



REVIEW

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Some cool considerations of external lumbar drainage during its widespread application in neurosurgical practice: a long way to go

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Abstract

External lumbar drainage (ELD) has gained wide popularity in neurosurgical practice since its' first introduction by F. Vourc'h in 1963. It manifests encouraging prospects in control of refractory intracranial hypertension, prevention of complications secondary to aneurysmal subarachnoid hemorrhage, prediction of shunt responsiveness in normal pressure hydrocephalus, management of cerebrospinal fluid (CSF) leakage, and application in bacterial meningitis and ventriculitis. But many questions on the efficacy and safety of ELD are remained to be answered by future studies. CSF overdrainage and ELD-related meningitis are the two most common and fatal complications due to inappropriate usage of ELD. Randomized controlled trials are badly in need to more safely and rationally guide the clinical application of ELD.

Keywords: Aneurysmal subarachnoid hemorrhage, Cerebrospinal fluid overdrainage, Complication, Meningitis, External lumbar drainage, Indication, Intracranial hypertension

Background

External drainage of cerebrospinal fluid (CSF) from the lumbar cistern via a plastic catheter was primarily described by F. Vourc'h in 1963 [1]. Since then, external lumbar drainage (ELD) of CSF has gained wide popularity in a variety of neurosurgical activities and procedures e.g. intraoperative cerebral relaxation, drainage of bloody or infectious CSF, control of refractory intracranial hypertension, preoperative evaluation of normal pressure hydrocephalus (NPH), prevention of complications secondary to aneurysmal subarachnoid hemorrhage (aSAH) [2–7]. However, just as each coin has its two sides, issues concerning the complications and unduly usage of ELD has also come [8–10]. In order to further explore the indications, contraindications, complications, recent developments and future considerations of ELD, we performed a comprehensive review of the related studies written in English on ELD in PubMed. And related articles in the reference lists of the identified studies were

also reviewed. Furthermore, a search of ClinicalTrials.gov was also conducted for ongoing studies.

Main indications

Controlling of intracranial hypertension

Since the 1920s, when ELD had not been introduced, there were some reports of cerebral herniation secondary to lumbar puncture (LP) [11–13]. But most of the reports of cerebral herniation at that time were those patients harboring intracranial tumors. The forefather of modern neurosurgery Harvey Williams Cushing had ever advocated that lumbar drainage of CSF should be forbidden in patients with intracranial hypertension (ICH) for fear of cerebral herniation. And it has been and even still is treated as a solid doctrine by many neurosurgeons. Since the time when ELD was first introduced by F. Vourc'h [1], debates on its indications, complications, and contraindications have never ended. Many neurosurgeons still considered ELD a contraindication of ICH. Nevertheless, till in the 1990s, ELD was gradually and prudently used to control refractory ICH and encouraging results were observed [5, 14–21] (Table 1). In 1996 Brain Trauma Foundation recommended a two-tier

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Table 1 Some of the studies that focusing on control of refractory ICH with ELD

First author	Year	Type of study	No. of patients	Age group	Outcome	Complications during ELD	
						CH	Meningitis
Baldwin HZ [14]	1991		5	Children	Significant decrease in ICP (3) Survived (3) GOS \geq 4 (2)	0	0
Levy DI [15]	1995	Retrospective	16	Children	Significant decrease in ICP (14) Survived (14) GOS \geq 4 (11)	0	0
Willemsse RB [16]	1998	Retrospective	7	Adults	Significant decrease in ICP (NA) Survived (5) GOS \geq 4 (3)	0	0
Münch EC [17]	2001	Prospective	23	Adults	Significant decrease in ICP (23) Survived (15) GOS \geq 4 (10)	2	0
Murad A [18]	2008	Prospective	8	Adults	Significant decrease in ICP (8) Survived (NA) GOS \geq 4 (NA)	0	0
Tuettenberg J [5]	2009	Prospective	100	Children and adults	Significant decrease in ICP (NA) Survived (55) GOS \geq 4 (36)	12	7
Llompert-Pou JA [19]	2011	Retrospective	30	Adults	Significant decrease in ICP (NA) Survived (23) GOS \geq 4 (18)	0	1
Murad A [20]	2011	Prospective	6	Adults	Significant decrease in ICP (NA) Survived (4) GOS \geq 4 (NA)	0	0
Murad A [21]	2012	Prospective	15	Adults	Significant decrease in ICP (NA) Survived (12) GOS \geq 4 (NA)	1	0

NA not applicable, GOS Glasgow Outcome Scale, ICP intracranial pressure, CH cerebral herniation

strategy for the management of patients with ICH, which was treated as a standard protocol for control of intracranial pressure (ICP) in many centers [20–22]. This strategy is not only used in patients with traumatic brain injuries (TBI) but also in patients with other intracranial diseases. The first-tier measures include osmotic solutions, ventricular drainage of CSF, moderate hyperventilation and the second-tier include decompressive craniectomy, barbiturate coma or therapeutic hypothermia. But there were usually some cases in which the two-tier strategy was ineffective or inappropriate. Emerging evidences have demonstrated that application of ELD leads to a significant decrease in ICP and an increase in cerebral perfusion pressure (CPP) [5, 21]. CPP and ICP have been demonstrated to independently affect outcome in patients with severe brain injury [5, 23–26]. As was worried by some

neurosurgeons, cerebral herniation did happen in patients with ICH after the application of ELD. The reported incidence of cerebral herniation ranged from 0 to 12 % (Table 1). But just as Tuettenberg J and colleagues stated temporary clinical signs of cerebral herniation do not lead to lower rates of neurological recovery or a higher mortality rate [5].

However, the published studies on control of ICH with ELD merely include a relative small number of patients and no prospective randomized controlled trial (RCT) has ever been published till now. As was pointed by Tuettenberg J et al. that ELD of CSF in patients with intracranial hypertension leads to a significant and clinically relevant reduction in ICP, however, it remains unclear whether drainage of CSF improves clinical outcome by reducing ICP [5]. This calls for future RCTs.

Aneurysmal subarachnoid hemorrhage

Aneurysmal subarachnoid hemorrhage manifests a challenge to the public health not only for the risk of fatal aneurysmal rebleeding but also for the high morbidity of cerebral vasospasm (CVS), ICH and shunt-dependent hydrocephalus. CVS and ICH are two of the most common complications of aSAH. They might occur independently or reciprocally. Although treatments targeting at the prevention of CVS as 3-H therapy, calcium-channel blocker, arterial papaverine infusion, and angioplasty have been applied in the past decades, symptomatic CVS, of which the incidence could be as high as 40 %, is still the main indicator of unfavorable outcomes [27, 28]. The occurrence of CVS involves many pathophysiological processes, but there is no doubt that subarachnoid blood and its degradation products contribute mostly. Some Japanese authors have been using CSF drainage in aSAH patients since the early 1980s, but with conflicting results [29, 30]. Klimo P Jr and colleagues showed a marked reduction in symptomatic CVS, vasospasm-induced stroke and the need for endovascular procedures after 9 years utility of ELD [28]. They hypothesized that lumbar CSF drainage is superior to drainage from the lateral ventricles or intracranial cisterns. They believed that drainage of CSF from the lumbar cistern would promote circulation of newly produced CSF and blood cells from the ventricles through the subarachnoid space, whereas CSF drainage directly from the lateral ventricles may contribute to stasis of blood cells within the subarachnoid cistern and hence actually add to the risk of vasospasm. This might help explain the conflicting results with different drainage modalities. Since then, many reports with promising results were published in the prevention of CVS with ELD after aSAH [31, 32]. The most important one among them is the LUMAS trial. This RCT recruited 210 patients with aSAH, and demonstrated that ELD of CSF after aSAH reduces the prevalence of delayed ischemic neurological deficit and improves early clinical outcome but fails to improve outcome at 6 months after aSAH.

ICH is a common complication of aSAH, it may be secondary to and exacerbate CVS. To our knowledge, there is still no specific guideline or recommendation for the control of ICH after aSAH. Most institutions follow the two-tier guideline of Brain Trauma Foundation for control ICP in aSAH patients [5, 20–22]. But there are two issues before the implementation of the two-tier therapy: a) aSAH presents challenges which require special therapeutic considerations for management of ICP especially in the setting of vasospasm; b) there would always be some cases with refractory ICH that could not be controlled with this guideline.

Osmotic solution as mannitol or diuretic as furosemide would decrease intravascular fluid volume. Sedation and barbiturate coma carry the risk of hypotension. Considering the side effects of hypovolemia and hypotension, which are inconsistent with the 3-H therapy of aSAH, the two-tier guideline is not always suitable for ICP control in aSAH patients [20, 21]. Even the two-tier therapy is initiated consecutively there still would be some refractory cases in whom ICP could not be satisfactorily controlled [5]. However, some reports have demonstrated encouraging results of ICP control with the utility of ELD in aSAH patients [5, 20, 21]. The one that should be pointed out was conducted by Tuettenberg and colleagues [5]. This prospective study included 100 patients (45 with TBI, 55 with aSAH) and followed a stepwise design according to the two-tier therapy before ELD. When the two-tier therapy was ineffective, ELD was initiated. It demonstrated a significant and long-lasting reduction in ICP and an increase in CPP after application of ELD but failed to prove that ELD could improve clinical outcome by reducing ICP. However, large-scale RCT is anticipated in the future to strongly verify the effectiveness and safety of ELD in controlling of ICH in aSAH patients.

Predictive value in normal pressure hydrocephalus

The term normal pressure hydrocephalus (NPH) was first described by Hakim and Adams in 1965, which consisted of a triad of clinical symptoms including gait disturbance, dementia, and urinary incontinence in patients with enlarged ventricles and normal intracranial pressure [33]. It was subsequently divided into two subtypes: idiopathic (primary) NPH and secondary NPH. Although permanent shunting is currently the most effective treatment modality, experience in the past decades indicated that the rate of postsurgical complications including death and severe residual morbidity could be as high as 30–40 % [6, 34, 35]. So an effective method that could accurately predict the responsiveness to shunting is of great importance. Historically, additional tests as isotope cisternography, measurement of CSF outflow resistance and repeated LP were developed to screen the potential responders to shunting but with limited efficacy [36–38]. However, an ELD for a period of 3–5 days is gaining acceptance as a more sensitive predictor for patients who might respond well to shunting [6, 38, 39]. Published studies demonstrated that the accuracy of prediction could be greater than 90 % [6, 38]. The question is although the predictive value of a positive ELD was high, that of a negative ELD was deceptively low because of the high rate of false negative results [6, 38, 39]. Thus patients with a positive ELD are sure the most appropriate candidates for permanent shunt placement, whereas, those with a negative ELD test should be advised for further investigation of additional tests [6, 39]. By the way, no RCT on this specific topic was available till now.

Management of CSF leakage

CSF leakage is commonly encountered in the circumstances of head trauma and iatrogenic injuries. Although most of the cases with CSF leakage resolved spontaneously within 24–48 h, delayed diagnosis and management may lead to life-threatening conditions [40]. Historically, the management of CSF leakage consisted of noninvasive (conservative) and invasive (surgical) therapies. Because of its nature of self-limitedness, CSF leakage can spontaneously resolve with merely conservative managements including bedrest, head elevation, prophylactic antibiotics and strict sinus precautions (e.g. avoiding nasal blowing or Valsalva maneuver) in a significant proportion of patients. Those patients without spontaneous resolution in a certain period of time were previously thought of definite candidates for surgical intervention by some authors [41]. However, the publication of many studies indicated that ELD could be considered a good option in whom spontaneous resolution of CSF leakage was not achieved before surgical intervention was initiated [40–43]. But there are still some questions that need to be raised before the extensive application of ELD: a) When ELD should be considered after the occurrence of CSF leakage? b) How long is most appropriate with respect to the duration of ELD? c) When ELD should be stopped if the resolution of CSF leakage was not achieved? In view of the fact that no RCT on this issue has ever been published, we should be cautious when considering ELD before the questions aforementioned are satisfactorily answered.

Intraoperative brain relaxation

It is well-known that a perfect intracranial surgery depends not only on the neurosurgeon's excellent skills but also adequate intraoperative brain relaxation (IOBR). Because satisfactory brain relaxation results in easier access to the target lesion and reduces iatrogenic injuries due to intraoperative retraction. Strategies that aim to get favorable IOBR include hyperventilation, CSF drainage and usage of hyperosmotic agents during neurosurgery, among which mannitol is considered as the standard and a first-choice hyperosmotic agent [44]. The principle mechanism of hyperosmotic agents in brain relaxation is the induction of water shift from brain tissues to intravascular space and the subsequent brain-bulk reduction. However, administration of mannitol can be associated with severe adverse effects such as hypovolemia, rebound ICP elevation, hyperkalemia and renal failure [45, 46]. Currently, hypertonic saline as a seemingly more promising hyperosmotic agent has gained renewed interest in the field of IOBR [44, 47]. But hypertonic saline increases serum sodium concentration greatly. Intraoperative ELD, which relaxes brain by draining out certain amount of CSF, has been successfully applied in numerous intracranial surgeries [2, 48–50]. It is

a safe and effective method for intraoperative brain relaxation and does not interfere with circulating blood volume and hydroelectrolytic equilibration. However, the application of ELD is not without complications. Intracranial hemorrhage and acute cerebellar tonsillar herniation were frequently reported after the introduction of ELD especially in patients with asymptomatic Chiari I malformation [9, 51, 52]. So it's true that ELD is an efficient modality in IOBR, whereas should be used prudently. Perhaps due to the difference in mechanism of brain relaxation, no study on comparing the efficacy of hyperosmotic agents and ELD in IOBR has ever been conducted.

Application in bacterial meningitis and ventriculitis

It is well known that bacterial meningitis and/or ventriculitis (BM/V) is an unavoidable complication of ELD. But more encouraging outcome has also been obtained by the use of ELD in pediatric and adult patients with BM/V compared with the traditional therapies [53–55]. With the accumulation of evidences that LP should not always be considered a contraindication in acute severe BM/V for fear of cerebral herniation [56], the application of ELD is warranted. But LP or ELD should be considered contraindication when the following situations were met: a) Signs of a cerebral mass lesion; b) Ongoing or impending cerebral herniation; c) Ongoing epileptic seizures; d) Papilledema; e) Severe coagulopathy; f) Infection at the site of LP [56]. The main pathophysiological mechanism by which ELD exerts its effectiveness might be control of ICH and drainage of cytotoxins in the CSF [53, 55]. But as a result of the limited literature on this issue, studies with larger number of patients and RCT design are anticipated in the future. And by the completion of this manuscript no study comparing the efficacy of ELD and repeated LP in BM/V has ever been published.

Complications of ELD

Although ELD is an effective and safe treatment modality which has been successfully utilized in a variety of neurosurgical procedures, it is not risk free. Complications even some fatal complications secondary to inappropriate usage of ELD were frequently reported. In general, these complications can be divided into three categories according to Acikbas: A) complications related to alterations in CSF drainage rate, B) complications due to mechanical failure of the catheter, and C) infections [57]. As complications related to CSF drainage rate and infections are preventable and modifiable, they are the main points of our discussion.

CSF overdrainage

CSF overdrainage is perhaps the most common complication of ELD, the incidence of which can be as high as 63% [58, 59]. It might alternatively be expressed as intracranial

hypotension, brain sag, sinking brain syndrome, sinking skin flap syndrome or CSF hypovolemia according to different reports and personal preference [51, 52, 59, 60]. And the clinical presentations of CSF overdrainage range from mere headache, cranial nerve palsy, mental state alteration, pneumocephalus, and intracranial hemorrhage to death [8, 9, 51, 52, 57, 59–61]. The commonly accepted mechanism of CSF overdrainage is downward displacement of intracranial contents due to the pressure gradient between the intracranial and intrathecal compartments [8, 51, 59, 61]. Although identification of brain sagging, venous engorgement, dura enhancement, pituitary enhancement and subdural fluid collection on MRI is superior [8, 59, 61, 62], emergent CT combined with clinical presentation may be more convenient and practical in reaching the diagnosis of CSF overdrainage in daily practice [52, 60]. The most commonly reported findings on head CT include effacement of the basal cisterns, ventricular collapse, diffuse edema, pneumocephalus and subdural fluid collection [59, 60]. A simple and practical assembly of diagnosis criteria used by Komotar RJ and colleagues includes clinical signs of transtentorial herniation, head CT scans revealing effacement of the basal cisterns with an oblong brainstem, and improvement of symptoms after placement of the patient in the Trendelenburg position (–15 to –30°) [63].

Though the term CSF overdrainage indicates excessive drainage of CSF, there is still no definite upper limit concerning the volume drained out in a certain period of time at present. The targeted volume ranges from 5 to 20 ml per hour according to different reports [52, 57–61], which is no more than the CSF production rate in an adult (roughly 20 ml/h). Though in our past study, we have found that the mean daily CSF volume drained out was statistically associated with the incidence of CSF overdrainage [52], we could also see the occurrence of CSF overdrainage even only a smaller amount of CSF was drained out. So, perhaps the optimum drainage volume per unit of time does not ever exist. The most reliable way to avoid overdrainage might be based on vigilant observation and timely radiological findings. When overdrainage happens, the most appropriate and efficient managements are temporary catheter clipping, Trendelenburg position and intravenous hydration.

ELD-related meningitis

Meningitis is a common and inevitable complication of ELD. The incidence varies among different reports, which could be higher than 40 % [10, 19, 57, 64–67] (Table 2). Although a myriad of reasons, such as primary diseases, drain indwelling procedures, patient population, and use of prophylactic antibiotics, could help explain the large variation in infection rates in different reports, a clear

Table 2 Studies with identified infected patients after ELD

First author	Year	No. of patients	Infected (percentage)
Coplin WM [67]	1999	312	13 (4.2 %)
Açikbaş SC [57]	2002	63	5 (7.9 %)
Schade RP [66]	2005	125	8 (6.4 %)
Scheithauer S [10]	2010	79	17 (21.5 %)
Leverstein-van Hall MA [65]	2010	216	14 (6.5 %)
Llompert-Pou JA [19]	2011	30	1 (3 %)
Chen C [64]	2014	94	42 (44.7 %)

Table 3 Studies with identified pathogens secondary to ELD

First author	Year	No. of Infected patients	Pathogen			
Coplin WM [67]	1999	13	CNS (5)			
			S aureus (2)			
			CNS, <i>Corynebacterium</i> Species (1)			
			K pneumonia(1)			
			Actinobacter calcoaceticus (1)			
			Enterobacter cloacae (1)			
			P aeruginosa (1)			
			Group A Streptococcus (1)			
			Açikbaş SC [57]	2002	5	S aureus (2)
						CNS (1)
Acinetobacter SPP (1)						
Schade RP [66]	2005	8	Enterobacter SPP (1)			
			S aureus (3)			
			CNS (1)			
			Escherichia coli (1)			
			P aeruginosa (1)			
Scheithauer S [69]	2009	20	Enterococcus faecalis (1)			
			Proteus mirabilis (1)			
			CNS (16)			
Hetem DJ [68]	2010	72	S aureus (4)			
			CNS (33)			
Llompert-Pou JA [19]	2011	1	S aureus (17)			
			Gram-negative bacteria (11)			
			Other Gram-positive bacteria (11)			
			Multiple microorganisms cultured (14)			
			CNS (1)			

CNS coagulase-negative staphylococci, *S aureus* staphylococcus aureus

definition of drainage-related infection might be the most urgent issue that should be answered by the future studies and guidelines [66, 68–70]. Generally speaking, the diagnosis of meningitis consists of the following points: a) no previous meningitis before lumbar drain insertion; b) sterile CSF culture at the time of lumbar drain insertion; c) continuous lumbar drainage >24 h before the positive culture was aspirated; and d) positive culture of a CSF specimen collected from the lumbar drain or from a lumbar puncture; e) clinical symptoms as fever, nuchal rigidity, and mental alteration that could not be explained by other causes [10, 65, 67, 68]. Alterations of leukocyte count, protein concentration and glucose concentration in routine CSF tests are supportive proofs of meningitis but with limited predictive or diagnostic value [67, 71]. Positive CSF-drain cultures are strongly associated with development of ELD-related meningitis [68]. At present, literatures solely focusing on the incidence, risk factors and preventive solutions of ELD-related meningitis are scarce [57, 67]. Most of the related articles are a mixture of ELD and external ventricular drainage (EVD) [10, 65, 66, 68, 69]. Because procedure complexity, drainage duration, and distance to the brain are all potential risks for intracranial infection, ELD-related meningitis should be treated as a unique entity from its EVD-related counterpart and be studied separately.

In patients with ELD-related meningitis, the responsible pathogens are diverse. But coagulase-negative staphylococci and staphylococcus aureus are the commonest causative organisms [19, 57, 66–69] (Table 3). Single organism infections are far more than those with multiple organisms (Table 2). Site leakage, drain blockage, frequency of CSF sampling, number of CSF sampling sites

are all reported risk factors for ELD-related meningitis, but the most important one may be the duration of catheterization [64–66]. Prophylactic antibiotics usage is controversial for prevention of drain associated infection [65–67]. A prospective study conducted by Leverstein-van Hall MA and colleagues indicates that a multidisciplinary approach, in which different preventive measures were combined, was associated with a significant reduction in incidence of drain-related meningitis [65].

In general, ELD-related meningitis is a complex entity, of which a lot of questions are with no satisfactory answers. As Kasper EM proposed, a number of points need to be raised when going ahead into further studies: a) What is the correlation of concurrent infections from indwelling catheters and possible concurrent systemic infections (fever)? b) What is the accuracy of CSF test result? c) Is there a temporal correlation between length of device use and risk of infection? d) Is there a risk from routine CSF sampling to carry an infection into a closed drainage system? e) Drainage placement techniques and protocols need to be addressed (eg, the distance to drain exit site as well as a rationale for (not) using antibiotics) [70]. By the way, till the completion of this manuscript, no RCT has ever been reported concerning the topic of ELD-related meningitis.

Ongoing clinical trials and future considerations

A ClinicalTrials.gov search of ongoing clinical trials concerning the application of ELD in neurosurgical practice was performed on Jan 9th, 2015. In all, 5 ongoing studies were identified, with 2 on aSAH, 2 on acute spinal cord injury, and the last one on intraventricular hemorrhage

Table 4 Ongoing studies concerning the application of ELD

Sponsor	Start Date	Design	Brief title	Aim
Charite University, Berlin, Germany	December 2010	Single blind, Randomized	EARLYdrain - Outcome After Early Lumbar CSF-drainage in Aneurysmal SAH	To investigate whether drainage of cerebral spinal fluid via a lumbar route will improve outcome after intracranial SAH
University of Erlangen-Nürnberg Medical School	June 2010	Open label, Randomized	A Randomised Controlled Trial of Lumbar Drainage to Treat Communicating Hydrocephalus After Severe Intraventricular Hemorrhage	To determine if usage of early lumbar drainage leads to less shunt surgery and less catheter associated complications in patients with communicating hydrocephalus after intracerebral hemorrhage with severe ventricular involvement
Odense University Hospital	August 2013	Open label, Randomized	Use of Lumbar Drain to Remove Clots in Patients Admitted to the Neuro-ICU After Subarachnoid Hemorrhage	To test if CSF obtained from ELD has a higher concentration of blood than CSF from external ventricular drain in patients suffering from SAH
University of British Columbia	March 2008	Single blind, Non-Randomized	Cerebrospinal Fluid (CSF) Drainage and Cytokine Profiling in the Treatment of Acute Spinal Cord Injury (SCI)	To evaluate CSF drainage as a potential neuroprotective strategy after acute spinal cord injury
St. Joseph's Hospital and Medical Center, Phoenix	October 2, 2015	Open label, Randomized	Cerebrospinal Fluid Drainage (CSFD) in Acute Spinal Cord Injury	To evaluate the safety and efficacy of CSFD and to provide a preliminary clinical efficacy evaluation of the combination of CSFD and elevation of mean arterial pressure in patients with acute spinal cord injury

(Table 4). Four of the 5 ongoing studies were designed in a randomized manner, while 1 was non-randomized. From the ongoing clinical trials and the published studies we could notice that clinical studies of high evidence level on the issue of ELD are few. In order to more safely and rationally apply ELD in neurosurgical practice, a lot of RCTs are needed in future investigations.

Conclusions

ELD is a useful and promising modality which has gained wide popularity in a variety of neurosurgical practices. Although, encouraging outcomes have been obtained in control of ICH, prediction of shunt responsiveness in NPH, management of CSF leakage and bacterial meningitis and ventriculitis, intraoperative relaxation, and so on, fatal complications as severe CSF overdrainage and ELD-related meningitis are urgent issues that need to be addressed in future studies. RCTs are badly in need to more safely and rationally guide the clinical application of ELD.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

GL and KH carried out the studies, participated in collecting data, and drafted the manuscript. YZ, JZ and ZH revised the manuscript critically for important intellectual content. XZ helped to draft the manuscript and gave final approval of the version to be published. All authors read and approved the final manuscript.

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