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Epidural Injection Technologies

Clinical Policy Bulletins | Medical Clinical Policy Bulletins

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Policy History

Last Review
04/08/2025
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Review History

Definitions

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Clinical Policy Bulletin Notes

Policy

Scope of Policy

This Clinical Policy Bulletin addresses epidural injection technologies.

I. Medical Necessity

A. Aetna considers epidural blood patching (EBP) medically necessary for the following indications:

1. Treatment of post-dural puncture headache (PDPH) if member exhibited prolonged headaches (greater than 24 hours);

2. Treatment of spontaneous intracranial hypotension in members with orthostatic headache for more than 2 weeks if *either* of the following selection criteria is met:

   a. Brain MRI documenting dural enhancement; *or*
   b. Spinal imaging documenting epidural collection of CSF or site of CSF leak;

3. Repeat epidural blood patching (EBP) if the initial patch does not produce prolonged relief and additional spinal imaging identifies a site of CSF leak.

B. Aetna considers transforaminal EBP medically necessary for the treatment of post-dural puncture headache when EBP using an interlaminar approach was ineffective.

II. Experimental, Investigational, or Unproven

The following procedures are considered experimental, investigational, or unproven because the effectiveness of these approaches has not been established:

- Prophylactic EBP
- EBP for the treatment of post-dural puncture tinnitus
- EBP for the treatment of suspected cerebrospinal fluid (CSF) leak not conforming to 3rd edition International Classification of Headache Disorders (ICHD-3) criteria for spontaneous intracranial hypotension (absence of features of a CSF leak via imaging; or CSF opening pressure of 6 cm H2O or greater)
- Epidural fibrin glue patching for the treatment of PDPH
- Epidural autologous platelet-rich-plasma patching for the treatment of PDPH
- Real-time pressure-sensing epidural guidance.

III. Related Policies

- CPB 0722 - Transforaminal Epidural Injections (..700_799/0722.html)

CPT Codes / HCPCS Codes / ICD-10 Codes

CPT codes covered if selection criteria are met:

Code	Code Description
62273	Injection, epidural, of blood or clot patch
CPT codes not covered for indications listed in the CPB:	
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed [epidural autologous platelet-rich-plasma patching]
0777T	Real-time pressure-sensing epidural guidance system (List separately in addition to code for primary procedure)
Other CPT codes related to the CPB:	
62320 - 62323	Injection(s), of diagnostic or therapeutic substance(s) (eg, anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic or lumbar or sacral (caudal) [not covered for epidural fibrin glue patching]
70551 - 70553	Magnetic resonance (eg, proton) imaging, brain
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural or subarachnoid) (List separately in addition to code for primary procedure)
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
HCPCS codes not covered for indications listed in the CPB:	
P9020	Platelet rich plasma, each unit [epidural autologous platelet-rich-plasma patching]
Other HCPCS codes related to the CPB:	
J1720	Injection, hydrocortisone sodium succinate, up to 100 mg

Code	Code Description
ICD-10 codes covered if selection criteria are met:	
G96.00 - G96.09	Cerebrospinal fluid leak
G96.811	Intracranial hypotension, spontaneous [Absence of features of a CSF leak via imaging; or CSF opening pressure of 6 cm H2O or greater]
G97.1	Other reaction to spinal and lumbar puncture [covered for post-dural puncture headache (PDPH)] [not covered for post-dural puncture tinnitus]
G97.2	Intracranial hypotension following ventricular shunting [spontaneous intracranial hypotension]
O29.40 - O29.43	Spinal and epidural anesthesia induced headache during pregnancy
O89.4	Spinal and epidural anesthesia-induced headache during the puerperium
R51.0	Headache with orthostatic component, not elsewhere classified
T88.59xA - T88.59xS	Other complications of anesthesia [covered for post-dural puncture headache (PDPH)] [not covered for post-dural puncture tinnitus]
ICD-10 codes not covered for indications listed in the CPB:	
H93.11 - H93.19	Tinnitus [post-dural puncture tinnitus]

Background

Epidural Blood Patching (EBP) for the Treatment of Post-Dural Puncture Headache

Post-dural-puncture headache (PDPH) is a complication of puncture of the dura mater. The headache can be severe and it entails the back and front of the head, and spreading to the neck and shoulders, sometimes

involving neck stiffness. It is exacerbated by movement, and sitting or standing, and relieved to some degree by lying down. Nausea, vomiting, pain in arms and legs, hearing loss, tinnitus, vertigo, dizziness and paresthesia of the scalp are common. It is a common side-effect of spinal anesthesia and lumbar puncture and may occasionally accidentally occur in epidural anesthesia. Leakage of cerebrospinal fluid (CSF) through the dura mater puncture causes reduced fluid levels in the brain and spinal cord, and may lead to the development of PDPH hours or days later. Some individuals require no other treatment than pain medications and bed rest. Persistent and severe PDPH may require an epidural blood patching (EBP), which entails injection of a small amount of autologous blood into the epidural space to stop certain types of spinal headaches. This resulting blood clot patches the hole in the spine and treats the patient's headache symptoms. It is also believed that EBP causes compression and relieves the pressure state in the head, which causes the headache. In a very small percentage of cases, the headache can recur, and EBP may need to be repeated. Epidural blood patching is generally well-tolerated, and has a low incidence of complications, which include slight back pain, stiffness in the neck and low-grade fever. Success rates of EBP varying from 60 to 95 % have been reported; this variability may be a consequence of a higher efficacy rate when EBP is used for small dural punctures. Epidural blood patching usually takes approximately 15 minutes and is carried out in an out-patient setting (No authors listed, 2001; Turnbull and Shepherd, 2003).

In a Cochrane review, Boonmak and Boonmak (2010) examined the possible benefits and harms of EBP in both prevention and treatment of post-dural puncture headache (PDPH). These investigators searched the Cochrane PaPaS Group Trials Register; CENTRAL; Medline and Embase in April 2009. They sought all randomized controlled trials (RCTs) that compared EBP versus no EBP in the prevention or treatment of PDPH among all types of participants undergoing dural puncture for any reason. One review author extracted details of trial methodology and outcome data from studies considered eligible for inclusion. These researchers invited authors of all such studies to provide any details that were unavailable in the published reports. They performed intention-to-treat (ITT) analyses using the Peto O-E method. They also extracted information about adverse effects (AEs; post-dural puncture backache and epidural infection). A total of 9 studies (379 participants) were eligible

for inclusion. Prophylactic EBP improved PDPH compared to no treatment (odds ratio [OR] 0.11, 95 % confidence interval [CI]: 0.02 to 0.64, 1 study), conservative treatment (OR 0.06, 95 % CI: 0.03 to 0.14, 2 studies) and epidural saline patch (OR 0.16, 95 % CI: 0.04 to 0.55, 1 study). However, prophylactic EBP did not result in less PDPH than a sham procedure (1 study). Therapeutic EBP resulted in less PDPH than conservative treatment (OR 0.18, 95 % CI: 0.04 to 0.76, 1 study) and a sham procedure (OR 0.04, 95 % CI: 0.00 to 0.39, 1 study). Backache was more common with EBP. However, these studies had very small numbers of participants and outcome events, as well as uncertainties about trial methodology, which precluded reliable assessments of the potential benefits and harms of the intervention. The authors did not recommend prophylactic EBP over other treatments because there were too few trial participants to allow reliable conclusions to be drawn. However, therapeutic EBP showed a benefit over conservative treatment, based on the limited available evidence.

Gottschalk (2015) stated that in most cerebrospinal fluid (CSF) leaks are iatrogenic and caused by medical interventions (e.g., lumbar puncture, peri-dural anesthesia and surgical interventions on the spine). However, spontaneous cerebral hypotension is currently detected more frequently due to improvements in diagnostic possibilities but often the cause cannot be clarified with certainty. There are various diagnostic tools for confirming the diagnosis and searching for the site of CSF leakage, such as post-myelography computed tomography (postmyelo-CT), indium-111 radioisotope cisternography and (myelo) magnetic resonance imaging (MRI), which show different sensitivities. In accordance with the authors' experience, native MRI with fat-saturated T2-weighted sequences is often sufficient for diagnosing CSF leakage and the site. For the remaining cases, an additional postmyelo-CT or alternatively myelo-MRI is recommended. In some patients with spontaneous cranial hypotension multiple CSF leaks are found at different spinal levels. The main symptom in most cases is an orthostatic headache. While post-puncture syndrome is self-limiting in many cases, spontaneous CSF leakage usually requires EBP. Lumbar EBP can be safely carried out under guidance by fluoroscopy. In the case of a cervical or dorsal blood patch, CT guidance is recommended, which ensures epidural application of the blood patch and minimizes the risk of damaging the spinal cord. Despite a high success rate at the 1st attempt with a blood patch of up to 85 %,

some cases require repeating blood patching. A targeted blood patch of a CSF leak should generally be favored over a blindly placed blood patch; nevertheless, if a CSF leak cannot be localized by CT or MRI a therapeutic attempt with a lumbar blood patch can be carried out. After a successful blood patch, intracranial hygromas and pachymeningeal enhancement in the head showed fast regression; however, epidural hygromas of the spine could persist for a period of several months, even though patients are already symptoms-free. The authors concluded that EBP is a safe and relatively simple method with a high success rate; thus; it represents the therapy of choice in patients with spontaneous CSF leakage as well as in cases of PDPH refractory to conservative therapy.

Kapoor and Ahmed (2015) stated that EBP is rarely performed at the cervical levels, primarily due to fear of neurological complications such as spinal cord compression. These investigators reviewed the literature to provide an evidence-based review of performance of cervical EBPs, with a specific focus on indication, technique, safety, and efficacy. They performed a comprehensive electronic literature search to include studies that reported on performance of cervical EBPs in patients with CSF leak at the cervical level. Data regarding indication, level of CSF leak, level of cervical EBP, volume of blood used, efficacy, and complications were collected. A total of 15 studies, reporting on 19 patients were included. All patients presented with a headache that increased in the standing position, and improved in the supine position. All patients were identified to have a CSF leak at the cervical level; 8 patients first underwent a lumbar EBP, without complete, long-term relief. All these patients, along with 11 patients who did not undergo a lumbar EPB prior to cervical EBP, reported complete, long-term pain relief; EBPs were mostly done in the prone position, using imaging guidance. An average of 5 to 8 ml of autologous blood was injected in the epidural space. No major neurological complications were reported in any patient. The authors concluded that the findings of this review suggested that cervical EBP can be performed for cervical CSF leaks associated with positional headache without a significant risk of serious AEs. This review provided Class II level of evidence that cervical EBPs were safe and effective in reliving positional headache due to CSF leak.

Suescun and associates (2016) noted that PDPH due to accidental dural puncture during epidural catheter placement is a source of morbidity for new mothers. It can interfere with maternal-newborn bonding and increase the length of hospitalization. This evidence-based article examined the question: For obstetric patients experiencing an accidental dural puncture during epidural placement, which non-pharmacologic prophylactic neuraxial interventions safely and effectively decrease the incidence of PDPH? A search of online databases revealed 4 systematic reviews with meta-analysis and a RCT meeting the inclusion criteria; 3 of the 4 systematic reviews used rigorous appraisal methods; 2 systematic reviews included non-obstetric populations and 3 included additional interventions. Subgroup analyses allowed examination of the interventions of interest. Non-pharmacologic prophylactic neuraxial interventions included prophylactic EBP, epidural saline administration, and intra-thecal catheter placement. There was a lack of standardization of interventions. The authors concluded that the evidence suggested there may be value in performing a prophylactic blood patch or placing an intra-thecal catheter. The risk of the intervention must be carefully weighed with the benefits. They stayed that further rigorous studies are needed to help determine the best methods to decrease the incidence of PDPH in obstetric patients experiencing an accidental dural puncture during epidural placement.

Furthermore, an UpToDate review on “Post-lumbar puncture headache” (Sun-Edelstein and Lay, 2018a) states that “Other agents that have been evaluated for the treatment of PLPHA in small controlled trials or case series include oral and intravenous caffeine, epidural saline, intramuscular adrenocorticotropic hormone (ACTH) and intravenous synthetic ACTH, oral gabapentin, intravenous hydrocortisone, oral theophylline, and subcutaneous sumatriptan, and sphenopalatine block … Of these, the limited available data suggest modest effectiveness for gabapentin, hydrocortisone, and theophylline. For patients with moderate to severe PLPHA that is prolonged (greater than 24 hours) and refractory to conservative measures, we suggest treatment with epidural blood patch (Grade 1B)”.

EBP for the Treatment of Spontaneous Intracranial Hypotension

Girgis and co-workers (2015) noted that spontaneous intracranial hypotension (SIH) is caused by spinal CSF leakage. Treatment is directed at sealing the site of leak, which is often difficult to localize. These researchers presented a case of near fatal SIH that was treated with thoracic EBP. A 47-year old man presented with orthostatic headache and bilateral cranial nerve VI palsies progressing over several weeks. Brain MRI showed features typical of SIH and identified an epidural collection stretching from spinal levels C6 to T4, but further imaging with MR myelography and radionuclide cisternography failed to identify a precise site of leak. The patient worsened in the hospital requiring craniotomy for evacuation of an evolving subdural hematoma (SDH). Epidural blood patch was performed at the T1 to T2 level, the presumed location of the leak due to presence of a bone spur on CT and the large corresponding CSF collection. This quickly led to resolution of the headache and cranial nerve palsies, and later to the complete resolution of his SDH. Through this case and review of the literature, the authors demonstrated that directed cervical or thoracic EBP should be considered for SIH as an alternative to the conventional lumbar EBP.

Ansel and co-workers (2016) stated that patients with a spontaneous CSF leak, normally at a spinal level, typically present with low-pressure headache. In refractory cases, EBP may be attempted. These investigators evaluated the efficacy of lumbar EBP in spontaneous, low-pressure headaches. They retrospectively analyzed notes of patients who had EBP performed for SIH in a single-center. Information regarding demographics, radiology and clinic follow-up was extracted from an electronic patient record system. Questionnaires regarding outcome were sent to patients a minimum of 6 months post-procedure. All patients received EBP in the lumbar region irrespective of the site of CSF leak. A total of 16 patients who underwent lumbar EBP were analyzed (11 women; mean age of 43 years). The site of CSF leak was evident in only 3/16 patients; 13 patients attended clinic follow-up; 3 reported complete headache resolution, 4 reported improvement in intensity or frequency and 6 described no change; 5 of 8 questionnaire respondents reported reduction in pain, and in these responders, mean headache severity improved from 9/10 to 3/10; 5 of 8 patients returning follow-up questionnaires reported sustained improvement in headache symptoms.

The authors concluded that EBP can provide sustained improvement in headache symptoms in selected patients with SIH, but an untargeted approach had a lower success rate than reported in other case series.

Rettenmaier and co-workers (2017) noted that SIH is a more common than previously noted condition (1 to 2.5 per 50,000 persons) typically caused by CSF leakage. Initial treatment involves conservative therapies, but the mainstay of treatment for patients who fail conservative management is EBP. Subdural hematoma (SDH) is a common complication occurring with SIH, but its management remains controversial. In this report, these researchers discussed a 62-year old woman who presented with a 5-week history of orthostatic headaches associated with nausea, emesis, and neck pain. Despite initial imaging being negative, the patient later developed classic imaging evidence characteristic of SIH; MRI was unrevealing for the source of the CSF leak. Radionuclide cisternography showed possible CSF leak at the right-sided C7 to T1 nerve root exit site. After failing a blind lumbar EBP, subsequent targeted EBP at C7 to T1 improved the patient's symptoms. Two days later she developed a new headache with imaging evidence of worsening SDH with mid-line shift requiring burr hole drainage. This yielded sustained symptomatic relief and resolution of previously abnormal imaging findings at 2-month follow-up. These investigators performed a literature review and revealed 174 cases of SIH complicated by SDH. This revealed conflicting opinions concerning the management of this condition. The authors concluded that although blind lumbar EBP was often successful, targeted EBP had a lower rate of patients requiring a 2nd EBP or other further treatment. On the other hand, targeted EBP had a larger risk profile. Depending on the clinic situation, treatment of the SDH via surgical evacuation may be necessary.

Staudt and colleagues (2018) noted that SIH is a progressive clinical syndrome characterized by orthostatic headaches, nausea, emesis, and occasionally focal neurological deficits. Rarely, SIH is associated with neurocognitive changes. An EBP is commonly used to treat SIH when conservative measures are inadequate, although some patients require multiple EBP procedures or do not respond at all. Recently, the use of a large-volume (LV) EBP has been described to treat occult leak sites in treatment-refractory SIH. These investigators described the management of a patient with profound neurocognitive decline associated with SIH,

who was refractory to conservative management and multiple interventions. The authors described the successful use of an ultra-LV-EBP of 120 ml across multiple levels, the largest volume reported in the literature, and described the technical aspects of the procedure. This procedure has resulted in dramatic and sustained symptom resolution.

He and co-workers (2018) noted that EBP is the mainstay of treatment for refractory SIH. These researchers evaluated the treatment efficacy of targeted EBP in refractory SIH. All patients underwent brain MRI with contrast and heavily T2-weighted spine MRI. Whole spine CT myelography with non-ionic contrast was performed in 46 patients, and whole spine MR myelography with intra-thecal gadolinium was performed in 119 patients. Targeted EBPs were placed in the prone position 1 or 2 vertebral levels below the CSF leaks. Repeat EBPs were offered at 1-week intervals to patients with persistent symptoms, continued CSF leakage, or with multiple leakage sites. Brain MRIs showed pachymeningeal enhancement in 127 patients and subdural hematomas in 32 patients; 152 patients had CSF leakages on heavily T2-weighted spine MRIs; CSF leaks were also detected on CT and MR myelography in 43 and 111 patients, respectively. Good recovery was achieved in all patients after targeted EBP. No serious complications occurred in patients treated with targeted EBP during the 1 to 7 years of follow-up. The authors concluded that targeted and repeat EBPs are rational choices for treatment of refractory SIH caused by CSF leakage.

Furthermore, an UpToDate review on “Spontaneous intracranial hypotension: Treatment and prognosis” (Sun-Edelstein and Lay, 2018b) states that “The most conservative treatment for spontaneous intracranial hypotension is avoidance of the upright position, with strict bed rest and the possible addition of analgesics … We suggest epidural blood patch (EBP) for patients with spontaneous intracranial hypotension who fulfill any of the following conditions (Grade 2C)”:

- An aggressive precipitating injury, a history of connective tissue disease, or joint hypermobility
- Headache unresponsive to a reasonable period of conservative treatment (e.g., bed rest and oral analgesics for 1 to 2 weeks)
- Severe headache or other disabling symptoms, regardless of duration

- Symptomatic for 2 weeks or longer at the time of diagnosis.

Cheema et al (2023) created a multi-disciplinary consensus clinical guideline for best practice in the diagnosis, investigation, and management of SIH due to CSF leak based on current evidence and consensus from a multi-disciplinary specialist interest group (SIG). A 29-member SIG was established, with members from neurology, neuroradiology, anesthetics, neurosurgery, and patient representatives. The scope and purpose of the guideline were agreed by the SIG by consensus. The SIG then developed guideline statements for a series of question topics using a modified Delphi process. This process was supported by a systematic literature review, surveys of patients and healthcare professionals and review by several international experts on SIH. The SIG stated that SIH and its differential diagnoses should be considered in any patient presenting with orthostatic headache; 1st-line imaging should be MRI of the brain with contrast and the whole spine. First-line treatment is non-targeted EBP, which should be performed as early as possible. The SIG provided criteria for performing myelography depending on the spine MRI result and response to EBP, and it outlined principles of treatments. Recommendations for conservative management, symptomatic treatment of headache and management of complications of SIH were also provided.

EBP Treatment of Post-Dural Puncture Tinnitus

Jia and Fadhlillah (2018) stated that audiometric disturbances are recognized as potential complications after spinal or epidural anesthesia; however, incidences of tinnitus occur less frequently. These researchers reported the case of a patient with severe bilateral tinnitus post-lumbar puncture who was treated with EBP. Subject was a 40-yearold ASA I woman (a medically fit patient with no known medical problem) presented with ongoing bilateral severe tinnitus for 6 days after a lumbar puncture. Venous blood (18 ml) was injected into the epidural space using a 16-G needle. The patient completed the Tinnitus Handicap Inventory (THI) Questionnaire before EBP, 3 hours, 24 hours and 1-month post-procedure. An audiogram was also conducted before and 1 month after EBP. The patient scored 84 (grade 5) on the THI before EBP; 3 hours post-procedure, her score improved to 16 (grade 1), with complete resolution by 24 hours. Audiogram revealed a low-frequency mild

sensorineural hearing loss in the left ear prior to the procedure. By her 1-month follow-up, her hearing was back to normal. The authors concluded that EBP is an effective treatment for post-dural puncture tinnitus. Its effects are instantaneous and complete resolution is achieved by 24 hours. These preliminary findings need to be validated by well-designed studies.

Epidural Fibrin Glue Patching for the Treatment of Post-Dural Puncture Headache

Wong and Monroe (2017) stated that EBP is the gold standard for the treatment of PDPH when conservative treatments have failed to provide any relief. However, alternative therapies are lacking when EBP persistently fails to improve symptoms. This case described a woman who developed PDPH secondary to accidental dural puncture during a spinal cord stimulator trial. She was successfully treated with epidural fibrin glue patch after multiple trials of EBP. The authors concluded that percutaneous injection of fibrin glue to seal the dural defect demonstrated promising outcomes for both immediate and long-lasting resolution of persistent PDPH in this patient. They stated that in the event of EBP failure, epidural fibrin glue patching may be a reasonable alternative for the treatment of persistent PDPH. These preliminary findings need to be validated by well-designed studies.

Furthermore, an UpToDate review on “Post-lumbar puncture headache” (Sun-Edelstein and Lay, 2018a) states that “Epidural patching with fibrin glue at the site of the CSF leak has been used successfully in small numbers of patients. Anecdotal evidence suggests that this method is effective, and thereby avoids surgery, in about 1/3 of patients who have failed epidural blood patch treatment. Further evidence of benefit in larger studies is needed before this technique can be routinely recommended”.

Epidural Autologous Platelet-Rich-Plasma Patching for the Treatment of Post-Dural Puncture Headache

Gunaydin and colleagues (2017) performed epidural patching using platelet-rich-plasma (PRP), which has the potential to regenerate and heal tissues via degranulation of platelets, in a 34-year old parturient

suffering from persistent PDPH after failed EBP. After her admission to the authors' unit, these researchers re-confirmed the clinical and radiologic diagnosis of PDPH. Cranial MRI with contrast showed diffuse pachymeningeal thickening and contrast enhancement with enlarged pituitary consistent with intracranial hypotension. Clinical and radiological improvements were observed 1 week after epidural patching using autologous PRP. The authors recommended using autologous PRP for epidural patching in patients with incomplete recovery after standard EBP as a novel successful approach. These preliminary findings need to be validated by well-designed studies.

Transforaminal Epidural Blood Patching

Amrhein and co-workers (2016) noted that EBP treatment of spontaneous intracranial hypotension arising from ventral CSF leaks can be difficult secondary to challenges in achieving ventral spread of patching material. Ina retrospective study, these researchers examined the safety profile and technical success rates of direct needle placement into the ventral epidural space via a posterior transforaminal approach. They reviewed consecutive CT fluoroscopy-guided EBP from June 2013 through July 2015. Cases were included if a posterior transforaminal approach was taken to place the needle directly in the ventral epidural space. Rates of technical success (defined as contrast in the spinal canal ventral epidural space) and optimal epidurogram (defined as contrast spreading into or beyond the middle third of the spinal canal ventral epidural space) were determined. Factors influencing these rates were assessed. All complications, inadvertent intra-vascular injections, and intra-thecal punctures were recorded. A total of 72 ventral epidural blood patches were identified; immediate technical success was achieved in 95.8 % and an optimal epidurogram in 47.2 %. Needle position within the spinal canal ventral epidural space was associated with obtaining an optimal epidurogram ($p = 0.005$). Inadvertent intra-vascular injection was identified in 29.3 % of cases, but all were venous. There were no inadvertent intra-thecal punctures or complications. The authors concluded that direct needle placement in the ventral epidural space via a transforaminal approach for treatment of ventral CSF leaks has an excellent technical success rate and safety profile. This technique can be considered as a therapeutic option in selected patients with ventral CSF leaks for whom traditional techniques are unsuccessful.

Choi and associates (2019) stated that post-dural puncture headache (PDPH) is a leak of CSF that lowers intra-cranial pressure and usually presents as a positional headache. If conservative treatments are not successful, EBP is the gold standard of treatment for dural puncture. The interlaminar approach is the most commonly used technique for an EBP. These investigators described a patient who was treated with a transforaminal EBP for PDPH following an acupuncture procedure on his lower back after 2 EBPs using an interlaminar approach had failed. The patient underwent an acupuncture therapy for management of chronic low back pain (LBP) due to post-laminectomy syndrome. After the procedure, the patient had a severe headache and the conservative treatment was ineffective. The 2 interlaminar EBPs (at the L2 to L3 and L3 to L4 levels) failed. These researchers performed transforaminal EBP at the L3 to L4 and L4 to L5 levels on the left side, the site of leakage in the MRI myelogram. His symptoms finally subsided without complication. The authors concluded that this case demonstrated that targeted transforaminal EBP was a therapeutic option for the treatment PDPH when EBP using an interlaminar approach was ineffective or when a ventral or far-lateral CSF leak was identified with imaging studies.

Choi and colleagues (2020) noted that EBP is a vital tool in the treatment of PDPH. Traditional interlaminar epidural needle insertion into the epidural space, however, may be challenging due to anatomical variations. As an alternative method, these researchers successfully performed an EBP via a transforaminal approach. In this single-case study, a mid-50-year old man with multi-level spinal fusion developed PDPH following a failed spinal cord stimulator electrode placement. A transforaminal EBP was carried out by injecting a total of 8-ml of autologous blood into the neuroforamen at the L1 to L2 level bilaterally. The patient's positional headache resolved immediately after the procedure. The authors concluded that this was the 1st case reported of a transforaminal EBP in a patient with diffuse epidural adhesive fibrosis secondary to multi-level laminectomies and spinal fusion. This case report highlighted potential risks and benefits of this novel technique and also discussed its therapeutic mechanism of action. These researchers believed that a transforaminal EBP should be considered in patients who are poor candidates for the traditional interlaminar EBP.

Real-Time Pressure-Sensing Epidural Guidance System

On July 6, 2022, the American Medical Association (AMA) issued a new technology-specific Category III Current Procedural Terminology (CPT®) to report the use of the CompuFlo Epidural system (Milestone Scientific, Inc.). The CompuFlo Epidural system is a real-time pressure sensing guidance system designed to accurately identify the location of the needle in real-time. According to the company, the clinical and safety benefits of the CompuFlo Epidural System are supported by numerous published studies showing reductions in epidural punctures and complication rates (yahoo!life, 2022).

Gebhard and colleagues (2019) conducted a study to compare continuous, quantitative, real-time, needle-tip pressure sensing using a novel computer-controlled epidural space (ES) identification technology (CompuFlo Epidural Computer Controlled Anesthesia System [CEI]; Milestone Scientific, Livingston, NJ) to fluoroscopy (FC) and traditional loss of resistance (LOR) for lumbar ES identification in labor and delivery (L&D) and chronic pain (CP) management. The study was a prospective randomized controlled non-inferiority trial consisting of 400 patients in total. Patients in the CP management arm (n=240) were scheduled to receive a lumbar epidural steroid injection and had their ES identified either with FC or with needle-tip pressure measurement. Female patients in the L&D arm (n=160) underwent lumbar epidural catheter placements and were randomized to either LOR or needle-tip pressure measurement. The primary outcome was successful ES identification which was protocol defined. Secondary outcomes included the performance of the procedure using one attempt, the absence of accidental dural puncture (ADP), subject-reported adequate pain relief 45 minutes after dosing of the epidural catheter (EAPR 45), and the duration of the ES identification procedure (in minutes). Non-inferiority of needle-tip pressure management was observed in relation to FC where pain management patients showed a 100% success rate of ES identification with both methodologies (OR, 1.1; 97.27% Confidence Interval [CI], 0.52–8.74; p=0.021 for noninferiority), and L&D patients experienced a non-inferior success rate with the novel technology (97.1% vs 91%; OR, 3.3; 97.27% CI, 0.62–21.54; p=0.019) using a a priori noninferiority delta of 0.50. The study concluded that objective lumbar ES identification using continuous, quantitative, real-time, needle-tip pressure measurement with the

CompuFlo Epidural Computer Controlled Anesthesia System demonstrated non-inferior success rates in comparison to FC and LOR for CP management and L&D, respectively.

Hidalgo (2019) conducted an open, prospective, single operator study to report the clinical experience with the CompuFlo® Epidural Instrument. Epidural block was given with the CompuFlo® Epidural Instrument in all consecutive patients receiving an epidural or thoracic block under the investigator's care over a two year time frame. The epidural needle was determined to have reached the epidural space marked by an increase in pressure (accompanied by an increase of the pitch of the audible tone) and then followed by a sudden and sustained drop in pressure of greater than 5 seconds accompanied by a sudden decrease of the pitch of the audible tone with resultant formation of a low and stable pressure plateau on the instrument's visual display. Outcomes evaluation included: incidence of accidental dural puncture, success of anesthesia, procedure time, volume of saline used for the epidural procedure, number of epidural attempts to reach the epidural space, number of needle redirections, and the operator's agreement with his tactile sensation of loss of resistance and the CompuFlo® pattern. The results for the 600 total cases studied noted success with all epidural blocks and no accidental dural punctures. Ninety-one percent of cases involved the correct identification of epidural space on the first attempt, and in 95% of cases there was a perfect correlation between an operator's tactile sensations and the CompuFlo® recordings as judged by the operator. This study concluded that epidural blocks via the CompuFlo® Epidural Instrument were associated with a very high success rate regardless of clinical setting (obstetrical, surgical or blood patch intervention) or at which vertebral level (thoracic or epidural) were done. Additionally, there was zero incidence of any accidental dural puncture.

Capogna et al (2020) conducted a prospective, simulation study to verify whether the high sensitivity of the CompuFlo® epidural system could aid the anesthesiologist to identify the epidural space very early, thereby, limiting the extension of the Tuohy needle into the epidural space. This study evaluated the Tuohy needle extension through a simulated ligamentum flavum during epidural procedure performed by 52 expert anesthesiologists utilizing the CompuFlo® epidural instrument or their standard loss of resistance to saline technique (LORT). The results

showed the mean (SD) needle extension length as 3.90 (3.71) mm in the standard technique group and 0.68 (0.46) mm in the CompuFlo® group (p<000001). The CompuFlo® group presented with extremely reduced variability of the data (F test 0.01) showing that results obtained with it are highly predictable. It was concluded that the needle arrested prematurely when using CompuFlo® to puncture a simulated ligamentum flavum in comparison to traditional LORT.

Babazade and colleagues (2022) conducted a study on cost-minimization analysis of real-time pressure sensing technology in parturient requesting labor epidural analgesia. The cost-minimization analysis involved total cost estimation, from the hospital perspective, for the hospital stay for delivery and readmission for epidural blood patch (EBP), if any. Patients were categorized into two groups by the presence of epidural replacement. Epidural placement success was determined as baby delivered without epidural replacement or additional analgesia technique or medications. Each patient group was further categorized into three groups: 1) No post-dural puncture headache (PDPH) or EBP; 2) With PDPH but no EBP; 3) With EBP. Patients receiving multiple epidural procedures for epidural anesthesia during hospitalization were considered to have epidural replacement. PDPH following epidural anesthesia was identified using the International Classification of Diseases (ICD), 10th Revision, Clinical Modification (ICD-10-CM) codes 074.5 and 0.89. Adjustment of all costs to the same time period (February 2019) was performed using the Consumer Price Index for medical care. Cost-minimization analysis compared real-time pressure sensing technology and traditional loss-of-resistance (LOR) technique. Cost-estimation included 4483 deliveries among 4353 parturient. In the 4483 deliveries, 469 (10.5%) had epidural replacement and 101 (2.25%) had post-dural puncture headache. To no surprise, patients who had epidural replacement and epidural blood patch incurred the highest cost, while those without, incurred the lowest cost (median cost $25,279.51 vs. $16,272.40). Real-time pressure sensing technology costs were about 504 US dollars less per hospital stay on average compared to the traditional LOR technique. Based on the same cost estimate for delivery and complication treatment on both arms in each of the six scenarios, real-time pressure sensing technology achieved a cost savings due to the lower likelihood of epidural replacement.

Treatment of Suspected CSF Leak

Carroll et al (2024) noted that spinal CSF leaks result in spontaneous intracranial hypotension (SIH). While 3rd edition International Classification of Headache Disorders (ICHD-3) criteria necessitate imaging confirmation or low opening pressure (OP) for SIH diagnosis, their sensitivity may be limited. The diagnostic criteria of ICHD-3 can be applied already on presentation or as soon after as the underlying disorder is confirmed. Criterion A is presence of the headache; criterion B is presence of the causative disorder; and criterion C is the evidence of causation. These investigators offered EBPs to patients with symptoms suggestive of SIH, with and without a documented low OP or confirmed leak on imaging. In a prospective, cohort study, these researchers examined the effectiveness of this strategy. This study employed a nested case-control design including all patients who presented to a tertiary headache clinic with clinical symptoms of SIH who completed study measures both before and after receiving an EBP between August 2016 and November 2018. The mean duration of symptoms was 8.7 ± 8.1 years. Of 85 patients assessed, 69 did not meet ICHD-3 criteria for SIH. At an average of 521 days after the initial EBP, this ICHD-3-negative subgroup exhibited significant improvements in Patient-Reported Outcomes Measurement Information System (PROMIS) Global Physical Health score of +3.3 (95 % CI: 1.5 to 5.1), PROMIS Global Mental Health score of +1.8 (95 % CI: 0.0 to 3.5), Headache Impact Test (HIT)-6 head pain score of -3.8 (95 % CI: -5.7 to -1.8), Neck Disability Index (NDI) of -4.8 (95 % CI: -9.0 to -0.6) and PROMIS Fatigue of -2.3 (95 % CI: -4.1 to -0.6); 54 % of ICHD-3-negative patients achieved clinically meaningful improvements in PROMIS Global Physical Health; and 45% in HIT-6 scores. Pain relief following lying flat before treatment was strongly associated with sustained clinically meaningful improvement in global physical health at an average of 521 days (OR 1.39, 95 % CI: 1.1 to 1.79; $p < 0.003$). ICHD-3-positive patients showed high rates of response and previously unreported, treatable levels of fatigue and cognitive deficits. The authors concluded that patients who did not conform to the ICHD-3 criteria for SIH showed moderate rates of sustained, clinically meaningful improvements in global physical health, global mental health, neck pain, fatigue, and head pain following EBP therapy. Pre-treatment improvement in head pain when lying flat was associated with later, sustained improvement after EBP therapy among patients who did not

meet the ICHD-3 criteria. Moreover, these investigators stated that further research is needed to confirm these findings. Classification of Evidence = IV.

The authors stated that this study had several drawbacks. First, in the absence of a control group given sham patches, these researchers could not exclude non-specific treatment effects as responsible for some of the improvement seen. Furthermore, it was possible that some portion of the improved patients had a primary headache disorder and the improvement was not related to the EBP. However, patients' pre-patch relief when lying flat was strongly associated with the subsequent likelihood of clinically meaningful benefit over a year after patching. In addition, the positive effects of patching appeared to increase, rather than diminish, over extended time periods and repeated patching. This pattern among responders strengthened a causal inference that patches had a specific therapeutic effect. Second, non-random completion of a post-treatment questionnaire (non-participation bias) could limit generalizability to outside groups of patients with orthostatic headache. These investigators compared available baseline measures of the patients who did not complete follow-up with those who did and found no significant differences, suggesting the participating cohort was representative of the larger group of all patients who received patches after completing baseline measures. Third, a recent report (Callen et al, 2023) suggested that 10 % of patients with an orthostatic headache and negative brain and spine MRI later had a CSF-venous fistulas (CVFs) identifiable with lateral decubitus digital subtraction myelogram -- a technique not available at the time of these data acquisition. These findings would suggest that 10 % of these researchers' subset of patients who did not meet the ICHD-3 criteria might have had an undiagnosed CVF and might have responded to epidural patching on that basis. Fourth, HIT-6 head pain scores improved to 64.1 ± 8.23 ($p < 0.001$) at a mean 521 days after the 1st patch, and these scores after patching were still in the severe range on average. Additionally, differing estimates of the within-person clinically meaningful change in the HIT-6 existed, and would yield different calculated rates of meaningful responders. Fifth, owing to the exploratory analysis of this project, p values were not adjusted for multiple testing; increasing the risk that any one of the significant findings reflected a type I error due to multiple testing; therefore, significant results must be interpreted with caution and bear repetition.

Cervical Epidural Blood Patch for the Treatment of Spontaneous Intracranial Hypotension

Ghatge et al (2024) noted that lumbar EBP is not successful in all cases of CSF leak, especially in the cervico-thoracic region. Ina retrospective study, these investigators analyzed the findings of a cohort of patients who had undergone computed tomography (CT)-guided cervical EBP for the treatment of SIH due to CSF leak in the cervical region. These researchers collected data from March 2009 to 2020. The inclusion criteria were clinical syndrome associated with CSF leak, headache coming on shortly after assuming the erect position and relief achieved by lying down, CT myelography evidence of CSF leak in the cervical region, and patient not responding to conservative management for 7 days. Exclusion criteria were patients with bleeding diathesis and infection. There were 6 women and 4 men; ages ranged from 32 to 57 years, with an average of 42. On presentation, all subjects underwent contrast-enhanced MRI and CT myelography. Cervical EBP was carried out under CT guidance. Assessment of headache was conducted on a 10-point numerical rating scale (NRS) before and after the procedure. Results were categorized into complete relief, partial relief, and no relief categories. A total of 9 out of 10 patients were completely recovered; and 1 patient was partially recovered. The average NRS scale was 9.6 before treatment, which was lowered to 0.4 following EBP. No neurological or vascular complications were observed. The authors concluded that CT-guided cervical EBP was an optimum and effective way for the treatment of SIH as a consequence of a leak in the cervical region. It exhibited a higher success rate than lumbar EBP. Moreover, these researchers stated that prospective RCTs of cervical versus lumbar EBP are needed to validate these preliminary findings.

Su et al (2025) stated that EBP is a minimally invasive and effective treatment for SIH); however, cervical EBP for SIH has little attention. These investigators examined the treatment the safety and effectiveness of cervical EBP in the treatment of SIH. A total of 59 cases of intractable SIH were examined by CT-guided cervical EBP at the Chinese PLA General Hospital from August 2014 to March 2024. The mean age of the 59 patients at symptom onset was 40.8 ± 9.5 years; 54/59 (91.5 %) patients experienced orthostatic headache. Pre-operative spine T2 scans with extensive fluid collection at the upper cervical region in 43/46 (93.5

%); 45/59 (76.3 %) patients had symptomatic relief with initial cervical EBP, and 14/59 (23.7 %) patients received further cervical EBPs. In the first 1 to 3 days following the EBP procedure, 11 (18.6 %) patients reported pain at the puncture site, and 15 (25.4 %) experienced neck pain. No other complications were observed during or after the procedure. At the latest follow-up, all patients showed good recovery. The mean follow-up was 28.9 ± 22.7 months. The authors concluded that CT-guided cervical EBP was a safe and effective treatment for patients with intractable SIH, especially in patients who had extensive fluid collection at the upper cervical region.

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