Validation of a bioabsorbable device that seals perforations after Tuohy needle dural puncture in an ovine model

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ABSTRACT

Background We designed a device to close accidental dural puncture via the offending puncturing epidural needle directly after diagnosis of the puncture and before removing the needle. The aim of this study was to quantify this device's ability to seal cerebrospinal fluid leakage.

Methods Forty-six anesthetized adult sheep were studied in a single-blind randomized controlled fashion in two equal groups.

An intentional dural puncture was performed with an 18-gage Tuohy needle on all the sheep between L6 and S1 levels. Contrast medium was injected through the needle. Twenty-three animals receive treatment with the sealing device. Two minutes after device placement, or dural puncture in the control group, a CT scan was performed on the animals to estimate contrast material leakage. A region of interest (ROI) was defined as the region that enclosed the subarachnoid space, epidural space, and neuroforaminal canal (the vertebral body above and half of its equivalent height in sacrum below the puncture site). In this region, the total contrast volume and the volumes in the epidural space (EPIDURAL) were measured. The primary outcome measure was the EPIDURAL/ROI ratio to ascertain the proportion of intrathecally injected fluid that passed into the epidural space in both groups. The secondary outcomes were the total amount of contrast in the ROI and the EPIDURAL.

Results The device was deployed successfully in all but two instances, where it suffered from manufacturing defects.

Leakage was less in the study group (1.0 vs 1.4 mL, p=0.008). The median EPIDURAL/ROI ratio was likewise less in the study group (29 vs 46; p=0.013; 95% CI (−27 to −3.5)).

Conclusion This novel dural puncture-sealing device, also envisaged to be used in other comparable iatrogenic leakage scenarios to be identified in the future, was able to reduce the volume of cerebrospinal fluid that leaked into the epidural space after dural puncture. The device is possibly a valuable way of preventing fluid leakage immediately after the recognition of membrane puncture.

INTRODUCTION

A widely accepted hypothesis to explain the etiology of postdural puncture headache (PDPH) after accidental dural puncture (ADP) during attempted epidural block procedure is the presence of cerebrospinal fluid (CSF) hypotension after continuous leakage of CSF. This leakage, in turn, can lead to "brain sagging" and cranial nerve sensory fiber stretching and stimulation, or intracranial hypotension.[1 2] Intracranial hypotension, also due to CSF loss following ADP, has also been proposed as a possible cause of PDPH by activating compensatory cerebral vasodilation to maintain intracranial volume, thereby causing vascular headache.[1 2]

Standard treatment modalities such as epidural blood patch (or iatrogenic peridural hematoma formation), by itself a potent cerebral vasoconstrictor,[3] and pterygopalatine ganglion blockade, also a cerebral vasoconstrictor,[4] are successful for managing PDPH after it has developed. Although prophylactic "blood patching" has been proposed,[5 6] to date, it is not used as a first-line approach in clinical practice, and no specific modality or device is available that can be applied immediately after detecting ADP while simultaneously attempting epidural needle placement.

The objective of this study was to evaluate the ability of a novel system specifically designed for implantation at the time an ADP has been detected during an epidural needle placement to seal the dural perforation and limit CSF leakage. PDPH serves as an obvious example of its potential use.

METHODS

Intentional dural puncture

Forty-six adult sheep (*Ovis aries*) of both sexes were randomly assigned to one of two groups: animals in group 1 (n=23) were given a lumbar puncture but did not receive treatment with the sealing device and thus acted as controls, while those in group 2 (n=23; the study group) were given a lumbar puncture and received treatment via the sealing device with the puncturing Tuohy needle. Group allocation was randomized by codes drawn from a sealed envelope. The envelopes were opened immediately before starting the procedure to reveal the randomization of each animal.

Clinical protocol

After catheterizing the anterior cephalic vein and sedating the animals with intravenous dexmedetomidine (10 µg/kg), the puncture site was prepared by shaving the lumbar area and then disinfecting it with alcoholic chlorhexidine. General anesthesia

was induced with intravenous propofol (3 mg/kg) and maintained with endotracheal administration of sevoflurane delivered via closed circuit mechanical ventilation in an air and oxygen mixture at 50% FiO_2. Routine monitors were applied and the animals were kept normothermic, normocapnic, normoxic, and hemodynamically stable throughout the experiment.

After positioning the animal in the sternal position, a lumbar puncture was carried out at the midline in the lumbosacral transitional space (L6–S1) with an 18 G Tuohy epidural needle (Perican, B-Braun, Melsungen, Germany).

In a previous preliminary study, the data of which is not included in this study, the authors evaluated different options in five fresh sheep cadavers to obtain the optimal interspace to perform the puncture, taking easy identification and angulation comparable to that used in humans into account. CSF was consistently observed at the needle hub in every specimen when a puncture was performed at the L6–S1 level.

The needle was passed through the ligamenta flava and advanced until the appearance of CSF. At this point, 0.4 mL/kg of ioversol radiopaque contrast (Optiray 320, Guerbet, Villepinte, France) was injected through the needle.

After the CSF leak was detected and the contrast was injected, we inserted the sealing system into the animals in the study group (group 2) according to the method described below. The Tuohy needle was then removed. In the control group, after the contrast medium injection, we waited for 2 s before removing the Tuohy needles. (Two seconds was the average time needed to insert the sealing kit into the proximal part of the Tuohy. This was calculated in several implantations of the kit in phantom models during a pilot study).

Description of the device

We designed and patented[7] a complete device kit for plugging ADP holes, including an implant, a barbed unidirectional thread, an applicator, and a flexometallic cannula. The main element of this kit is a synthetic patch inserted through the Tuohy epidural needle directly into the spinal subarachnoid space. The patch has a central orifice, and the barbed thread passes through this hole, which facilitates the holding of the implant against the dural sac by terminal widening (figure 1) that prevents the thread and patch from separating.

The patch unfolds inside the dural sac once it passes through the tip of the needle, along with the barbed thread, and then plugs the puncture hole through which it was inserted. In a preliminary study (not included), the patch was tested and validated using phantoms, sheep and human cadavers. All patches unfolded properly during postmortem quality control.

Table 1 andfigures 2–4 outline the content of the device kit. The biocompatible materials used in this device and the results of its bioabsorbability studies are described in the online supplemental material.

Table 1 Comparison of epidural leakage by treatment status*

Variable	Groups: Without implant	Groups: With implant	P value†‡	95% CI
Sample size, n	23	23		
EPIDURAL median (range) in mL	1.4 (0.4–3.2)	1.0 (0.2–1.9)	0.01	−1.02 to −0.02
ROI median (range) in mL	3.4 (1.7–4.7)	3.2 (2.0–4.8)	0.44	−0.97 to 0.37
EPIDURAL/ROI in percentage	46 (18–84)	29 (10–69)	0.01	−27.0 to −3.5

EPIDURAL, the volume of contrast fluid (in milliliters) found in the epidural area; ROI, the total volume of contrast fluid (in milliliters) found in the region of interest, measured at the L6 and S1 vertebrae, including the fluid enclosed in the subarachnoid space, epidural space and foraminal canal; EPIDURAL/ROI, the percentage of contrast fluid found in the epidural area relative to the total amount of fluid found in the ROI. A higher percentage implies that proportionally more contrast has leaked into the epidural space.
*Medians, minimums and maximums, p values, and 95% CIs of the variables studied.
†P values compare groups with and without implant.
‡medpb2 test used to compare medians for two independent samples using a percentile bootstrap method.
EPIDURAL, total contrast volume and the volumes in the epidural space; ROI, region of interest.

Technique used in placing the device

After injecting the contrast medium, the proximal end of the patch applicator was connected via a universal Luer lock connection to the Tuohy needle (figures 1 and 5). The applicator houses the folded dural seal patch and the barbed thread inside the canal near its tip. The flexometallic cannula was then advanced through the applicator. The cannula pushed the folded implant and barbed thread through the internal orifice of the Tuohy needle until the implant passed through the tip of the needle into the subarachnoid space held by the thread where it unfolded

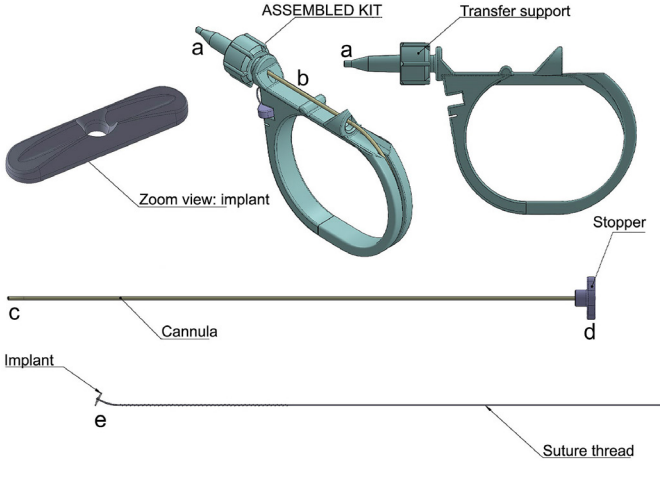

Figure 1 Detail of device to plug dural gaps showing separate elements and the assembled kit. The thread and patch complex are housed inside the cannula. a=tip of transfer applicator; b=flexometallic cannula mounted in transfer applicator; c=distal tip of flexometallic cannula; d=stopper at proximal end of cannula; e=implant mounted at distal end of barbed thread.

Figure 2 Implant deployed after the flexometallic cannula has been advanced through the Tuohy needle to displace the folded patch and barbed thread into the subarachnoid space. a=the terminal end of the barbed thread has been modified to be wider in diameter than orifice in the patch to anchor it into the patch; b=the first millimeter of the thread is devoid of spines; c=implant; d=cannula positioned at tip of Tuohy needle.

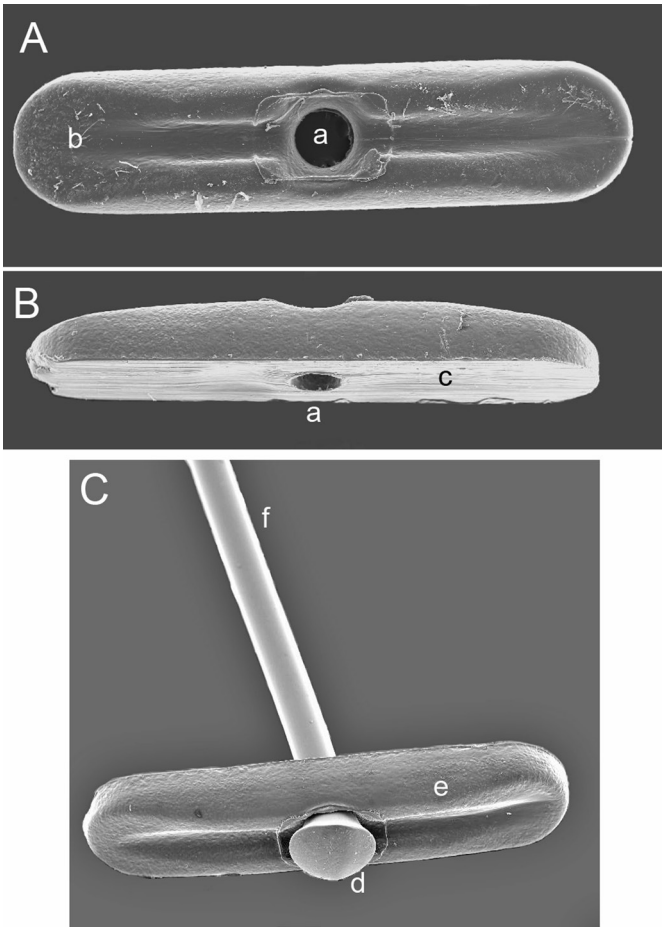

Figure 3 Implant and implant–barbed thread complex. (A) Patch as viewed from interior of intrathecal space. a=patch orifice; b=patch surface in contact with cerebrospinal fluid. (B) Oblique view of patch. c=patch surface in contact with arachnoid tissue. (C) Thread pulled though to anchor it to patch. d=widened terminal end of thread; e=patch; f=thread.

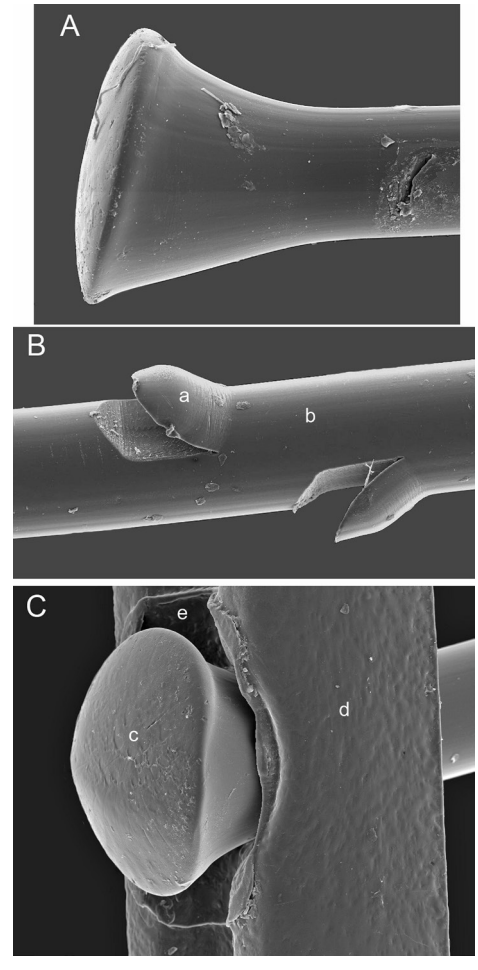

Figure 4 Scanning electron micrograph views of thread and thread anchored in patch. (A) Widened end of thread showing that there is no spine over the first millimeter of the thread. (B) Spines on thread, a=spines; b=body of thread. (C) c=widened terminal end of thread anchored in patch; d=patch; e=orifice of patch.

(figure 2). This step coincided with the complete insertion of the flexometallic cannula, which was inserted into the hub of the needle. This prevents the flexometallic cannula from entering the subarachnoid space. The flexometallic cannula is a hollow tube that accommodates the full length of the barbed unidirectional thread. The barbed thread is free inside the cannula, and the internal diameter of the cannula allows the spines of the thread to be free so that it can move when the cannula is removed (figures 3 and 4).

The implant has a rectangular shape with an orifice in its center (figures 2–4). The barbed thread and the implant are not joined; they are two independent pieces. The first millimeter of thread does not have spines. Its distal end is barbed such that it is greater in diameter than the thread so that it is unable to slip through the orifice of the patch. When the thread/patch complex is loaded into the Tuohy needle, the distal barb is positioned such that after it has been deployed, it will be on the surface of the patch that will be in contact with the CSF. Applying traction to the thread fixes the implant to the internal surface of the arachnoid.

After advancing the patch inside the dural sac, the flexometallic guide, applicator, and epidural needle (in that order) were removed, leaving the patch on the inside of the dural sac. When the needle was withdrawn, the thread was in the same location that the needle originally occupied. For this reason, the outward traction of the barbed thread ensured that the implant would remain in position at the site of the dural puncture.

Slight tension was applied to the portion of the thread that protruded through the skin to force the patch tightly against the arachnoid layer (internal surface of dural sac). It was then cut at the skin and it retracted into the subcutaneous tissue.

CT scan study

Two minutes after performing dural puncture in both groups and placing the implant in the study group, we performed 16 slices of helicoidal CT scans (Brivo CT385, GE Hangwei Medical Systems, Beijing, China) with longitudinal and transverse slices and a scanning area ranging from the thoracic segments to the coccygeal region to estimate contrast material leakage. For both groups, the time from puncture to image capture was the same. The thickness of the CT slices was set as 1.25 mm. After the patch technique, CT imaging, and scan verification by a veterinary radiologist, the study animals were humanely euthanized.

CT image analysis

The images obtained from the CT scan in digital imaging and communication format were used to analyze the CSF leak in the puncture area with Mimics Research software (V.17.0,

Materialize, Belgium) according to the following procedure (figure 6):

1. Contrast liquid segmentation: segmentation (partitioning the digital image into multiple segments) was used to simplify a complex image into something easier to analyze. Segmentation of the radiopaque contrast gave us a clear image of the total liquid mass.
2. Bone segmentation: the same process was carried out on the images of the bony structures.
3. Definition of the region of interest (ROI): to define the ROI, the L6 to S1 vertebrae were located, the height of the L6 vertebrae was measured, and the ROI was extended to S1—a level equivalent to half the height of L6, including the subarachnoid and epidural space and the foraminal canal.

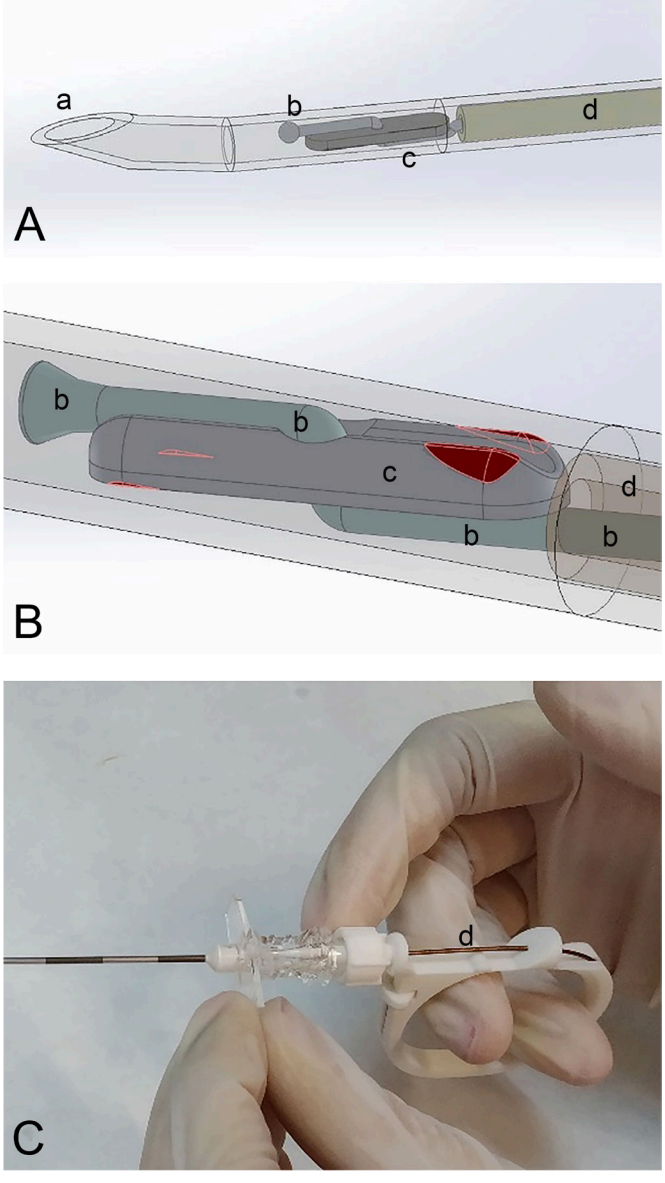

Figure 5 (A) Detail of tip of Tuohy needle showing the thread and patch complex ready to be deployed when the cannula is advanced to the needle tip. (B) Enlarged view of the thread and patch complex folded inside the needle lumen. (C) Attaching the transfer applicator to the Tuohy needle hub using a Luer lock connector. a=tip of Tuohy needle; b=barbed thread; c=patch; d=cannula.

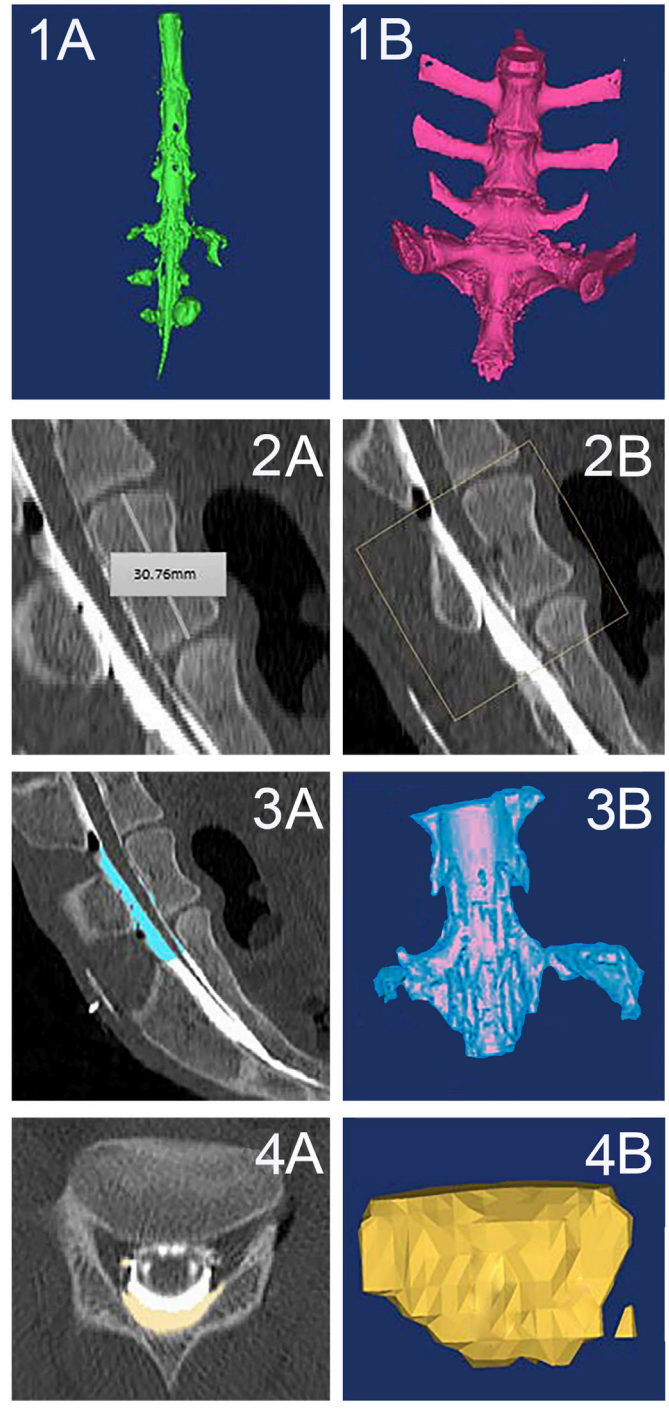

Figure 6 Analysis of the procedure used. (1A) is a 3D reconstruction (anteroposterior view) of all contrast liquid seen in the CT study. (1B)–(3D) reconstruction of bony elements in lumbosacral region (anteroposterior view). (2A) and (2B) Delimitation of the region of interest (ROI), sagittal view. (3A) and (3B) Contrast liquid identification in the ROI in light blue (3A and 3B) showing the sagittal view and 3D reconstruction in the anteroposterior view, respectively). (4A) and (4B) Inside the ROI, and selection and quantification of contrast in the epidural area in yellow. (4A) shows a cross-section of CT and the epidural contrast is marked in yellow. Online supplemental material and (4B) show an axial cross-section and an anteroposterior view of 3D-reconstructed epidural contrast in the ROI, also marked in yellow, respectively. The color on the surface of the images was modified using Adobe Photoshop (Adobe, San Jose, California, USA). The texture was kept and the color was added to make the images easier to understand.

4. Contrast liquid segmentation in the ROI (amount of total liquid found within the ROI): this process gave us a clear view of the total amount of radiopaque contrast allocated in the ROI.
5. Inside the ROI, selection and quantification of the contrast fluid identified in the epidural area (ie, the volume of fluid found outside the dural sac).
6. Calculation of the proportion of contrast fluid found in the epidural area with respect to the total amount of contrast liquid was found in the ROI.

Criteria followed for segmentation

We strove to maintain continuity of the structures between consecutive CT slices (figure 7). To begin the segmentation, a slice in which the epidural space and subarachnoid space was best identified with edges clearly seen was chosen. It was then used to infer the remaining successive slices following the continuity of the structures. Because the epidural space surrounding the dura mater, had a coronal circular morphology, we considered the presence of any liquid on the outside of this circular structure and extending to the foraminal canal where the nerve root cuffs exit (figure 7) as leaked fluid.

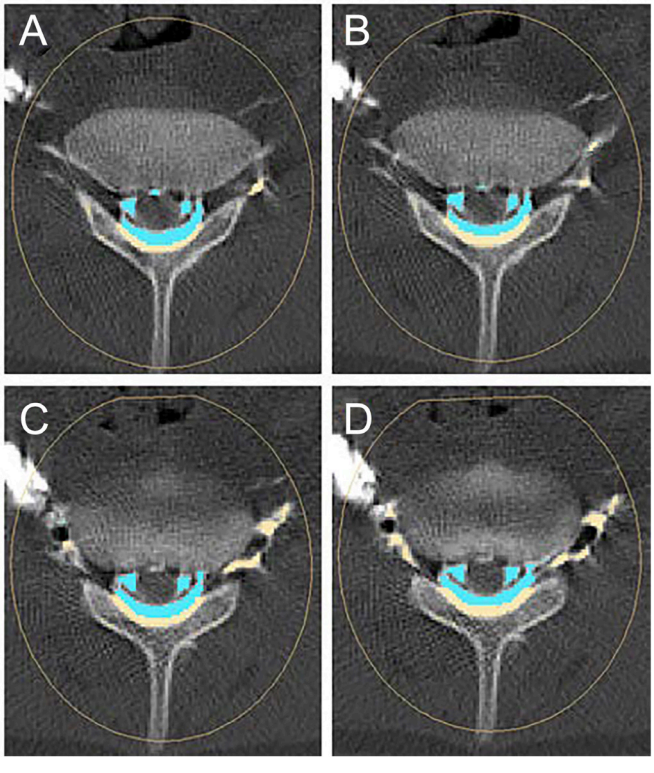

Figure 7 Cross-sectional view of the CT. CT scan image sequence, as an example of four consecutive slices (cranial to caudal) in which epidural and intrathecal contrast were segmented. We followed the principle of the continuity of the structures to segment the contrast fluid in the epidural area (blue corresponds to the contrast medium within the subarachnoid space and yellow represents the epidural space filled with epidural fat). The colors in the surface of the images were modified using Adobe Photoshop (Adobe, San Jose, California, USA). The texture was kept and color was added to make the images easier to understand.

Variables

ROI contrast volume

The quantified total volume of contrast fluid (measured in millimeters cubed by CT reconstruction programming) was found in the ROI defined for the L6 and S1 vertebrae.

Epidural contrast volume

The quantified volume of contrast fluid (measured in millimeters cubed by CT reconstruction programming) was found in the epidural area.

Epidural/ROI volume (%)

To compare the two groups, this variable was defined as the percentage of contrast fluid found in the epidural area in relation to the total amount of fluid found in the ROI expressed as a percentage, thus:

$$\text{Epidural}\,\frac{\text{volume}}{\text{ROI}}\ (\%) = \frac{\text{Epidural contrast volume}}{\text{ROI contrast volume}} \times 100$$

Statistical analysis

This was a randomized, single-blinded study in which the data from the animals of each group were encoded. The person who evaluated the CT images and measured the variables did not know that to which group each animal belonged. The codes assigned to the animals were only exposed after the statistical analysis had been completed.

The statistical study was carried out using R statistical software (V.3.6.4).[8] The effect size was calculated with the pwr.t2n.test function from the pwr package[9] for groups of different sample sizes (n1=20; n2=23). The alpha error was set at 0.05, the beta error was 0.8, and the alternative hypothesis was considered "greater than." An effect size of 0.77 was obtained. The normality of the weight and age of the animals was verified with a Shapiro-Wilk test using the Shapiro test function in the stats package of R.[8] Finally, a robust test was performed to compare these two independent groups using the medpb2 cut medians function from the WRS2 package.[10] We considered statistical differences to be defined as $p<0.05$. The trim level for the means was 0.2. The data are presented numerically as the medians (minimum to maximum) and are graphically presented as the medians, interquartile ranges, and minimums and maximums.

Scanning electron microscopy

The implant, the barbed thread, and both of them mounted were studied under scanning electron microscopy (figures 3 and 4). The microscopic technique has been described in our previous papers.[11–13]

The primary outcome measure was the total contrast volume and the volumes in the epidural space (EPIDURAL)/ROI ratio as a measure of the proportion of intrathecally injected fluid that passed into the epidural space. Secondary outcomes were the total amount of contrast in ROI and EPIDURAL.

RESULTS

The implant placement technique was performed without difficulties and in less than 30 s in all but two instances where we had to restart placement because the implant became stuck inside the Tuohy needle. This problem occurred because the patch was not properly folded within the transfer element. The patches were replaced and the procedures were performed without further incident. On the radiologist's advice, we excluded three cases from the statistical analysis because of the poor quality of the CT images. These three animals belonged

to group 1, which did not receive an implant. The mean weight (±SD) of all the animals was 42±11 kg and their mean age was 3.0±0.5 years.

The injection was performed at the L6-S1 vertebral level in all cases due to the scarce anatomical variability of the sheep's spine, the ease of recognizing the sacral ridge by palpation, and the researcher's accumulated experience in lumbar puncture in sheep.

Epidural contrast volume was lower in the study group versus the control group (1.4 vs 1.0 mL, p=0.008, respectively). The median EPIDURAL/ROI ratio was lower in the study group (study group=29; control group=46; p=0.013; 95% CI (−27 to −3.5)); in relative terms, 37% less contrast material was detected outside the epidural space in the study group.

ROI values were not different between the two groups (3.4 mL vs 3.2 mL, p=0.44). There was no statistical difference between total CSF volumes found at the same level of the dural sac, represented by the sum of CSF encountered inside the subarachnoid space plus the epidural space and foraminal canals.

These results are presented in table 1.

The animals were euthanized areas where the device was placed were dissection and microscopically evaluated. Traumatic subdural and intrathecal hemorrhage were not found.

DISCUSSION

Over the past decades, there has been scant progress in the search for techniques to effectively prevent PDPH. The epidural blood patch procedure is recognized as the most effective treatment for ADP, although its application requires a second epidural puncture (which itself is not without new risks) and the introduction of a volume of autologous blood (that has been manipulated) that then forms an iatrogenic epidural hematoma. Using a biologically compatible and inert implant may represent a method to prevent CSF loss and thus perhaps PDPH. Human cohort and randomized controlled trials are required to confirm this. Although ADP was conveniently used (and shown to be effective) for this study, it could perhaps also be used in future as yet recognized, defined, and identified analogous scenarios such as vascular, urinary, or pleural punctures, among others, where early and efficient sealing immediately after puncture may be clinically advantageous.

The material chosen for manufacturing the implant was poly (L-lactide-co-D, L-lactide) copolymer. It has been tested in various fields of medical diagnosis and therapy. Its biocompatibility, degradation, and excretion profile make it one of the most reliable and proven materials and is approved by the US Food and Drug Administration.[14] The entire kit passed cytotoxicity and histocompatibility tests were performed in rodents.[15]

Studies of dural lesions caused by different needles have shown that lesion closure occurs independently in the dura mater and arachnoid layer.[11–13] Closure is faster in dura because of the effect of the dura mater's elastic fibers. It is slower in the arachnoid layer because closure requires cellular repair.[13 16] In a clinical setting, the implant we describe would be placed in the minutes after the generation of the lesion, thus the loss of CSF would be compensated for by normal CSF production.

The device we tested contained a minute polylactic acid implant with a specific configuration that allowed it to unfold once it exited the tip of the Tuohy needle. Thus, the patch remained inside the dural sac and blocked the gap created by the epidural puncture needle, taking advantage of the fact that when the ADP occurred, the needle was already in position at the site of the perforation.

Given that the 18 G needle in the standard kit has an outer and inner diameter of 1.3 mm and 1.1 mm, respectively, it is able to deliver the implant to the inside of the dural sac to plug the lesion. Moreover, rapid retraction in the lesion diameter—by up to 80% in the minutes after its generation[13]—means that the implant surface area can easily exceed that of the lesion.

Our proposal is a relatively easy technique to master. Once the dural lesion has occurred and the CSF leak appears, the stylet of the Tuohy needle is replaced inside the epidural needle to prevent more CSF loss, while an assistant opens up the kit. While the needle is secured with one hand, the system can then be inserted and threaded.

As for spinal cord injury, the blunt design of the implant is highly unlikely to injure the spinal cord or the roots of the cauda equina. However, a great number of epidural techniques are performed at the lumbar spine, at the level of the dural sac distal to the termination of the spinal cord. Furthermore, the first millimeter of the Tuohy needles was inside the subarachnoid space after ADP, thus the introducer does not come into contact with the edges of the dural lesion that are protected by the external surface of the needle. The implant therefore always opens within the CSF; in addition, the movements of the introducer and implant do not enlarge the size of the lesion. The initial CSF leakage ensures that the implant will be placed within the subarachnoid space and pulled from the inside out, sealing the dural lesion.

Because the epidural volume and total contrast volume administered varied between individual animals depending on their weight, we used the EPIDURAL/ROI ratio as the main study variable to standardize our measurements. However, the intrathecal contrast may become distributed cranially or caudally beyond the delimited area in the immediate proximity of the puncture site. The amount of contrast medium inside and outside the epidural space is a metric[17] that considers the variability between each animal caused in part by ventral migration toward the foraminal canal.

Under normal conditions, the amount CSF leaking past the implant will most likely be even less than that seen in our results considering that this experimental method produced an increase in CSF pressure beyond normal after injecting a 0.4 mL/kg ioversol solution.

We have to emphasize that the implant is expected to be kept in place by the traction of the synthetic barbed thread. After removing the needle, this thread will be anchored in the spinal ligaments, thus preventing the implant from moving.

If another approach to the epidural space is required, the presence of the implant does not preclude performing the technique at a different intervertebral space, similar to what would take place in non-treated ADPs.

The clinical signs of intracranial hypotension typically appear after 24 hours. It seems reasonable to speculate that this occurs because this is when the accumulated leaked volume is relatively large. However, studies by Reina *et al*[11–13 17] on leaked volumes are perhaps more appropriate, as they demonstrate, similar to the current study, that in the first few minutes after ADP, CSF leakage is at its highest prior to contraction of dura mater elastic fibers that reduce the size of the puncture hole.

There are several factors in the observed spread of CSF into the epidural space in sheep that are not addressed by our current study and could be viewed as limitations.

First, the present study shows the results of dural closure 2 min after puncture. We do not know the effect if the implant remains until its reabsorption. Based on the microscopic studies,[11–13] it may be acceptable to assume that immediate retraction of the

lesion edges after an acute dural tissue injury could facilitate an initial reduction in CSF leakage, after which the leakage volume would tend to decrease until the perforation has completely healed. We do not know whether the reduction in fluid leakage from the dural sac into the epidural space contained by the patch will help to accelerate patient recovery or whether any effects could be attributed to the patch's potential to facilitate healing around the foreign body or to its mechanical effects. In addition, it remains unknown whether the implant's irritation of the edges of the lesion could stimulate local inflammatory mechanisms that might favor faster fibrosis and complete sealing of the lesion. Future research will be required to clarify these and other uncertainties regarding the use of this device.

Second, although a significant reduction in CSF leakage was demonstrated after the application of the patch in this animal model, because humans have an upright posture and thus different CSF pressures, it remains to be proven if this device in fact limits the CSF leakage in human subjects and if this reduction in CSF leakage will decrease the incidence or severity of PDPH.

Third, as the results were obtained with a Tuohy 18 G needle, used at L6-S1 vertebral level, the conclusions are only applicable to this type of needle and lumbar vertebral level, and future studies with other types and sizes of epidural needles and introduction equipment will be required.

Finally, because not all patients develop PDPH after ADP, it remains to be debated following further research if it is ethically acceptable or feasible to place a device with potential complications and costs in 100% of patients for a condition (PDPH) that occurs in less than 100% of patients. The clinical scenarios for which this device or its future possible modifications are used in dictate the answer to this question.

This study represents a first step in proposing a new method to prevent or reduce PDPH using the same needle with which the dural sac perforation occurred. The effect of this implant in the short term has been evaluated and future studies will be necessary to understand its effect in the medium and long term as well as its safety.

CONCLUSIONS

In conclusion, we have introduced a novel, small, resorbable, and biocompatible device that effectively reduces flow through iatrogenic puncture holes made by an 18 G Tuohy needle in the dura of sheep. Among its potential advantages is the immediacy of the possible solution, that is, applying it at the time, the ADP is detected as well as the simplicity of its design. This animal model represents a first step toward the validation of this new method and the elements used in it, looking to a possible future evaluation by cohort via randomized control trials in humans, and perhaps via modifications in the size or design of the device for other as yet identified future clinical scenarios that may develop due to other membrane perforations.

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Online Supplementary Material

The bioabsorbable device was made with: (a) an implant, (b) a barbed unidirectional suture, (c) an applicator, and (d) a flexometallic cannula.

(a) A polylactic acid implant, measuring 3.50 mm in length, 0.80 mm in width, and with a maximum thickness of 0.43 mm, is intended to plug the leak from inside the dural sac. Degradation is progressive, and in flat PLA elements, degradation can range from 11 weeks to more than 1 year.[1-3]

(b) A 4-0 barbed unidirectional suture (V-Loc™ 90, Covidien, Dublin, Ireland) coupled by thermodilation to the patch. Its spicules provide fixation to the muscle and ligament planes it crosses, thus preventing distal migration. The Covidien V-Loc™ 90 has shallow barbs with circumferential distribution that grasp tissue at numerous points, spreading tension across the wound. It is composed of glycolide, dioxanone, and trimethylene carbonate. Tensile strength is 90% at 7 days and 75% at 14 days. Degradation occurs between 90 and 110 days.[1] Different authors have studied the properties of barbed sutures and clinical outcomes.[2–7]

(c) A transfer element or applicator that houses the patch and thread assembly and allows transmission to the lumen of the epidural needle with one hand.

(d) A multilayer flexometallic cannula with a polyamide coating containing a braided mesh (Nordon Medical, Westlake, OH, USA) that in turn houses the barbed suture thread. Because it is easy to push and does not easily kink, the cannula helps the patch–thread assembly advance toward the dural sac.

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