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What is the Evidence for Post-Patch Care?

Hello, I'm Lalani Carlton Jones. I'm an attending consultant neuroradiologist at Guy's and St. Thomas and King's College Hospitals in London in the UK. Thank you very much to Andy Callen and the Spinal CSF Leak Foundation for including me as part of this day. So when Andy first asked me to talk about what is the evidence for post-patch care,

I immediately thought, well, I can answer that in very few words, which is that there's very little. And this talk was a little difficult for me to write because as a neuroradiologist, I usually write talks with more imaging content in them. So, so this was a little bit more challenging, but it was interesting to go into what evidence actually exists. But to be able to talk about post-patch care,

we need to briefly consider the different types of patches we're talking about, and broadly these can be divided into non-targeted and targeted patches, and I'm going to show you a couple of imaging examples. I had to sneak them in there to show you what type of patches I'm talking about. So, one of the most frequently performed interventions for patients with post-dural puncture headache is a non-targeted epidural blood patch.

And in this example case, you can see that this patient has an acute hypotension presentation, you can see that they've got venous distention, there's smooth dural thickening, it's pretty minimal but there's smooth dural thickening and enhancement, overlying the... cerebral hemispheric convexities. There's pretty diffuse epidural fluid in the spine.

We often see this diffuse appearance of fluid in an acute leak. And in this case, the patient had a high-level thoraco-lumbar epidural blood patch. And that's what many places do. They do a single or two level thoracic and or lumbar large volume blood patch for patients like this in the first instance,

often the acute and emergent management in most places. We do all of our patches under imaging guidance, either fluoroscopy or CT. CT, that's in this case where we've placed a needle here, you can see, in the dorsal epidural space and we inject contrast to, to know our positioning and to ensure an adequate injectate spread of blood, and to also be able to assess thecal deformation.

But when I've localized a leak by myelography, then I prefer to do a targeted patch, and I will do a targeted injection of fibrin sealant directly at the site of leak, sometimes with the addition of a small volume of blood here. And sometimes I've also given a bit of dorsal blood to get compression from both sides.

So here the patient had a ventral leak at T11-12, we can see this characteristic split in the contrast column on ultrafast dynamic myelography, we can see the site of the defect where there's contrast egress coming out of the ventral dura into the ventral epidural space here. And here I've taken a bilateral transforaminal approach to the ventral epidural space at this level.

And to ensure that we get a good fibrin spread across the midline contrast, giving us a good spread across the midline to ensure that it's covering the dural defect. Here's an example of a targeted fibrin sealant, a unilateral leak. This was a nerve root sleeve tear at the T8-T9 level here. And I've placed a needle.

Here you can see there's epidural spread of contrast. And also brought the needle back a little bit and retracted into that sort of contained collection. And you can see here this cast of fibrin filling that little contained leak. The patient did very well from that. And finally, here's an example of a targeted fibrin sealant injection for a CSF-venous fistula, which was at the T6-7 level.

Here you can see the CSF-venous fistula, draining vein. And we've done a two-needle approach here. One at the site of the junction of the diverticulum and the vein, and then another needle placed paravertebrally, and that's to build the paravertebral wall of fibrin as well as get foraminal spread of fibrin, and you can see there's some spread into the epidural space here as well dorsally.

So those are the different types of patches, and there's a lot of focus on the diagnosis of SIH, the localization of leaks by myelography, and the subsequent treatment. And clearly that's a crucial part of the patient's journey, which is often long and arduous. But getting to the point of having an epidural blood patch or fibrin sealant injection is only half the story.

What happens after the patch is just as important and receives much less attention in the medical literature. So, following a patch, patients understandably want to know how to protect it and make sure it's going to be effective. And these are the types of questions that they will very reasonably want to know the answers to.

They'll often ask, how long should I be resting for? What position should I be resting in? What should I and shouldn't be doing? And what symptoms can I be expecting over the next few days' to months' period? What answers we give them, and how do we know they are the best answers, or that they're even correct?

Well, it's important to recognize that there's no agreed set of answers to these questions and no best protocol of post-patch care. The practice and advice varies between different expert centers, though there are some commonalities and broad themes. Now this variation was highlighted in a 2021 survey by Charles Louy and Rachelle Tache from Cedars Sinai, and you can watch a YouTube video of their presentation at the SIH Symposium using this QR code, which I'll show again at the end of the talk.

But it's very interesting because if I just take a few of the aspects from that talk, you can see here these are some graphs which show post-patch practices in terms of how much bedrest was advised or how much for example, light activity would have been careful to avoid, or BLT, which is better known as the bending, lifting, twisting motions.

And what we can see here is that the number of centers giving these different varying aliquots of time for these practices is completely varied between centers for the duration of bed rest, restrictions on activities, and limits on weights to be lifted after patching. So what do I do in practice? Well, this is the advice I give to patients.

I tell them to spend as much of the next 24 hours lying as flat as possible, with bathroom privilege as they can lie slightly propped up, and then for the next six weeks, I say avoid bending, lifting, twisting. Don't lift objects that weigh more than five pounds. If you have to cough and sneeze, you should do that through an open mouth and really avoid anything that increases intra-abdominal pressure such as constipation.

I warn them that anywhere from 20 to 60 percent of patients will experience some symptoms of a rebound syndrome that can be very variable. From a mild headache to worsening headache, visual symptoms, nausea, and vomiting, but it's usually transient, peaking 24 to 72 hours. But we give our patients a supply of acetazolamide and then anti emetics to take home if these bad symptoms develop.

We follow up patients with a telephone call at 24 hours in the first instance to see how they're getting on. And then escalate care where necessary. But in this talk, I'm going to look particularly at the elements of post-patch care and what their purpose is, and then I'm going to consider what we mean by evidence and the different strengths of evidence that can exist for medical care, and finally look at the current practices and if there is actually any literature evidence to support that practice.

So let's start by looking at what we're trying to achieve with post-patch care. Well, post-patch care can broadly be divided into measures intended to improve the effectiveness of the patch that's been performed, decrease the chance of it failing, and then into the treatment of symptoms that can follow a patch.

So, to make a non-targeted patch more effective, we have to consider how it works. And that's not really clear exactly, but we, there are purported mechanisms. And firstly, it could be a pressure effect in the epidural space, which increases CSF pressure and reduces thecal compliance. That may possibly aid primary intention closure, and that's what gives early symptom relief.

But secondly, if blood gets to a leak site, it may form a barrier across a dural defect, preventing CSF leakage and allowing healing to occur. And the likelihood of this is more variable. Now, with targeted fibrin injections, the mechanism depends on the

type of leak. For dural defects, we think that there's possibly an effective occlusion of the defect, potentially allowing healing to occur.

For CSF-venous fistulas, two mechanisms may be at play. It could be due to occlusion of the outflow of the draining vein. If fibrin glue enters the vein directly, it's probably the main factor in achieving a good outcome. But there's also possibly a mechanical effect of glue outside the veins compressing down a venous network, may lead to venous stasis.

We're not exactly clear on, on, on how, but there are, these are the sort of purported mechanisms. So therefore, to increase a patch's likelihood of working, post-patch care can influence spread of blood from the injection to the defect, apparently, but this only really applies to non-targeted epidural blood patches, and formation and adherence of a blood clot or fibrin patch across the defect.

And these could potentially be influenced by the patient position and duration of post-patch bed rest. So, decreasing the chances of a patch failing includes measures to prevent rises in intraspinal CSF pressure to reduce the strain on the dura. And you could achieve that through potentially restricting certain activities, such as bending, lifting, twisting, avoiding increases in intra abdominal pressure or intrathoracic pressure, such as those caused by constipation, coughing, and sneezing.

Now, following patches of any kind, there are symptoms that occur fairly often and for which patient counselling and a treatment plan are warranted. So, I often tell patients that pain at the site of an injection is a pretty common occurrence, and nausea and vomiting can occur as a side effect of the analgesia that we put patients on, particularly if they're opioid-based, or as a part of rebound hypertension,

and that they can get a new headache as a result of rebound, depending on the population, can be seen in up 60 percent of patients, but rebound is going to be the subject of a separate presentation so I'm not going to go into any further detail about that. But we need to know how we can tell if what we're actually doing works is the best way of managing the patient.

And for that, we need to consider the different types of evidence in medicine. Now, many hierarchies of evidence levels have been proposed with varying levels of complexity. Now, often they're depicted as a pyramid with each level considered stronger than the one below, but it's also less commonplace. So the lowest, weakest level of evidence, but one on which much of medical practice has been based is expert opinion.

And sometimes this is informally referred to as eminence-based medicine. Then case reports and case series are descriptions of individual patients and groups of patients, but without comparison to a control group. They're pretty common, but they're a weak form of evidence. Now, case control studies are a more useful type,

where in these patients with and without the disease are compared retrospectively to look for risk factors for a certain outcome.

For example, comparing patients who do and who don't develop rebound hypertension after a patch to see how often each group had venous sinus stenosis on a pre-treatment MRI for example. Now, cohort studies work the other way around to case control studies. Patients are divided into groups based on their exposure or not to a predetermined factor and then studied to see how often the outcome of interest occurs.

Now, an example of this would be comparing headache scores in patients who lie supine versus those who lie prone during the bed rest. For randomised controlled trials, patients are randomly allocated to different interventions groups and then studied prospectively for the outcome of interest. Now, these are difficult to conduct well and can lead large number of patients to identify treatment effect.

So they are vanishingly rare to the point of non existence in, in spinal CSF leak. And finally, systematic reviews and meta analysis take the data from multiple studies and calculate pooled effects of different interventions. But the lack of trial data and good quality cohort studies in spinal CSF leak makes this a difficult section of the pyramid to build.

So what evidence is there for the way that patients are currently managed after patching? Well, let's look at what the current practices are and if there are any evidence to support this. And the problem is that the evidence, where it exists at all, is almost entirely in this bottom half of the pyramid.

But moreover, some of the evidence is based on patching for patients with post-dural puncture headache, rather than spontaneous intracranial hypertension. Now, currently there are two sets of published consensus guidelines that, amongst other things, consider aspects of post-patch care. Both published this year.

The UK Multidisciplinary Consensus Guidelines for the Diagnosis and Management of SIH, and then the International Multidisciplinary Working Group Guidelines on Post-Dural Puncture Headache. So let's have a look at some of the evidence in these publications. Now, firstly, with regard to post-patch positioning, there's no consensus on how to position a patient after a patch or for how long.

So, for non-targeted patches, positioning might theoretically influence the spread of blood from the injection to the leak site, maybe in the thoracic spine. Now, the UK guidelines suggest either supine or Trendelenberg positioning. The PDPH guidelines do not specify the position for bed rest. Now for targeted patches, positioning to encourage migration to the leak side is not needed because it's targeted at the leak side already.

So simple supine positioning would be all that has therefore been suggested. But there are currently no published studies comparing the different positions. Now, in terms of duration of bed rest, there is huge variability in how long patients are advised to remain on bed rest from one hour to three days.

Now, the UK guidelines suggest a broad range from two to 24 hours for both non-targeted epidural blood patches and for targeted fibrin patches. But the PDPH guidelines conclude that there is insufficient evidence to recommend a specific duration of bed rest. That's an understandable position as there is currently only one published study looking at this, and that was back in 1994 with a study of patients with post-dural puncture headache who were randomized to 30 minutes, one hour, or two hours of bed rest after a lumbar epidural blood patch. And then the headache was measured by a visual analogue scale pre-patch, and at the end of bed rest, and at 24 hours. Now, the headache decreased in all groups, but the greatest reduction occurred in the two-hour group, to our bed rest group, but there are no other published studies to guide the duration of bed rest after a patch.

Currently, that is, but there are two studies registered on the ClinicaTrials. gov website that consider post-patch bed rest, both from Paris. There's the SIHT study, which is a single blind, randomized trial to compare Trendelenburg and supine positions of bed rest for 24 hours after a blood patch. Now, they've recruited 64 patients and the trial was completed in March 2021, but no results have yet been published or posted.

And then there's the CHROBLOOD study, which will look at the conditions for performing a blood patch for PDPH and the occurrence of chronic headaches at one and six months. And amongst the factors to be examined is the duration of bed rest. Now, this study opened in June this year and hopes to enroll 100 patients by January 2025.

Now, with regard to restriction to activities, the activities that are restricted after a patch are often referred to, as I've mentioned, these bending, lifting, and twisting, and similar precautions are recommended for patients following spinal surgery. And in the UK guidelines, a figure of 4-6 weeks was agreed on, whilst the PDPH guidelines suggested only 1-2 weeks.

But there's no evidential basis for these recommendations, they are just regarded as common sense. And finally, a common question is about exercise in the post-patch period. Now, this advice is pretty empirical, and I've taken this from the Duke patient information sheet, which I also give this advice to patients.

So, say initially, intentional exercise should be avoided, and then in the first few months, you can have a gradual return to light, low impact exercise, such as walking or using an elliptical machine. And then beyond three months, exercise can be increased, but those with an element of strenuous bending, lifting, or twisting such as yoga, pilates, tennis, golf, they should be avoided where possible.

But again, no published evidence about this. So. Practical advice for patients on how to limit activities after patching can actually be found in this really excellent 2017 SIH Symposium video and again I'll put this QR code up at the end of this talk. But patients, I essentially advise patients to avoid constipation, as straining at the stool can increase intra-abdominal pressure and potentially increase that chance of a patch failing.

And that can be done through simple dietary means, increasing food intake fiber using stool softness or laxatives, and, thinking about opioid-induced constipation, considering that and trying to prevent it or mitigate against it. I tell them to avoid forceful coughing against a closed mouth, and really the care here is based on physiological principles and common sense, but without published evidence.

I tell patients that pain at the injection site is really common. It's seen in over 80 percent of patients the following day. We can manage that symptomatically with local heat, simple analgesics such as acetaminophen, occasionally requiring something stronger, including opioids. But once again, there are no studies forming the basis of this practice.

Nausea and vomiting, I tell them, is pretty common as a side effect from opioids or from rebound hypertension, so we often give antiemetics prophylactically or for symptomatic relief, but again, this is more experience-based medicine rather than supported by any evidence. So, as was shown in that 2021 survey from Cedars Sinai, there are significant variations in practice regarding the different aspects of post-patch care.

And, in part, that likely stems from there being no consensus on what best practice is, from this near total lack of good quality evidence regarding post-patch care. Now, whether or not that variation is actually deleterious to patients is also unknown. But the flip side of the start of good quality studies means that there are substantial opportunities for interested researchers to plug the gaps.

As we have seen, there are already a couple of recently completed and ongoing studies looking at bed rest after blood patching, but much remains unknown about what is optimal care. And part of the difficulty arises from needing to look at a subset of patients with a relatively uncommon condition, making recruitment of adequate numbers of patients within a time frame a challenge.

And this can be partly overcome by development of patient registries and multi-center collaborations for research. So, so in summary, there's a significant variation in post-patch care practice, which is based on very little evidence, but there's lots of potential for future research opportunities. Here are the links to those brilliant talks I mentioned please go, do go and view them.

Thanks very much.