

West Virginia University - Center for Excellence in Disabilities (WVU-CED)
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>> Hello.
>> Are you there, Dr. Najib
>> Yes, this is Umer. Can you hear me?
>> This is Lesley. We will get you situated. Do you know how to steam the screen from me for your slides? Do you prefer them for yourself--
>> I can try.
>> Okay. You go up to the top of the menu share. And you can steam the screen there. We can go ahead and do that. Great. All right, you have mountains on your desktop?
>> Yes.
>> Okay, that's it. Fantastic.
>> If it's all right, with you, are you ready to get going?
>> Yes, I am.
>> Okay. It's 2:00 o'clock. It is the time to get started. And so, I'll do a quick introduction. Um, thank you for everyone who is joining us and I'm sure a few others will join us. We have the opportunity to hear about migraines today. Um, Dr. Umer Najib serve as Associate Professor of Neurology Medical Directory of Ambulatory Services, Dept. of Neurology Program Director, Headache Medicine Fellowship West Virginia University
So pretty busy. He completed the neurology training at WVU in fellowship in-- at bring ham at Harvard University. Else a research fellow in none invasive modulation at Harvard University at that time. Dr. Najib has co-authored several peer review publication. (Record read.) including but not limited to migraine and chronic pain here at the Rockefeller neurology institute here.
I'll mention brief housekeeping, please make sure that your honor setting is on mute either through your computer or phone whichever way you're connecting with us. We will have time for questions at the end and then also, because we're doing this through WebEx we have the chat function. Down at the bottom you have menus and there's a little comment box at the bottom. You can click that, choose whether you want to send it to one person or the group so that we can address questions at the end through that as well. Okay. With that, Dr. Najib I'll turn it over to you.
>> Thank you so much. Thank you for the nice introduction. Um, so everyone now knows I'm

Umer Najib. I'm going to talk about migraine today. And I, when Dr. Cottrell had asked me to present at this, there were few options. I chose this topic because this is something we see most disability issues with, and we see our patients suffering from migraine to have certain challenges which are unique to the underserved populations.

And I'm going to briefly going to talk about those as well: Okay. So let me-- okay, perfect. I'm going to talk about the on and off label use of certain medications and devices. I do not have any current financial disclosures.

the objective of my talk would be to give you an overview of migraine, discuss briefly the diagnosis of migraine, outline the basic treatment principles in migraine patients, and then talk about the disability associated with migraine especially in the underserved populations. And finally identify some of the resources that are available at locally at our headache center and nationally online as well.

So-- my PowerPoint just crashed. Let me see what's going on. Can everyone hear me? Are you all still able to hear me?

>> Yes.

>> Okay. I'm quickly going to restart the software. I apologize. Okay, well, hopefully it's not going to crash again.

So let's start with the lifetime prevalence of some common headache disorders. As you can see from these numbers, tension type headaches or some patients like to call it regular headaches, they're universal. Migraine is not universal, but it's still very common. It's present enough to 20% of the population, and that's about 37 million patients with migraine. It's actually more common than diabetes and asthma combined and yet it's severe and disabling. In the primary headache disorders is cluster headache. You might think it's rare, .5%. But the prevalence is as common as MS, multiple sclerosis. Something you hear about a lot. But you don't hear a lot about cluster headache patients. It's considered one of the most painful disorders known to men. In the secondary group, sinus diseases is common. But interestingly the nonvascular-- it's quite small. Partly this is due to the fact that tumors are infrequent occurrences. But also partly because contrary to the popular belief, headache is not a particularly common presentation of two mores.

Now, moving onto migraine which will be the focus of today's talk, so what is migraine? And it's a complex disease. And this is one way of defining migraine. Is a neuro biological disorder which has both genetic and environmental components which causes a hyper responsive brain state. And that leads to episodic attacks which includes severe headache, nausea and vomiting, light and sound sensitivity, activity intolerance among a host of other symptoms.

Migraine is be classified into either episodic migraine or chronic migraine episodic migraine is patients with migraine who have less than 15 headache days per month. Chronic migraine and defined as patients who have more than 15 or more headache days per month with alleviate of them being typical migraine attacks.

Let's quickly go where the migraine epidemiology. I mentioned 37 million patients suffering from migraines, 12 to 13% of the U.S. population. Chronic migraine is present in about one to 1 to 2% of adults. One in four persons get migraine. It's the third most prevent leapt illness in the world. And the direct cause associated-- amount with migraine is amount to \$32 billion. There are several risk factors for disease progression or for transformation of episodic migraine patient to chronic migraine patient. And some of these risk factors are named here. As you can see, most of these risk factors are the population that we serve in our state most of

these are prevalent. Low socio-economic status, low education, obesity. Depression. And the use of acute medication and acute treatment are some of the risk factors.

According to WHO. This is the sixth most disabling illness in the world. The peak prevalence is around the age of 40. The greatest impact is between the ages of 25 to 55. And you can see by the two graphs, it affects, females much more than males.

So how do you diagnosis migraine, the diagnosis is bases on pattern recognition. The vast majority of headaches that are seen in by a healthcare provider are primary headaches or those which do not have a link cause. But making those diagnosis is not just about excluding things that may be causing headaches.

It's about diagnostic criterias as well. And this is the diagnostic criteria for migraine without aura. I'm going to briefly mention here the two main sub types of migraine, migraine without aura and migraine with aura. About two-thirds of patients have migraine without aura and about one third of patients have migraine was aura which further has several subtypes.

As you can see by this diagnostic criteria. This is the international headache society diagnostic criteria for migraine that there are several unique disease characteristics that need to make the diagnosis. Some of it is unilateral location, pulsating of the pain, moderation of the pain, aggravation the pain, nausea, vomiting, light and sound sensitivity.

So how do we evaluate? The initial, the clinical priority of the first diagnostic evaluation is to identify the warning signs. And they also include abnormal neurological exam. Even in the history, or in the physical presentation and if their warning signs are present, then suspicion of a secondary headache disorder meaning a headache because of on underlying cause should be considered. In the absence of the warning signs, the headache disorders is a primary headache disorder such as a migraine and diagnostic criteria should be reviewed.

Are those warning and signs and red flags-- here are some of those. The typical recommendation is, new onset of headache, after the age of 50, 70, elderly population, if the headache pattern is unusual, if it does not qualify as certain diagnostic criteria, if there's a positional component to the headache, if it's worsening and these indicate an underlying trigger or component with a change in ventricular pressure. If there's worsening over time. Abnormal examination. No response in treatment. These could be considered warning signs. This would warrant investigations or testing. There is no rule for EEG and the testing of headache disorders, particularly migraine. And, uh, you will be surprised how often patients go through these tests, go through an EEG during the work for headache disorders, the work for migraine which is inappropriate.

Neuroimaging is the mainstay of evaluation when a secondary headache disorder is suspected.

So which scan would you order? Now here are some of the things to consider when we think about ordering a brain scan. CT is good to rule out-- if there's a history of trauma. A CT scan is used for. If a problem or disease with the bones or sinuses is being considered CT scan is help. Out of these situations, MRI is the study of choice unless you're suspecting bleed and sinus disease. And during work up off headache disorders, MRI with contrast is much more useful than MRI without contrast. The reason for that is, in order to evaluate for pressure changes and tumors, contrast is good with MRI. The certain other kinds of imaging modalities can be used NR geography or MRA is useful when underlying abnormalities is considered such as dissection, intracranial and MRV or MR venogram is helpful when serious changes are being considered. And pregnancy is one situation where an MRV is help. Because, to evaluate for cerebral sinus thrombosis.

So if I see a patient, who does not have any warning signs, and who fulfills the criteria for migraine, do I need to order imaging? And the answer is no. The American academy of neurology came out with a statement that if the person meets the criteria for migraine and has a neurological exam, then imaging is not recommended.

I am so sorry. I think there's? Sort of conflict-- it just crashed again. Okay. So we restart from where we were. This is an interesting study in 2000, more than a thousand patients who fulfill the criteria for migraine and have a normal neurological exam on two had abnormality in imaging. In patients who did have an abnormal neurological exam with the normal exam, if someone meets the criteria for migraine, the imaging is 99.9% to be normal and abnormality won't change the management.

I want to talk about specific white matter lesions. And I bring this up because, healthcare providers often end up ordering an MRI on patients who have migraine. And then they see nonspecific white matter lesions written in the report. And that's a-- that's a big concern for patients. And then MS is being considered and neurological disorders are considered at that point. Migraine patients have nonspecific white matter lesions significantly more than normal population. Unless the radiologist tells put that the white matter lesions are in a particular pattern, just having nonspecific white matter lesions who has migraine is very normal.

Way want to talk about migraine aura. I briefly mentioned that one third of migraine patients have migraine with aura. What is aura? Aura is any focal neurologic event, particularly visual or motor. Usually precedes the headache, either positive, negative, or negative phenomenon. Typically spreads and is reversible in nature. This is the diagnostic criteria for migraine with typical aura. And you can see the highlighted parts include either reversible visual symptoms, revertible sensory symptoms such as numbness or pins and needle like sensation. Reversible speech symptoms. They gradually develop for at least five minutes and last between typically last between five and 60 minutes.

And one of the symptoms needs to be unilateral. What does all this mean? Well, one thing, when the spreading nature mean that if there are sensory symptom, the patient will experience them either in the hand first and then gradually would spread over the arm, face, and so on. Visual symptoms will start in the center of the periphery vision or start in the periphery ? and there's gradual progression and completely reversible. The most familiar pat everyone is visual aura. The visual aura is typically described as a flash bulb sensation or as a set off shimmering, bright zigzag lines in the field of vision. Um, it's important to note here that simply having blurred vision or foggy vision is not visual aura. It has to be the visual aura is either a positive symptom or loss of vision, central line spot, and so on.

How do we manage migraine then? The two types of therapies for migraine patients. There's abortive treatment which suggests something to use to stop an attack to abort an attack and then there is preventive treatment. These are the treatments or the medications that a patient uses on an ongoing basis to prevent migraine attacks from occurring.

Everyone needs abortive treatment, meaning all migraine patients need abortive treatment. When the onset migraine patients require preventive treatment. The recommendation is if the headache frequency is about one per week or more than that, then preventive treatment should be considered.

The most commonly used preventive treatments are daily oral medications and we're going it talk about them in a few minutes.

Toxin until recently was the only FDA approved preventive treatment for chronic migraine patients and there are several new medications that you might heard about recently in the

news, some of which are approved by the FDA some are in the pipeline, new class of medication, CRGP, receptor peptide. I'll touch on them.

Let's start with the abortive therapy. Abortive treatment is these are the medications the patient will take when an attack starts to stop an attack. There are several nonspecific options listed here. But migraine specific abortive therapies are mainly Triptans. The mainstay -- because it gets in oral form or nasal form or even injectable form have a low viability. The only way to effectively use is through IV infusions for those patients needs to be admitted.

Triptans are the mainstay. There are seven Triptans in total. And six of them are now generic. One is still not generic, but the other ones are generic now.

Two of them are available as oral tablets. There are two available as nasal sprays and one available as injection, Sumatriptan, in some countries they're available without prescriptions, over the counter. U.K. is one of them. These are the common Triptan side effects tingle, warming, flushing chest discomfort, dizziness. He mention this because this is important. Patients who experience these are not having an allergic reaction to Triptans. Over several years of my practice, I can count in one hand patients who had allergy with Triptan. You will be surprised how many patients a see in the emergency center where the Triptan is listed as an allergy. And we do another trial of Triptan and it's fine. All of these are common Triptan side effect, it is not allergic reactions.

There are serve contraindications-- patients with poorly controlled hypertension or risk factors, multiple risk factors we have to be a legal careful in those patients because Triptans are constrictors. Someone who has a blocked vessel, having basal constriction as a side effect of Triptan use can complicate things.

This is another important concept to understand. There have been multiple studies done which has shown Triptan nonresponse is not consistent. Um, most of the times, someone who is considered a non-responsible enter to Triptan is either use the medicine too late, using a low inadequate dose of med indication, and using inappropriate form place of medication and so on. Five studies shows switching a Triptan that is ineffective to an effective one can change response. Increasing the dose can result in a response, can switch a nonresponder to a responder by giving an appropriate dose. This has showed this with Triptan-- you can see going higher than the dose. The response rate is at-- which is huge.

Peter showed that using alamo Triptan early on when the disease is still mild, results in a much better response compared to when it was used later on in the duration of the migraine.

This is based on the physiology of migraine and the site of action of Triptans. Triptans work on receptors where it starts; if there's a delay of one to two hours, the process has moved ton to deeper areas of the brain where Triptans are not able to penetrate which is inside the brain barrier.

Another important concept to understand in the patient, barbiturates and opioids have no role in the treatment of migraine. Opioids is now you showing that opioid use, not only increases the risk of ER visits, but can also cause opioid induced hyper-- with repeated use. Headache medicine and medicine treatment there's no role for opioids. And I also mentioned barbiturates they're perhaps more used in the primary setting compared to Triptan in migraine patients. It's interesting that there is no evidence that these work in migraine patients.

For barbiturate compounds, only one wasn't migraine which was not placebo control and was not a positive trial.

So this practice is not based in evidence at all. And almost all barbiturates result in worsening of the decease. There's no role for barbiturates and opioids in the treatment of migraine

patients.

So that was all about the abortive therapy. Now I'm going to quickly talk about preventive therapy.

You now as I mentioned four headache days a month or one per week experiences, then migraine prevention or preventive therapy is considered.

If a patient does not have quite that frequency but the migraine singly interferes with their daily- - the patient experiences significant adverse effect from the abortive medications, even in those cases, preventive therapy can be considered.

So what is the room of the preventive therapy? And this is very important to-- it's important to educate the patient. To understand that migraine prevention does not mean that they will never have another headache. It means that the frequency, the intensity of episodes will be reduced.

The breakthrough headaches will still occur, they still require treatment with abortive medications, and patients should be impressed to focus on their overall pattern of improvement rather than isolated headache events.

These are the current preventive treatment options that we have. Of course, lifestyle modification helps in reducing triggers, treating triggers, avoiding triggers helps. pharmacologically treatment involves oral preventives. The main medication are antiepileptics, Topiramate are the two main migraine prevention. And there were two beta-blockers which are FDA approves for the preventive treatment of episodic migraine. And we Triptan is also used and is mainly used for migraine prevention.

As you can see none of these medications were designed for migraine. But found to be useful because they do cause changes.

botox was the only approved FDA therapy for migraine. Patients who had 15 or more headaches a month. Compared to the less frequent ones.

CGRP are the new up coming class of medications which is specifically designed for migraine treatment. CGRP is shown to be elevated in migraine patients, it's associated with the migraine attack and the propagation of migraine attacks as well. In the first of this class, Erenumab was approved this year in the prevention of migraine. Since then two more medications-- have been recently approved not quite commercially used yet. One of these approvals was last week. Over the next few weeks or months, these will be commercially used. Start commonly used as well.

Then there are certain nonpharmacologically options for the treatment of migraine with the studies showing benefit including trans cranial magnetic stimulation, and certain devices which perform stimulations and I'll briefly talk about that.

As I mentioned these are the two big areas of development these days. Calcitonin gene related modulation, and two kind of modification in the type line, CGRP antibodies receptor antibodies and receptor antagonist. And then new modulation is another wave of active research and with at least two devices which are FDA approves and several others in the pipeline. Neuro modulation

Chronic migraine face certain challenges. And chronic migraine patients in West Virginia face certain more challenges than elsewhere in our country.

So as I mentioned earlier, until recently until measure of this year, botox has the only approved treatment for prevention. However, West Virginia Medicaid refuses to cover for it even with a highly restricted pathway. And it's interesting that West Virginia Medicaid used to cover for botox before it got FDA approval.

This is the only med Medicaid in the category to deny botox. Which is not only covered by Medicare but major insurer. More interestingly, West Virginia Medicare,-- and this is (indiscernible). Cervical dystonia. Chronic migraine is the only disease that it does not cover botox for.

There are several challenges that our patients face. Economic burden has been-- I mentioned this in the beginning that the annual direct and indirect cost combined amount to \$36 billion associated with migraine. But interestingly, our population in of West Virginia is affected disproportionately by this. The national health survey from 2015 data shows that the migraine prevalence is the highest in the population with an annual income less than \$35,000. About 20% of those patients, the progress was up to 20% as oppose to 12 or 13% in the general population.

Under the age of 65 Medicaid insured even higher. 26%. And over the age of 55, prevalence was highest in the group with Medicaid and Medicare, 64%.

There's another unique consideration for our population. We looked at one month data recent will be. This was a couple of months ago at our headache center. And the average distance traveled by the patient was about 70-miles one way. About 73% of these patients traveled 25-miles, more than 50% over 50-miles and more of the a quarter of the patients traveled over 100-miles with the longest distance being 235-miles one way.

That's important to note here I've been talking about Medicaid and the failure to cover for the FDA approved treatment options. About one third of our population relies on Medicaid for insurance coverage. I'm talking about the WVU headache center date A

In the country there were only 484 UCNS headache specialists. So specialist-- there were three of us in West Virginia. Unfortunately four are here in WVU none in the rest of the states. To put this this perspective, this means there are roughly 890,000 people with migraine for every UCNS headache certified physician. That's a huge number. And of course, you you know, we-- the headache specialists are not on the the physicians treating people with migraines, if you double and triple the number of physicians treating migraines, the number is still too low many

according to the American academy of neurally, there were only 6,000-- two and a half thousand people with migraine per one neurologist.

The WVU, the comprehensive center, are this is the only center I mentioned. We are a group of five providers with three of us board certified in headache medicine. This is the on headache medicine fellowship training program in the state. So the website-- I'll share the links towards the end as well. And of the treatment, the treatment options that I motioned in the slides, is offered at the WVU center.

We are also part of multicenter clinical trials not just headache, but headache, and post-traumatic headache, and disorders. These are some of the trials that are currently ongoing which include CGRP-- use of CGRP an at the body, migraine in cluster patients in post-traumatic disorder patients, device trials and so on.

We at the WVU have offer several types of neuro modulation techniques. They range from occipital nerve stimulation to trans cranial magnetic stimulation, frontal nerve stimulation. Vague al nerve stimulation. And what we have been advocating for and what we have been trying to do is to be part of, to ensure that we're part of all the major clinical trials that are ongoing. Which is one way of helping our patients who have access to the latest and the greatest. And another thing that we try to do is negotiate to be part of those clinical trials.

We try that in our patient population, most of the clinical trial have a-- (inaudible) What we tried to do is convince them that if the disease is not covered by the insurance, then for those patients, they'll extend the open liberal arm to at least one year and we've had great success in convincing the industry to do that because we have in mind, our Medicaid patients, one third of our patient population who has restricted access to some of these treatments.

And I'm-- I'm---- I'm going to do it again. Okay. So some of the resources that are available for migraine patients, American migraine foundation has a wonderful website with a host resources for patients. Um, and I'm sharing this link with everyone. Migraine disease.com is another organizations which has a host of resources for the patients and the American headache society is the main physician society of our headache specialist. And they also offer a lot of resources for migraine patients.

Then there's local resources. The WVU has website with patient resources and another website with the ongoing clinical trials. With the integration into the Rockefeller neuroscience institute. Some of these websites are being updated in transition from being posted on one server to another server. Some of this information is going it change over the next few months. But you-- I'm pretty sure that these web links will be functional and be able to connect patients to the desired pages.

And, uh, this is it for me today. I'm-- I'll be happy to answer any questions at this point.

>> Thank you, Dr. Najib. Does anybody have any questions before we go to the chat room? All right. I have actually two you questions. If you don't mind.

>> Okay.

>> Um, one relates to the few slides you you had up there about West Virginia stat statistics, we serve individuals with disabilities with Medicaid and Medicare. And that is the group you you emphasized that had a higher prevalence. My question pertains to the additional factors why you think the prevalence is higher. Anything related to SES-- does the treatment use-- [Background Noise]. There might be on other medications differ at all from those who do not have disabilities?

>> So to answer the first question, we don't have good data to exactly figure that out, these-- some of the data that I shared from the national health surveys, some of the reasons were, in the U.S., for instance, low economic status is associated with high visits for the treatment of headache disorder. And one of the hypothesis was, it not only results in a higher treatment cost but in-- there have been separate studies done that ER visits result in inadequate therapy. That was one hypothesis. And another hypothesis is that, there are some, there are requirements for step therapy, for instance, restricted, step therapy-- by Medicare which results in inadequate treatment. And, uh, some of the other factors then involve indirect cause the indirect cause from missing work, not just from missing work but from not performing, not performing while at work, patients who suffer with migraine, so the concept of presentism-- so there are several things that are hypothesized. But I'm not aware of data that would be difficult to pin point what exactly happens here.

Now, for the other question, patient who's have comorbidities than others, that's a big challenge. The migraine studies, prevalence studies in migraine patients have shown that the treatment challenges include with patients with untreated sleep disorders, sleep apnea. Not only limits the use of certain me indications butt unless those are created the outcome of migraine therapy are also limited. And that becomes a big challenge, that-- for the patient to have comprehensive care. We try to provide that for the patients, but I mentioned that someone's driving from 100-miles away, for them to see a sleep specialist, a behavioral

specialist and headache specialist, it's more trouble. And that's very difficult.

>> Okay. So kind of related to stepping off that one, and I'll be quiet and let anyone ask you questions. Because we see individuals with various ages, and various conditions, if we learn that they are experiencing migraines, of nil of the types you you you mentioned here, what should we uncover into our referral information, information referral process? Should we ask them to discuss who their primary care provider? Should we refer them to you in the Rockefeller center? What should we invoices now you you that we know you're here.

>> I would suggest to refer the patient to the headache center. Although, you know, I can argue that, it's just not possible for one center to serve the whole state. But what we are trying to establish is, we are trying to identify local primary care providers who are comfortable in treating this disease. But the model that we're looking forward to create in, that we do the initial evaluation and then we give a set of recommendations, statewide set of recommendations. If the provider is comfortable following the steps in conversation with us, we gladly send the patients back to them. They can follow those steps, will identify other problems that need to be addressed, other comorbidities that need to be addresses. Some of them might be able to address them. From a migraine standpoint give very detailed recommendations and introductions, like starting the medication on, how long is the dose what to expect from medication: Once some of those things can be tried. They can come back, but, if the primary care provider is comfortable doing that, patients prefer that, and we prefer that because you you you know, that way we are able to help other patients.

So I would say that so far we've been fortunate that we have had, we've informed several primary providers and were comfortable with those. And several success stories to share in that regard. So I would suggest to refer them to us so that we can do the initial evaluation and plug them in the system.

>> Great. Thank you. And then if anyone has questions, just remember you you probably put your system on mute. If you you you do have a question, go ahead and unclick it. All right. Well, hearing none, web we are grateful form your time today. And the presentation was helpful to us and relatable to what we do over here. So you you might be getting more emails, more calls from over this way.

>> Absolutely. I'll be happy to listen. Thank you, thank you for having me here.

>> All right. Thank you. Appreciate it. We'll be sending out evaluations. Dr. Najib I'll send you you you information for any type of professional development, okay?

>> absolutely. Thank you.

>> Everyone have a good day. Thank you.