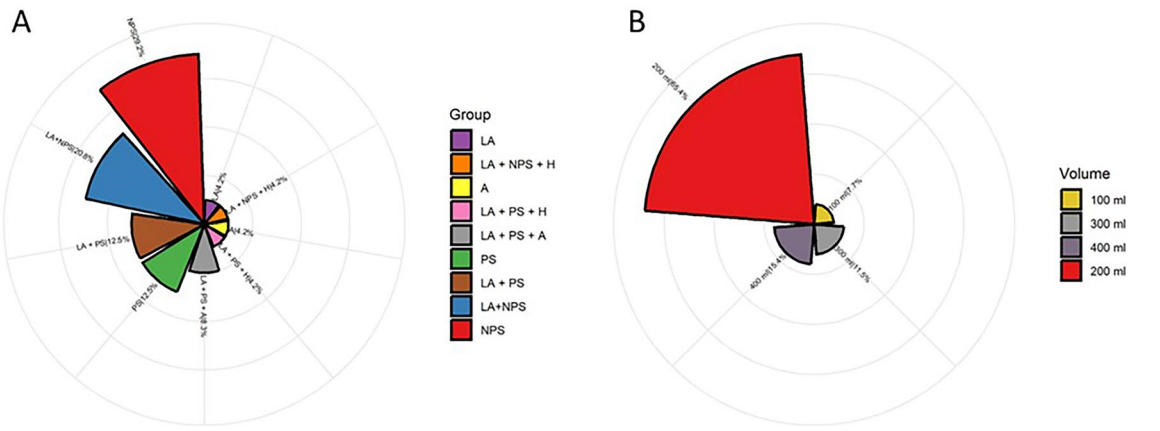

Fig. 4 **a** Drugs injected at the end of EE. *LA* local anesthetic, *NPS* non-particulate steroid, *H* hyaluronidase, *A* antibiotics, *PS* particulate steroids. **b** Volume of saline injected during EE

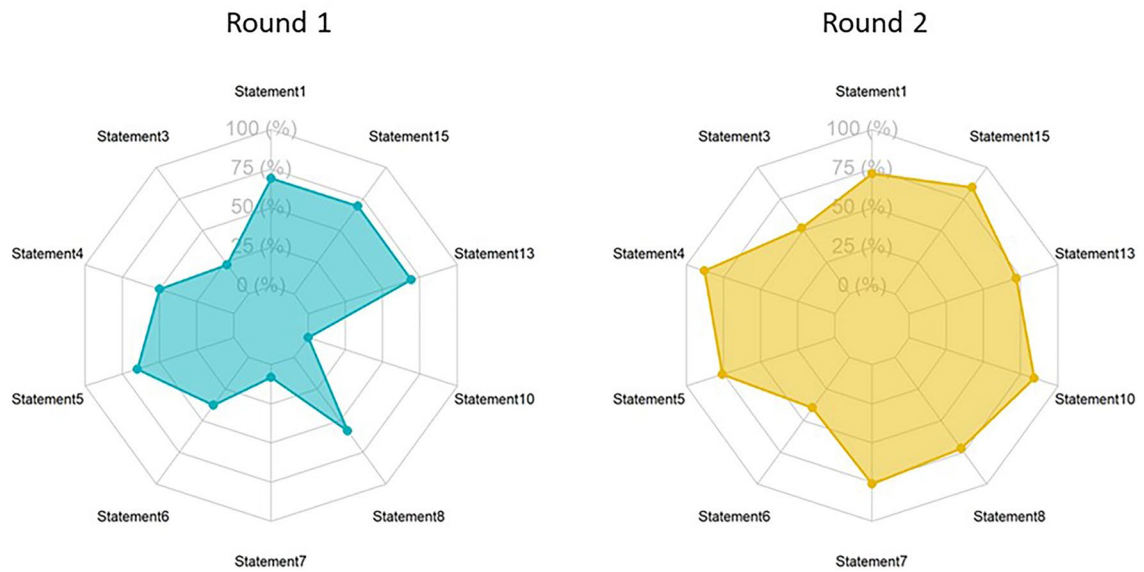

Fig. 5 Comparative agreement rate between the first and second Delphi rounds. Statement 1 (first round agreement 69% vs. second round agreement 72%), statement 3 (23% vs. 52%), statement 4 (50% vs. 88%), statement 6 (38% vs. 40%), statement 7 (8% vs. 76%), statement 8 (58% vs. 72%), statement 10 (0% vs. 84%), statement 13 (69% vs. 72%), statement 15 (69% vs. 84%)

respectively, with a 100% response rate for both rounds. The demographic characteristics of the panel of experts are reported in Table 2. The participants were mostly male (81%), with a median age of 58 years. Most experts completed residency in anesthesiology and pain management (96%), and half of the participants had more than 10 years of experience in EE.

In the first Delphi round, 47.4% of statements (9 out of 19) reached the consensus threshold of 70% agreement with a score of at least 6 (Fig. 2). The remaining 10 statements were reformulated and presented for evaluation in the second round (Table 3).

During the second round, 8 out of 10 revised statements reached consensus, showing an

increased percentage of agreement (Fig. 3). However, consensus was not achieved for two statements: statement 3 (disc herniation) and statement 6 (interlaminar access).

The drugs most commonly used at the conclusion of EE are non-particulate steroids (29.2%), followed by a combination of local anesthetic and non-particulate steroids (20.8%). Particulate steroids, either alone or in combination with local anesthetics, are used by 12.5% of the participants. A mix of local anesthetic, particulate steroids, and antibiotics is used by 8.3%, while local anesthetics alone account for 4.2% of usage. Other combinations, such as local anesthetics with non-particulate steroids and hyaluronidase, or antibiotics alone, are less common, each reported by 4.2% of the sample. Additionally, most practitioners (65.4%) use an average of 200 ml of saline, a volume considered relatively safe (Fig. 4).

The comparative agreement rates between the first and second Delphi rounds for the statements that did not initially reach the consensus are reported in Fig. 5.

DISCUSSION

EE is gaining recognition for effectively treating epidural space pathologies, especially FBSS/PSPS and CLBP linked to radiculopathies or LSS. EE is typically performed using percutaneous access to the epidural space through the sacrococcygeal ligament, utilizing a specialized set of instruments designed for this purpose. This set typically includes an introducer needle, a safety J-guide (Seldinger wire), a dilator, and a sheath. Seldinger technique and a 14-gauge Tuohy needle are used to establish percutaneous access to the epidural space. Once the dilator and guide wire are removed, an endoscope equipped with a video-guided catheter is introduced into the epidural space via the introducer. The video-guided endoscope is carefully maneuvered in a cephalic direction under direct visualization of the epidural space. Fluoroscopic imaging is simultaneously employed to confirm the vertebral level reached by the endoscope tip. To enhance the visual field, the epidural space is irrigated and expanded using saline infusion during the procedure. For epidurolysis, a Fogarty balloon filled with contrast medium is deployed to break down adhesions. Additionally, a surgical lysis of dense epidural scar adhesions is performed using a radiofrequency dissector with a spherical steel tip (0.80 mm diameter, 1 mm working depth). This dissector employs QMR technology to achieve mechanical lysis without causing a significant temperature increase, ensuring precise and safe adhesion management. These instruments are approved through the US Food and Drug Administration (FDA) regulatory process and comply with country-specific medical device regulations or European medical product licensing standards. The surgical technique described is commonly employed in Italy and certain European countries, such as Spain and Germany, but remains less adopted in others. The lack of standardized surgical procedures and instrumentation (also because of limited availability in certain countries) leads to variability in clinical outcomes. Consequently, definitive guidelines for EE have yet to be established.

This Delphi study aimed to obtain expert consensus on 19 statements related to clinical indications, preoperative assessment and management, and technical aspects of performing and reporting EE, in order to identify best practices for EE.

Clinical Indications (Statements 1–3)

In the field of clinical indications, experts reached consensus on the use of EE for LSS (statement 1, 72% agreement) and FBSS/PSPS (statement 2, 81% agreement). However, no consensus was achieved for its use in disc herniation with radicular pain or radiculopathy (statement 3, 52% agreement). The evidence supporting the use of EE for LSS includes few studies demonstrating significant pain relief and improved outcomes. Specifically, Igarashi et al. [6] found that EE combined with steroid injections provided substantial pain relief in patients with LSS. Lee et al. [35] showed that EE with a Ho-laser (ELND) was effective in alleviating axial LBP, suggesting that patients with LSS with primarily axial LBP might be ideal candidates

for ELND. Additionally, Raffaeli et al. [8], using their technique based on radiofrequency/QMR, reported that 67% of patients with LSS experienced overall pain improvement 1 year after EE. Marchesini et al. [36] found EE effective in reducing pain both immediately and 1 month after treatment in patients with FBSS and LSS, although the benefits gradually diminished over 24 months. Additionally, studies have shown that both epidural injections and percutaneous adhesiolysis can effectively provide temporary pain relief in patients with LSS [37–39]. Since percutaneous procedures are effective, it is reasonable to assume that the endoscopic approach, which offers direct visualization of the epidural space, would be equally beneficial. In conclusion, EE can be considered a viable intervention for patients with LSS, though further research is needed to confirm its efficacy and establish standardized protocols.

EE has been endorsed with varying levels of recommendation by several guidelines and recommendations for the treatment of FBSS/PSPS [9, 40–44]. In this study, broad consensus was achieved regarding the clinical indications of EE for FBSS/PSPS. However, when the studies were combined, a high degree of variability in outcomes related to pain and disability was reported [41]. This variability may be due to differing techniques (e.g., drug-only treatments versus mechanical/surgical removal of adhesions) or surgical tools (e.g., laser or radiofrequency dissectors), patient characteristics, or type of spinal surgery, with poorer outcomes observed in patients who underwent stabilizing procedures compared to non-stabilizing ones [45], and following lumbar fusion compared to discectomy and laminectomy [46]. Moreover, extensive fibrosis and multiple surgeries further reduce success rates [47], while matching adhesion location to pain source can improve long-term outcomes [48]. Careful patient selection is crucial for optimizing EE success and strengthening the evidence for its use in FBSS/PSPS. Multiple studies have revealed significant heterogeneity in the underlying pain conditions and morphological changes associated with this label [49, 50]. A preoperative endoscopic assessment could potentially optimize the management of FBSS by allowing for more precise characterization of morphological alterations in the epidural space, based on anatomical, morphological, or vasculoinflammatory findings. For instance, if pain is caused by inflammation and neurochemical changes, treatment may be effective without the need for complete lysis. Conversely, in cases of microfibrosis, it can easily be efficiently removed using a Fogarty balloon catheter.

Although the literature supports the clinical benefits of EE for pain and disability in FBSS/PSPS, more high-quality research is needed because of high variability in study outcomes.

The lack of consensus on the clinical indication of EE for radiculopathies caused by herniated discs is likely due to the small number of studies in the field. Early research reported favorable outcomes in 65% of patients with pain from herniated discs for which traditional discectomy was not indicated or other interventions failed [51]. More recently, Hazer et al. [52] found significant pain and disability improvements, especially in patients not operated on, while others have introduced trans-sacral epiduroscopic laser decompression for lumbar disc herniation, showing promising results [53, 54]. Given the limited evidence, EE for herniated discs should be approached cautiously and reserved for highly selected patients who are not suitable candidates for traditional surgery.

Preoperative Assessment and Management (Statements 4–5)

Regarding preoperative assessment and management, experts agreed with the usefulness of lumbosacral spine X-ray or MRI before planning an EE (statement 4, 88% agreement). Given the considerable anatomical variability of the sacral hiatus, including variations in the number of sacral vertebrae, sacral morphology, and other atypical alterations, preoperative imaging is highly beneficial. For instance, MRI can offer critical preoperative insights to help avoid potential complications, such as identifying large or multiple Tarlov cysts [55]. Sekiguchi et al. [56] found that the sacral canal's diameter averages 6.0 ± 1.9 mm, with some cases measuring less than 2 mm, making 22G needles impractical. Additionally, 3% of sacral hiatuses were

closed. Therefore, as it was suggested, precise imaging of sacral morphology is crucial for safe and effective EE [16].

Experts also agreed on the importance of a preoperative anesthetic assessment before EE (statement 5, 76% agreement). As a surgical procedure requiring sedation and anesthesia, EE should always be preceded by this evaluation, which includes identifying drugs that could affect the outcome, such as anticoagulants, and providing an opportunity for informed consent where risks and benefits are discussed with the patient.

Technical Aspects of Performing EE (Statements 6–15)

Experts agreed that interlaminar access is less safe than sacral access (statement 7, 76% agreement), but no consensus was reached on its use when sacral access is not possible (statement 6, 40% agreement). The interlaminar access presents some safety concerns, as it involves navigating closer to the dura mater, spinal cord, and nerve roots, which increases the risk of accidental dural puncture and nerve injury. In the Avellanal study [23], involving 19 patients with FBSS, only 6 patients (31.6%) experienced significant pain improvement 3 months after the procedure. Six others showed no improvement, while 2 (10.5%) had worsened pain at 6 months. Additionally, 4 patients (21%) experienced dural puncture, and 4 others had transient neurological symptoms, resulting in a 42% overall complication rate, as noted by Fai et al. [57].

Interlaminar access should not be attempted as an alternative to sacral hiatus access, as these approaches are not equivalent. Interlaminar access may be considered only when other approaches are not feasible, and the choice of approach should always be discussed with the patient as part of the informed consent process before EE.

Consensus on the use of epidurography during EE was reached in the second round, with 72% agreement. Epidurography is indeed a valuable tool for evaluating the extent, location, and characteristics of pathological sites prior to initiating the EE procedure. By injecting a contrast medium into the epidural space and using fluoroscopy or computed tomography (CT) imaging, epidurography provides real-time, detailed visualization of the anatomy and precise localization of adhesions as well as their relationship with surrounding structures. This information may help in planning the endoscopic approach. While MRI can broadly observe adhesions, its diagnostic precision is low [58]. In contrast, epidurography offers high diagnostic accuracy by clearly identifying blockages at adhesion sites [59]. However, it is important to note that only direct endoscopic visualization enables the identification of pathological tissues and provides accurate characterization of their morphological and functional features, which cannot be achieved through contrastography or MRI alone [1, 8, 56]. Consequently, performing a lysis procedure based solely on contrast imaging is inadvisable, as it may lead to tissue damage, including the dura, hemangiomas, or other structures as a result of the inability to differentiate tissue types.

Experts broadly agreed on the importance of combining saline infusion and mechanical/surgical lysis of adhesions during EE (statement 9, 96% agreement). Saline infusion is essential for clearing the surgical field of blood and fluids, enhancing the surgeon's visibility, and distending the epidural space to facilitate instrument maneuverability and improve procedural efficiency. Additionally, it dilutes inflammatory mediators potentially reducing post-procedural pain and inflammation [60]. Mechanical/surgical epidurolysis using specific instruments is crucial for precise and controlled removal of adhesions and scar tissue. These specialized tools potentially enhance the efficacy of the procedure, allowing for better outcomes and shorter procedure times.

In this study, experts agreed that epidural lysis of adhesions with a Racz catheter is not a preparatory procedure for EE (statement 10, 84% agreement). While both epidural lysis of adhesions with a Racz catheter and EE aim to treat epidural adhesions and related pain, they are distinct procedures and are not typically used sequentially. While comparative studies specifically focusing on the effectiveness and complication rates of EE versus the

Racz procedure are lacking, some general observations can be made. Both procedures involve similar risks due to accessing the epidural space. However, EE offers the advantage of direct visualization, potentially reducing complications related to instrument misplacement or medication delivery by allowing more accurate targeting of the treatment area. This blind approach makes it challenging to avoid vessel and dura laceration when abnormalities are present in the spinal canal. Additionally, it overlooks the underlying morphology, reducing its effectiveness in accurately identifying the pain-triggering zone and determining the extent of tissue removal [8].

In contrast, the Racz procedure, though lacking direct visualization, is less technically demanding and may be preferred depending on the practitioner's expertise.

A strong consensus was reached for using local anesthesia with light sedation as the preferred technique for EE (statement 11, 88% agreement) and for the importance of an anesthetic plan that allows detection of alarming symptoms like neck pain, double vision, or headache [59] (statement 12, 92% agreement). Local anesthesia with light sedation is favored because it effectively manages pain at the surgical site while reducing anxiety and discomfort without the risks associated with general anesthesia [61]. Additionally, patients under light sedation remain conscious and can report any unusual sensations [62].

This study found consensus on the practice of injecting medication into the epidural space following EE (statement 13, 72% agreement). Rapčan et al. [47] observed that while both mechanical lysis alone and with added hyaluronidase and corticosteroids improved pain at 6 months in patients with FBSS/PSPS, only the medication group sustained relief at 12 months, indicating a notable benefit of adding drugs to mechanical procedures. However, a systematic review suggested that both epidural saline and steroids with saline have effects beyond placebo and are effective [37]. These findings imply that the primary benefit of EE may come from the mechanical removal and distension of pathological structures, with medication offering additional but not necessarily targeted benefits. Further research is needed to evaluate the effectiveness of medications used during EE compared to other strategies.

Experts agreed in the first round that a dural tear requires immediate interruption of EE (statement 14, 77% agreement). An approach that we believe to be scientifically sound, in light of the results reported by the authors [1], demonstrated that endoscopic exploration of the subdural space during an EE procedure in patients with FBSS/PSPS has never led to the identification of pathological findings such as adhesive arachnoiditis or reactive fibrosis in the subdural compartment. This was observed even when severe fibrotic pathology was identified in the posterior epidural space during the same endoscopy. Therefore, continuing the exploration after creating damage to the dura would only risk placing the instrumentation in the subdural space, potentially harming the arachnoid or nerve roots, without offering any diagnostic or therapeutic benefit.

A dural tear, or dural puncture, is a serious complication that necessitates stopping the procedure to manage the tear and prevent severe consequences [63]. If a tear is detected, the procedure should be paused to evaluate the dural lesion and the patient's symptoms (e.g., headache, nausea, clear fluid leakage). Management includes stopping further manipulation, attempting to seal the tear, and positioning the patient in a supine position to reduce cerebrospinal fluid leakage. The decision of whether to resume the procedure depends on clinical judgment and the patient's stability.

Consensus on the maximum volume of saline infusion during EE was reached only in the second round (statement 15, 84% agreement). High infusion rates during EE can increase epidural pressure, potentially injuring tissues or causing severe complications like optic nerve compression, which could lead to vision problems or blindness [64]. To mitigate these risks, an international consensus recommended limiting the infusion volume to 200 ml per procedure [65]. Most panelists (65.4%) adhere to this limit, considering it relatively safe. However, the literature shows significant variability in the volumes used, ranging from 120 to 650 ml [20] and up

to 1200 ml [66] without detecting higher percentage of complications compared to literature findings. Factors such as infusion rate, volume, fluid leakage, and epidural space compliance affect epidural pressure, making precise pressure control challenging [67].

Technical Aspects of Reporting EE (Statements 16–19)

Regarding the technical aspects of reporting EE, experts agreed on the importance of documenting hyperemia grading and describing its characteristics, such as arterial or venous ectasia, blood flow interruption during structure stretching, and neoangiogenesis, at the end of the procedure (statement 16, 84% agreement). Hyperemia provides valuable information about the local tissue response, potential inflammation, or injury, and is observed in epiduroscopic images as areas of increased blood flow in the dura root sleeve, peridural membrane, or other epidural structures compared to normal areas [68].

Grading hyperemia helps assess the tissue response, with mild hyperemia potentially indicating a normal reaction and severe hyperemia suggesting significant inflammation or complications. This information can guide post-procedural management, such as the need for anti-inflammatory medications or adjustments in patient activity. Documenting hyperemia grading also provides a baseline for future follow-ups. A strong consensus was also reached on the importance of reporting the severity of epidural fibrosis using validated scales (statement 17, 96% agreement). Epidural fibrosis, caused by excessive fibroblast proliferation around the nerve root, can impact post-procedural management and the need for additional interventions [69]. Documenting fibrosis severity at the end of EE helps guide treatment decisions and ensures consistent assessments, improving communication among clinicians. An example of a grading system is the one proposed by Bosscher and Heavner [58]: grade 1 represents loose strings and sheets of fibrosis; grade 2 consists of more organized, continuous fibrous material, not resistant to the endoscope; grade 3 involves dense fibrous material, where the endoscope can only be advanced with difficulty; and grade 4 consists of dense fibrous material, where the endoscope cannot be advanced.

Raffaelli and colleagues [1, 8] classified fibrotic conditions on the basis of both macroscopic characteristics, identifying four subgroups of fibrosis, and functional characteristics, specifically functional/dynamic instability secondary to compartmental fibrosis that exerts traction on the dura. In the state of "dynamic instability," pathological fibrotic structures adhere to the dura, restricting its natural ability to respond to physiological stimuli. This leads to the dura becoming essentially "frozen," losing its elasticity and mobility. Any applied force, such as traction or compression, is then transmitted further, potentially affecting perineural structures, interfering with nerve root nutrition and blood supply, and causing pain. This condition may be exacerbated by local vascular stasis, hyperemia, and aseptic inflammation due to fibrous tissue bridging around vessels.

A detailed report at the end of EE should include the extent, location, and any related findings such as nerve root compression or vascular involvement. Whenever possible, images or videos of the fibrosis should be attached for future reference.

Consensus was reached on the importance of reporting the presence or absence of allodynia after balloon catheter opening during EE (statement 18, 73% agreement). Allodynia in this context is likely caused by mechanical, inflammatory, and sensitization factors affecting nerves and surrounding tissues. Raffaeli et al. [1] defined this condition as a "compartmental syndrome," similar to complex regional pain syndrome (CRPS).

This consideration regarding a possible resemblance to CRPS is based on clinical and anatomical findings observed during EE. However, the intent is not to equate the two conditions but to describe a "CRPS-like pattern" observed in specific cases characterized by hyperaemia, hypervascularization, and dura mater sensitivity in the absence of adhesive fibrosis. This distinction aims to establish a framework for classifying epidural findings and enhancing the consistency

Table 4 Key aspects of consensus statements on EE

Most important statements	Key aspects
Indications for FBSS/PSPS and spinal stenosis	EE is indicated for patients with failed back surgery syndrome (FBSS)/persistent spinal pain syndrome (PSPS) to manage chronic pain
Preoperative imaging	Conduct preoperative imaging (e.g., MRI, X-ray) to assess spinal morphology and detect any complicating conditions before EE
Anesthetic assessment	Perform a comprehensive anesthetic assessment to ensure patient safety, determine appropriate anesthesia, and manage any anesthesia-related risks
Local anesthesia with light sedation	Use local anesthesia combined with light sedation to keep patients comfortable and responsive, allowing better communication and early detection of complications
Mechanical lysis with saline infusion	Combine mechanical lysis of adhesions with saline infusion to maintain a clear operative field, facilitate tissue separation, and improve procedural effectiveness
Documenting hyperemia and fibrosis	Document the severity of hyperemia and fibrosis using validated scales, providing detailed information about the extent, location, and characteristics of these conditions
Reporting technique used	Accurately describe the technique used for EE, including tools and methods, to ensure comprehensive clinical documentation and facilitate future treatments
Monitoring and managing allodynia	Monitor for allodynia during the procedure as this patient's response can help guiding pain management strategies
Dural tear management	Have protocols in place for managing dural tears, including immediate interruption of the procedure and appropriate management to prevent complications
Use of epidurography	Utilize epidurography with contrast medium injection during EE to enhance visualization, guide the procedure, and assess epidural pathology
Injecting medicine post-procedure	Inject appropriate medications post-procedure to manage pain and inflammation, following best practices for targeted delivery and patient safety
Maximum saline volume	Adhere to a maximum saline volume of 200 ml during the procedure to avoid complications related to increased epidural pressure

of terminology in clinical practice. Nevertheless, dedicated studies are needed to further investigate this phenomenon, clarify its underlying mechanisms, and validate this suggestion.

Patients should be informed about the possibility of temporary pain sensitivity post-procedure as part of the healing process.

Additionally, full consensus was obtained on the importance of accurately describing the technique used for EE (statement 19, 100% agreement). Precise documentation is crucial for maintaining a comprehensive medical history, guiding future treatments, ensuring legal compliance, and adhering to medical standards.

FUTURE PERSPECTIVES

The consensus reached by the expert panel provides a framework for best practices in EE within the Italian pain therapy network, guiding clinical decision-making, improving patient outcomes, and laying the groundwork for standardized guidelines. However, further high-quality research is essential to fully understand the long-term efficacy and safety of EE. Establishing a national registry for EE procedures could advance the field by systematically collecting data on effectiveness, safety, and technical challenges, enabling large-scale outcome analysis and the identification of best practices. This would facilitate the monitoring of procedural success rates, complication frequencies, and long-term patient outcomes, contributing to evidence-based improvements in clinical protocols. Unfortunately, the equipment used for EE in Europe is not easily accessible in the USA even if it is FDA approved, and this procedure has fallen out of favor because of reimbursement issues. Additionally, exploring the integration of robotics into EE [70] could offer greater precision, stability, and control, potentially enhancing visualization and access within the epidural space, and making EE a more reliable and effective option for managing chronic spinal pain.

STUDY LIMITATIONS

Although this study provides valuable insights into the use of EE for treating chronic spinal pain through a modified Delphi approach, it has several limitations. One major limitation is the potential for bias, as the selection of Italian experts may not fully capture the diversity of opinions within the field at an international level. Additionally, there was a possible selection bias due to the predominance of male participants and a high percentage of anesthesiologists from northern Italy, reflecting regional and professional disparities in pain medicine, as noted by Occhigrossi et al. [27] in a Delphi study on percutaneous radiofrequency neurotomy for lumbar facet joint syndrome. The study also faced challenges with the consensus threshold, which was set at 70%. The determination of this threshold can vary in Delphi studies depending on factors like the number of experts, the agreement scale, and the complexity of the topic. Given the diverse practices and lack of standardized guidelines in our field, a 70% agreement threshold was chosen, though this may have influenced the outcomes. The 19 statements used in this study were developed by a restricted group of experts from the scientific board, which may have limited the scope of topics addressed. Broader participation in developing the statements could have enriched the study by bringing in a wider range of perspectives and additional relevant topics. Lastly, the study's focus on a specific national context might limit its applicability to other countries with different healthcare systems and pain management practices, thus requiring further research to validate these findings in diverse settings.

CONCLUSIONS

The consensus reached by the panel of experts provides a comprehensive framework for best practices in EE, covering indications, technical considerations, and potential complications. A summary of the most important statements, highlighting key aspects for physicians involved in EE management, is provided in Table 4. By incorporating this expert consensus into their clinical decision-making, EE practitioners can enhance patient care and potentially improve treatment outcomes for chronic spinal pain conditions.

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Declarations

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